

Battling the Opioid Epidemic – Regulatory Efforts and Enforcement Trends.

By Andrew A. Schillinger, JD

“We, as clinicians, are uniquely positioned to turn the tide on the opioid epidemic.”

Dr. Vivek H. Murthy, Former US Surgeon General

DISCLOSURE STATEMENT

- The presenter has no financial disclosures.
- The information is to provide a general overview of the opioid epidemic and efforts to combat the problem.
- The views of the presenter are personal and may not reflect the views of Providence and/or any of its affiliates.
- This information should not be construed as legal advice and/or opinions.

Objectives of Presentation

- Provide a general overview of opioid epidemic from a national perspective.
- Review historic pain management views and/or standards.
- Review national efforts and trends to roll back the opioid crisis.
- Review risk management practices for clinicians and providers.
- Stakeholders partnering together to mitigate this public health crisis.





HHS: The Opioid Epidemic: By the Numbers

- More people died from drug overdoses in 2014 than in any year on record (> than 6 out of 10 inv. opioids)
- 2014 – more than 240 million opioids Rx written. (Enough to give every American adult their own bottle.)
- On an **average day in the US:**
 - More than 650,000 opioid prescriptions dispensed
 - 3,900 people initiate nonmedical use of Rx opioids
 - 580 people initiate heroin use
 - 78 people die from opioid related overdose

[CDC - The Opioid Epidemic: By the Numbers \(06.15.16\)](#)

OIG: Opioids in Medicare Part D: Concerns About Extreme Use and Questionable Prescribing

- 2016 - 43.6 million Medicare beneficiaries covered
- 1 in 3 beneficiaries received opioids in 2016
- Medicare paid \$4.1 billion for 79.4 million opioid Rxs
- 80% Schedule II or III (highest potential for abuse)
- 1 in 10 received on a regular basis
- 501,008 received high MED of greater than 120 mg a day for at least 3 months (not include cancer/hospice)*
- Generally older adults more at risk for adverse events as dosage increase
- Approx. 90,000 at serious risk of opioid misuse or OD**

OIG: Opioids in Medicare Part D: Concerns About Extreme Use and Questionable Prescribing

- Approx. 115,851 prescribers ordered opioids for at least one beneficiary at serious risk of opioid misuse/OD.
- Prescribers with questionable patterns wrote 256,260 Rx for those at serious risk costing Part D \$66.5 million.
- **Nurse practitioners (mainly family or adult health) and PAs make up one-third of the prescribers with questionable prescribing patterns.**
- **Conclusion: “Prescribers play a key role in combatting opioid misuse. They must be given the information and tools needed to appropriately prescribe opioids....”**

Prescription opioid use, misuse, and use disorders in U.S adults: 2015 National Survey on Drug Use and Health (AHRQ Aug. 1, 2017)

- More than 1/3 of adults reported using Rx opioids in the past year and nearly 5% reported “misusing” opioids (use not directed by prescriber)
- Majority misused w/out Rx (friends/family)
- Most misused to manage pain



Pediatric/Adolescents & Opioids

- 2007: A controlled medication was prescribed at 2.3 million visits by adolescents.*

