LEGISLATIVE UPDATE – OPIOID CRISIS
IMPACT OF GLOBAL, FEDERAL, AND STATE INITIATIVES

TPF 10TH Annual Scientific Meeting

11.4.2018

CM SCHADE, MD, PHD, PE, FIPP

Advanced Pain Solutions

Past President Texas Pain Society

CM Schade, MD, PhD, PE

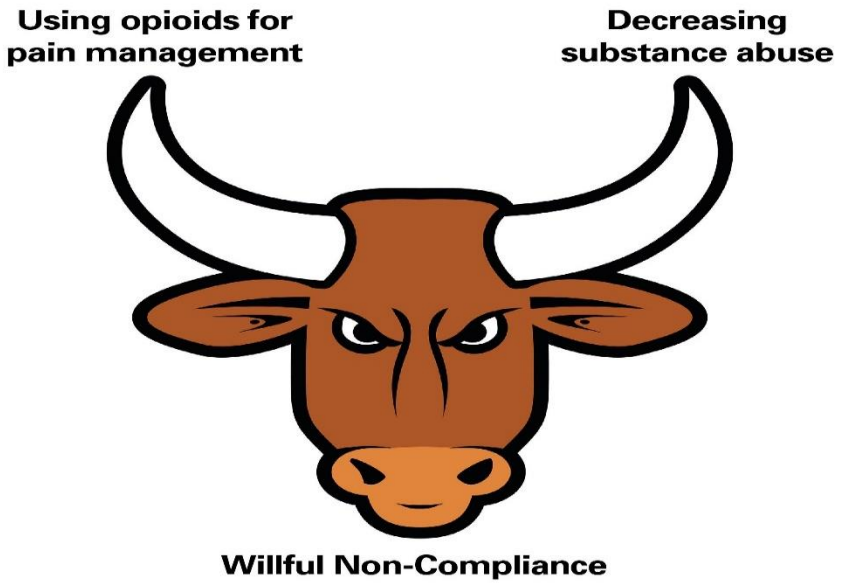
CM Schade, MD, PhD, PE has 41 years of experience in the treatment of chronic pain. He is practicing Pain Medicine full time in Mesquite (the Dallas Metroplex), Texas. He is ABA Board Certified in Pain Management, a Fellow of Interventional Pain Practice and a Diplomate of the American Board of Anesthesiology, American Board of Pain Medicine, American Academy of Pain Management and American Board of Interventional Pain Physicians.

Dr. Schade has a PhD in Electrical Engineering and Computer Science from Stanford University and is a Licensed Professional Engineer.
Colonel Schade also served 10 years with the US Air Force as a Flight Surgeon and served as the Air Force Surgeon General's Consultant in Chemical Warfare.
He is a pioneer in the field of spinal cord stimulation and has made multiple contributions that have advanced spinal cord stimulation and pain therapies and has gained national recognition for his work.

Dr. Schade is also a strong supporter of patient rights and is a Director Emeritus of the Texas Pain Society, Past-President of the Greater North Texas Pain Society, a Texas Medical Association Delegate and represents Pain Medicine on the Texas Medical Association's Interspecialty Society, is the Pain Medicine Delegate on the Medicare Carrier Advisory Committee and is Past-President of the Texas Pain Society.

NO RELEVANT FINANCIAL DISCLOSURES

The Horns of a True Dilemma



"We often struggle to balance reducing our patients' pain with increasing their risk of opioid addiction."