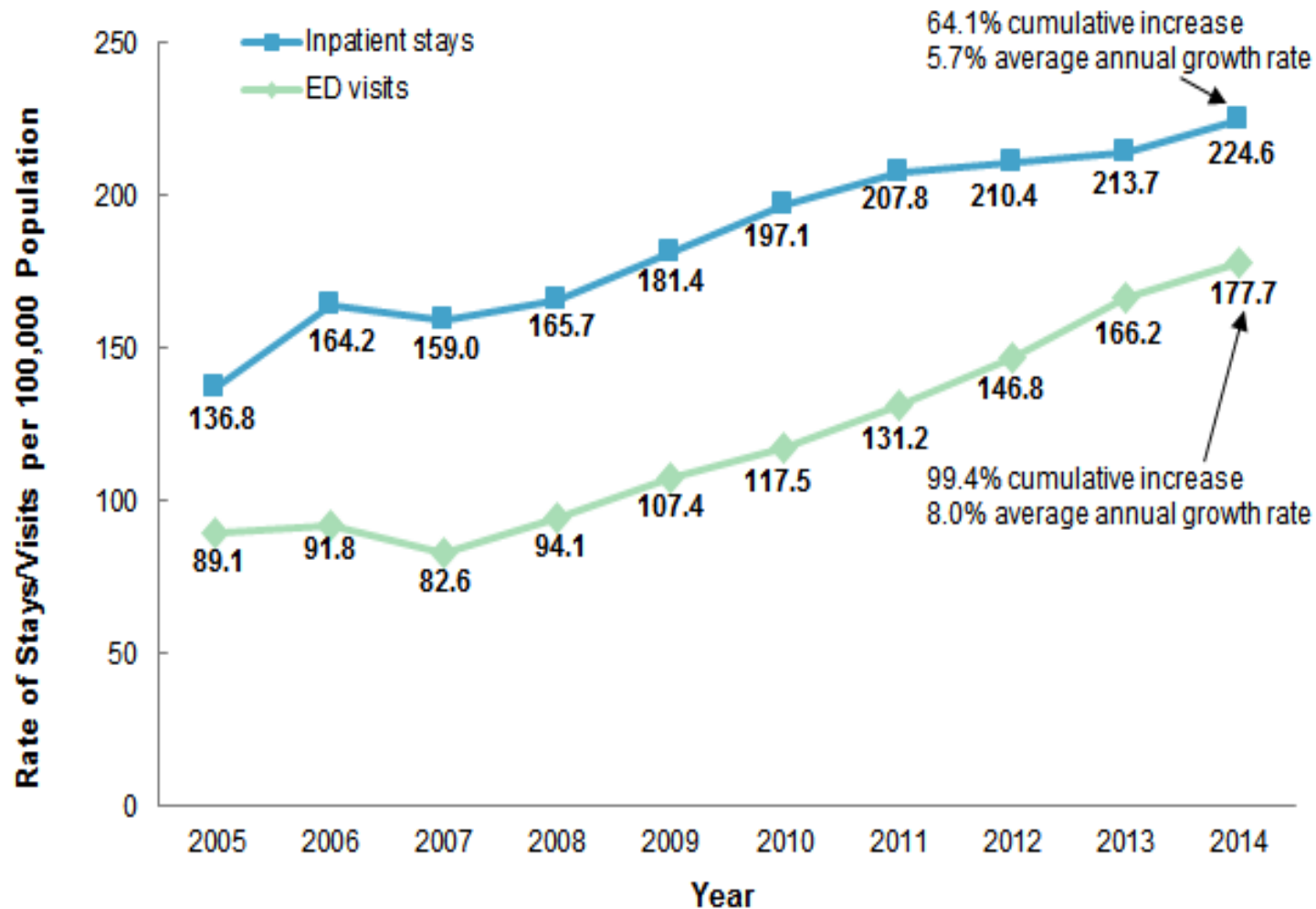
- Between 1994 and 2007, controlled medications were prescribed at an increasing proportion of visits from adolescents (6.4%–11.2%).*
- Controlled medications were prescribed 23.4% to adolescents for common conditions, such as back pain.*
- Nonmedical use of prescription drugs by adolescents and young adults has surpassed all illicit drugs except marijuana.*
- The annual rate of opioid poisoning for adolescents and children–related hospitalization increased by 165% from 1997 to 2012.**
- In September 2016, the American Academy of Pediatrics recommended halting codeine use among children because of the risk of breathing complications.**

Industry Payment to Phys. for Opioid Products (2013-15)

- 375,266 nonresearch opioid-related payments were made to 68,177 physicians totaling \$46,158,388.
- Most fees were for speaking fees or honoraria (63.2% of all payments).
- Physicians in anesthesiology received the most in total annual payments.
- Conclusion: “1 in 12 US physicians received a payment involving an opioid during this 29-month study.”

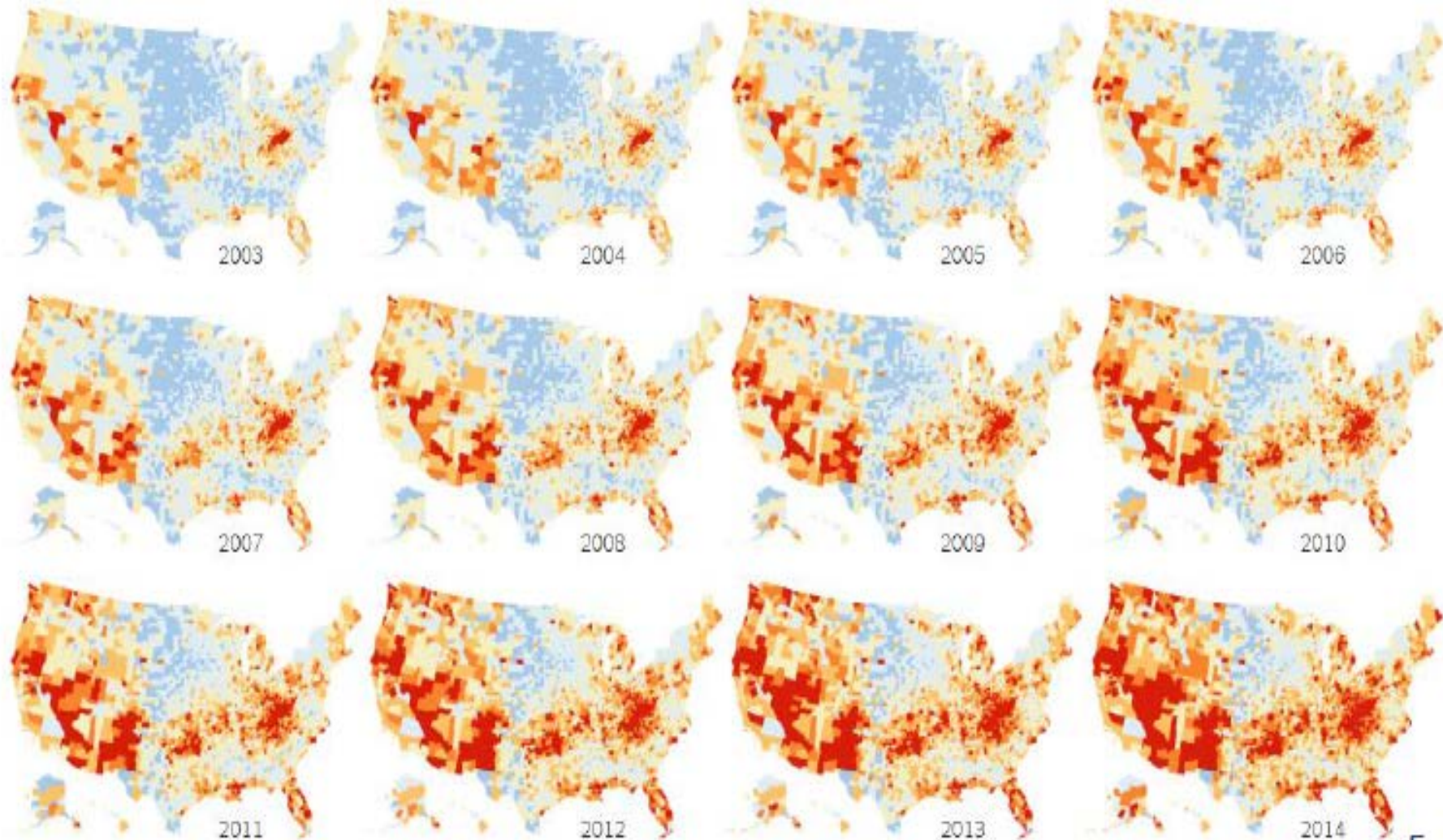
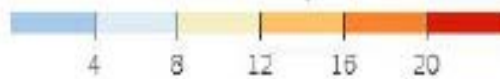
Increase in Opioid Related Admissions and ED Visits

Figure 1. National rate of opioid-related inpatient stays and emergency department visits, 2005-2014



The Rise of the Opioid Epidemic

Overdose deaths per 100,000



Historic View of Opioid Use

“Most experts agree that patients who undergo prolonged opioid therapy usually develop physical dependence but do not develop addictive disorders. In general, patients in pain do not become addicted to opioids. Although the actual risk of addiction is unknown, it is thought to be quite low...Fear of causing addiction (i.e., iatrogenic addiction), particularly with opioid use, is a major barrier to appropriate pain management.”

Pain: Current Understanding of Assessment, Management and Treatments § I, 5(b), National Pharmaceutical Council, and Joint Commission on Accreditation of Healthcare Organizations collaborative project (Dec. 2001).

Historic Hospital Pain Standards

PC.01.02.07: The hospital assesses and manages the patient's pain.

JC statement on foundation of standards:

- “The hospital educates all licensed independent practitioners on assessing and managing pain.
- The hospital respects the patient's right to pain management.
- The hospital assesses and manages the patient's pain.”



Historic Hospital Pain Management Survey Questions

12. During this hospital stay, did you need medicine for pain?

- Yes
- No → If no, Go to Question 15

13. During this Hospital stay, how often was your pain well controlled?

- Never
- Sometimes
- Usually
- Always

14. During this hospital stay, how often did the hospital staff do everything they could to help you with your pain?

- Never
- Sometimes
- Usually
- Always



President Trump says opioid crisis is a national emergency

August 11, 2017, HHS Secretary Price:

"President Trump is taking strong, decisive action in directing the Administration to use all appropriate emergency and other authorities to respond to the crisis caused by the opioid epidemic."

HHS.gov

U.S. Department of Health & Human Services



Root Cause of Opioid Epidemic

- **Early 1990s perception that pain is undertreated.**
- **Professional associations/accrediting bodies adopting and/or supporting treating pain as a 5th vital sign.**
- **Guidelines/Standards required close monitoring and documenting pain and aggressive treatment of pain.**
- **Development of professional guidelines to treat chronic opioid analgesic treatment (“COAT”) based on outcome data for acute/cancer pain.**
- **Opioid treatment relatively cheap compared to other therapy interventions (i.e., PT, OT, Psych., Biofeedback).**
- **Payers and pharmaceutical industry encouraged opioid treatment and distribution to treat chronic pain.**



Xtampza (Oxycodone) ER Safety Warning

- “Xtampza ER exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient’s risk prior to prescribing Xtampza ER and monitor all patients regularly for the development of these behaviors or conditions.”
- Risks:
 - Life threatening respiratory depression especially in following patients: elderly, cachetic and debilitated, and respiratory depression
 - Concomitant use or discontinuation of cytochrome P450 3A4 inhibitors and inducers
 - Interactions with CNS depressants
 - Adrenal insufficiency
 - Severe hypotension
 - Increased intracranial pressure, brain tumors, TBI, impaired conscious.
 - GI Conditions (contraindicated for obstruction including paralytic ileus)
 - Seizure disorders
 - Withdrawal



Federal Efforts to Fight Opioid Abuse

- CDC in March 2016 Released – [Guidelines for Prescribing Opioids for Chronic Pain](#) (Primacy Care Setting)
- CDC awarding \$ to improve safe prescribing practices – (i.e., Pres. Drug Mon. Programs)
- [SAMHSA Opioid Overdose Prevention Toolkit](#)
- [CMS, Medicaid Program Integrity, What is a Prescribers Role in Preventing Diversion of Prescription Drugs](#) (Feb. 2016)

Federal Efforts to Fight Opioid Abuse

HHS expands access to opioid treatment by expanding access to medication assisted treatment (MAT) for opioid use disorders (11/16/16)(allowing PAs and ARNPs to take FREE 24 hour training to prescribe buprenorphine and apply for a waiver)

HHS Mobile App to support MAT for Opioid Use disorder

(Provides info on medication approved by FDA for use in treatment of opioid use disorder and treatment approaches, treatment guidelines, ICD-coding, and CME info; critical helplines and SAMSHA treatment locators)



Surgeon General: Pledge for Healthcare Professionals

- 1) Educate ourselves to treat pain safely and effectively;
- 2) Screen our patients for opioid use disorder and provide or connect them with evidence based treatment;
- 3) Talk about and treat addiction as a chronic illness, not a moral failing

See <http://turnthetiderx.org/join/#>.

“Scientific evidence is lacking for the benefits [of opioids] to treat chronic pain.”

“In general, do not prescribe opioids as the first-line treatment for chronic pain.”

[TurnTheTideRxpocket Guide](#)



2018 Hospital Pain Management Survey Questions

HP1: During this hospital stay, did you have any pain?

- Yes
- No → If no, Go to Question ____

HP2: During this Hospital stay, how often did the hospital staff talk with you about how much pain you had?

- Never
- Sometimes
- Usually
- Always

HP3: During this hospital stay, how often did hospital staff talk with you about how to treat your pain?

- Never
- Sometimes
- Usually
- Always

The enhanced pain assessment and management standards include the following new requirements:

- Identifying a leader or leadership team that is responsible for pain management and safe opioid prescribing
- Involving patients in developing their treatment plans and setting realistic expectations and measurable goals
- Promoting safe opioid use by identifying high-risk patients
- Monitoring high-risk patients
- Facilitating clinician access to prescription drug monitoring program databases
- Conducting performance improvement activities focusing on pain assessment and management to increase safety and quality for patients

2017 NATIONAL HEALTH CARE FRAUD TAKEDOWN

The Department of Health and Human Services Office of Inspector General, along with our state and federal law enforcement partners, participated in an unprecedented nationwide health care fraud takedown in July 2017.

SCOPE

This year's takedown features a large-scale federal and state partnership to combat health care fraud and the opioid epidemic. Enforcement activities took place nationwide, from Washington to Puerto Rico. This **multi-agency enforcement operation is the largest in history**, both in terms of the number of defendants charged and loss amount.

More than **400 defendants** in **41 federal districts** were charged for their alleged participation in schemes involving more than **\$1.3 billion in false billings** to vital health care programs. Of those subjects charged, **115 are medical professionals**—particularly doctors and nurses. **Thirty** Medicaid Fraud Control Units participated in the takedown.

2017 TAKEDOWN By The Numbers

- 412** Defendants Charged, Including
- 115** Medical Professionals
- \$1.3** Billion in Losses
- 41** Federal Districts
- 30** Medicaid Fraud Control Units
- 295** Exclusion Notices
- 350** OIG Agents

Source: DOJ and HHS OIG



Federal Enforcement Trends - OIG

- **Pharmaceutical Executives Charged in Racketeering Scheme** (December 8, 2016; U.S. Attorney; District of Massachusetts) <http://go.usa.gov/x8p4g>. Charges relate to a nationwide conspiracy to bribe medical practitioners to unnecessarily prescribe a fentanyl based pain medication and defraud healthcare insurers.

- **Doctor Found Guilty Of Drug Distribution And Causing The Death Of A Patient** (December 8, 2016; U.S. Attorney; Eastern District of Pennsylvania) <http://go.usa.gov/x8p42> A former physician convicted of 308 felony counts of prescribing large amount of oxycodone and methadone “outside the usual course of professional practice and without medical necessity.” He was convicted of healthcare fraud as well for fraudulently billing and having staff give patients pre-signed prescriptions.

- **Owner of Several 'Clean and Sober' Residential Facilities in Snohomish County Sentenced for Drug Trafficking** December 9, 2016; U.S. Attorney; Western District of Washington



Federal Enforcement Trends -DOJ

9/16 DOJ settles with physician for \$200,000 to resolve allegations that he violated FCA by writing prescriptions for oxycodone and other controlled medications without medical justification, and for billing services without medical justification.





Federal Enforcement Trends - DOJ

1/17/16 - McKesson agrees to pay \$150 million for failing to detect and report pharmacies suspicious order of prescription pain pills. The settlement also requires McKesson to suspend sales of controlled substances from distribution in CO, OH, MI, and FL. Agreement also imposed new and enhanced compliance requirements. Violations are related to Controlled Substance Act from 2008-12.

http://hosted.ap.org/dynamic/stories/U/US_PAIN_PILL_SHIPMENTS?SITE=AP&SECTION=HOME&TEMPLATE=DEFAULT.



Federal Enforcement Trends - DOJ

12/23/16 - Cardinal Health, Inc. agreed to pay \$44 million to resolve allegations it violated the Controlled Substance Act (“CSA”) in certain states by failing to report suspicious order of controlled substances to pharmacies. Settlement also resolves a civil investigation in Washington State concerning alleged violations of CSA-record keeping requirements.



Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Wednesday, August 2, 2017

Attorney General Sessions Announces Opioid Fraud and Abuse Detection Unit

Attorney General Jeff Sessions today announced the formation of the Opioid Fraud and Abuse Detection Unit, a new Department of Justice pilot program to utilize data to help combat the devastating opioid crisis that is ravaging families and communities across America.



WA State Enforcement Trends – Ex.

Health | Local News

DEA, state crack down on pain doctor over opiate prescriptions, citing 18 deaths

Originally published July 15, 2016 at 4:33 am | Updated July 15, 2016 at 2:27 pm

- Seattle Pain Center closed and Dr. Frank Li stripped of his medical license.
- “Respondent and mid-level providers he employed provided dangerously substandard care to vulnerable patients suffering from chronic pain.”
- Multiple patients deaths from 2010-2015 caused by “acute drug intoxication.”

<http://www.doh.wa.gov/LicensesPermitsandCertificates/MedicalCommission/PractitionerRegulation/LegalActions>.

WA MQAC Prescribing Actions

- (5/31/17) MD Arnold Case: “Respondent continued prescribing of excessive quantities and doses of controlled substances....”
- “Respondent made little effort to examine, diagnose, treat, test, or monitor patients with chronic non-cancer pain, anxiety, and other issues that were treated with controlled substances.”
- “Respondent frequently wrote prescriptions for Schedule II through V controlled substances in large quantities and in combinations of lethal doses.”
- “Review of PMP reports for Respondent’s patients reveals indiscriminate prescribing of Schedule II and III opioid medication.”
- <http://www.doh.wa.gov/LicensesPermitsandCertificates/MedicalCommission/PractitionerRegulation/LegalActions>.

WA MQAC Prescribing Actions

- (4/27/17) PA Hughes Case: “Respondent prescribed potent opioid medication for numerous patients, often combined with benzodiazepines, contrary to the standard of care and the pain management rules....”
- “Respondent’s continued pattern of opioid prescribing contrary to the standard of care and in violation of his 2015 Stipulations places chronic pain patients at risk.”

<http://www.doh.wa.gov/LicensesPermitsandCertificates/MedicalCommission/PractitionerRegulation/LegalActions>.

WA MQAC Prescribing Actions

- (2/2/17) MD Travers Case: “Respondent has maintained a pattern of dangerous pain management for the treatment of non-cancer pain and a disregard about the serious harm and risk of harm improper opioid dosing poses to patients.”
- “Prescribed massive doses of opioids despite indications of drug misuses and diversion, clear sign of opioid tolerance, and no clear rationale offered for the high doses prescribed.”
- “failed to utilize pain specialist consultants when prescribing opioids in excess of 120 mg morphine [equivalent] dose... (MED) daily....”

Board of Osteopathic Medicine and Surgery

(11/15/16) DO Alsager: “inappropriately prescribing potentially dangerous medications without conducting necessary patient examinations.”



Doctors Increasing Face Charges for Patient Overdoses (7/31/17)

The number of doctors penalized by the US Drug Enforcement Administration has grown more than fivefold in recent years. The agency took action against 88 doctors in 2011 and 479 in 2016, according to an analysis of the [National Practitioner Data Bank](#) by [Tony Yang](#), an associate professor of health administration and policy at George Mason University. Many other doctors have been sued in civil suits.

Increased Civil Liability - Malpractice

- Malpractice claims related to chronic pain management have increased in recent years.
- One study found that 17% of claims were related to medication management problems, and the majority of these claims involved patients with a history of risk behaviors associated with medication misuse (82%)

[Sehgal, N. et. al, Prescription Opioid Abuse in Chronic Pain: A Review of Opioid Abuse Predictors and Strategies to Curb Opioid Abuse \(Pain Physician 15:ES67-ES92 2012\)](#)

WASHINGTON STATE EFFORTS TO FIGHT OPIOID ABUSE

- “[I]nappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.”
- “All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances.”
- **“Appropriate pain management is the treating physician's responsibility [and]...inappropriate treatment of pain to be a departure from standards of practice....”**

[See WAC 246-919-850](#); [see also, WAC 246-919 et. seq.](#)



WA Prescribing Guidelines

“Clinically meaningful improvement is defined as an improvement in pain AND function of at least 30% as compared to start of treatment or in response to a dose change. A decrease in pain intensity in the absence of improved function is not considered meaningful improvement except in very limited circumstances such as catastrophic injuries (e.g. multiple trauma, spinal cord injury, etc.)....Continuing to prescribe opioids in the absence of clinically meaningful improvement in function and pain, or after the development of a severe adverse outcome (e.g. overdose event) is not considered appropriate in care.”

See 2015 AMDG Guidelines at 9.





Risk Management Strategies

- Follow all state and federal laws.
- Follow state guidelines and document compliance. When diverge from guidelines document reason supporting decision and monitor closely.
- Use state prescription drug monitoring program and document compliance
- Consider Rx naloxone for patients on opioids
- Refer to therapy (psych, OT, PT) or pain specialists as necessary
- Consult with specialists
- Evaluate patients for opioid use disorder when appropriate
- Regularly assess patients condition to determine if receiving clinically meaningful improvement and document it in EMR
- Use MAT and support treatment services
- Regularly evaluate risk of harm or misuse
- Talk to patient about treatment plan and use pain contract when appropriate

Communication Strategies with Patients

Re: Prescribing Opioids

- 1) Science/peer reviewed literature has shown there is insufficient data to support prescribing opioids to treat chronic pain.
- 2) Prescribing high dosage or long term opioids increases risk of addiction or OD.
- 3) Opioid use increases risk of complications: falls, respiratory distress, constipation, etc. (i.e., worse outcome)
- 4) Current prescribing guidelines limit opioid amount/dosage
- 5) Ethically/legally required to do what is in your best interest.
- 6) I will prescribe you non-opioids (or limited opioid prescription with appropriate taper etc.) and refer you to interdisciplinary therapy to help with your rehab, improve your function and health, and manage your pain.

*** Address tapering, MAT and Naloxone where appropriate





Provider/Health System RM Strategies AND Activities to Support Public Health

1. Education to Prescribers (Rx guidelines and best practices, PDMP, opioid use risks, MAT, multimodal analgesia, interdisciplinary therapy, tools/resources, prescriber risks, TJC 2018 standards)
2. Monitoring prescribers (internally and externally)
3. Opioid research (conducting/promoting)
4. Education to payers on alternative forms of treatment that should be covered by insurance
5. Work with external stakeholders including legislators and government agencies

Partnering Together

WSHA and WSMA Recommendations:

- **Overdose Prevention** – Implementing protocols and policies in the ED and primary care setting for overdose education and take home naloxone for at-risk individuals;
- **Expanding Access to Treatment** – Initiating medication assisted treatment (MAT) in emergency departments and coordinating outpatient treatment for at-risk individuals;
- **Integrating PMP Data into Clinical Workflows** – Furthering utilization of the Prescription Monitoring Program (PMP) and integration of PMP data into EMR;
- **Expanding Access to Treatment** – Developing and implementing a tool kit to support providers in increasing the number of patients treated with MAT;
- **Improving Opioid Prescribing Practices** – Leveraging data and guidelines to support appropriate opioid prescribing practices; and
- **Develop Low-Barrier Methadone and Buprenorphine Access** – *under development.

Questions

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