- Vivek Murthy, United States Surgeon General, August 2016

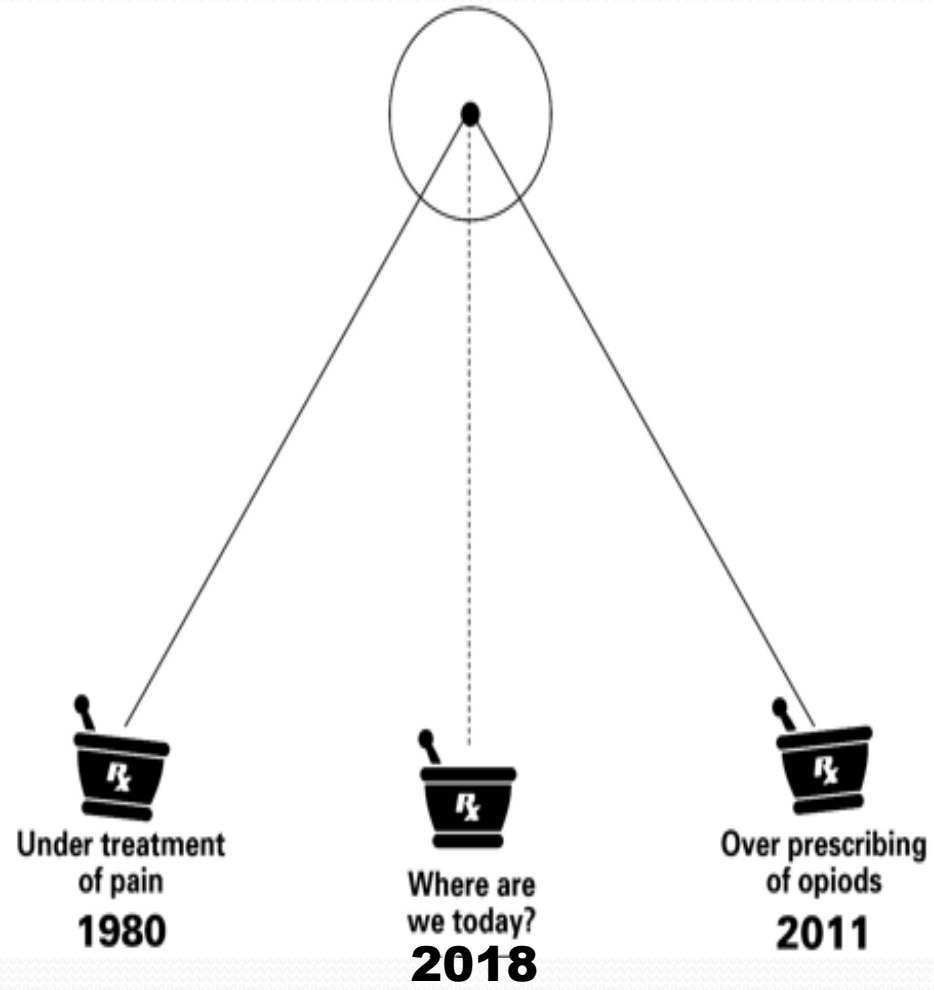
"The benefit of tolerable pain levels and functional lives may outweigh the risk of opioid use for these patients."

- CMS Opioid Misuse Strategy 1-5-2017

"What can you do to prevent opioid misuse?"

- Jerome Adams, MDA United States Surgeon General, September 2018

The Opioid Pendulum



The United Nations Says Untreated Pain is "Inhumane and Cruel"

"The issue remains equally compelling closer to home. Surprisingly, the UN report states that over a third of patients in the United States are not adequately treated."

United Nations General Assembly. Report of the Special Rapporteur on torture and other cruel, inhuman, or degrading treatment or punishment Juan E. Mendez. New York, New York; Human Rights Council. 2013:51-56

Multiple Congressional Committees Are Addressing the Opioid Crisis

- **Senate Health, Education Labor and Pensions (HELP)**
- Senate Finance Committee
- Senate Judiciary

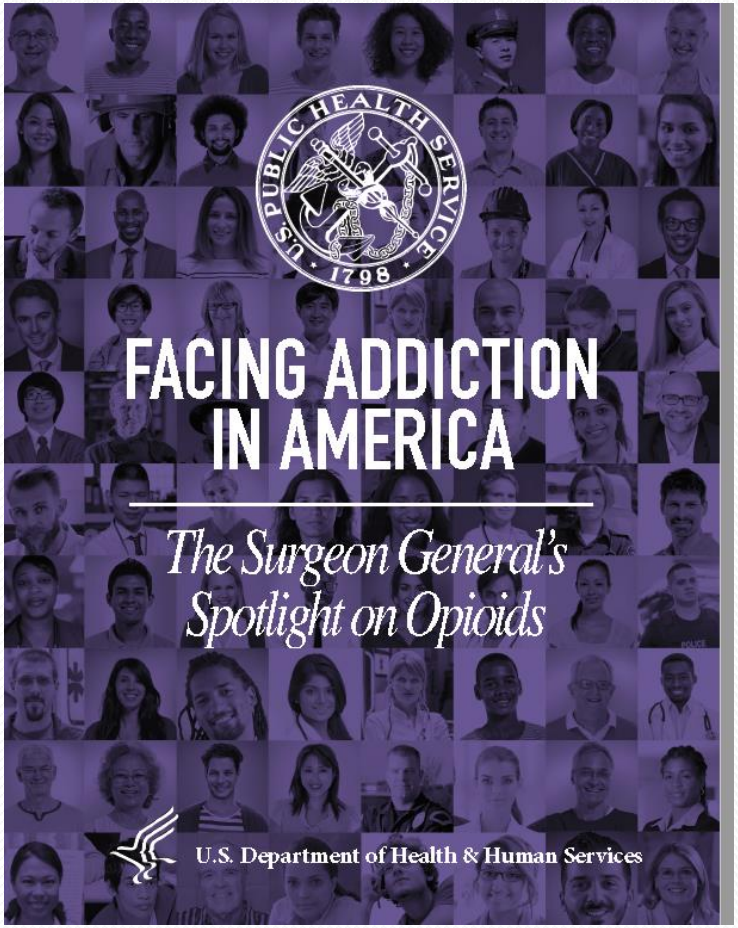
- **House Energy and Commerce Committee (Subcommittee on Health, and the Subcommittee on Oversight and Investigations)**
- **House Ways and Means Committee**
- House Judiciary
- House Committee on Oversight and Government Reform
- House Committee on Education and Workforce

Pain Care Coalition

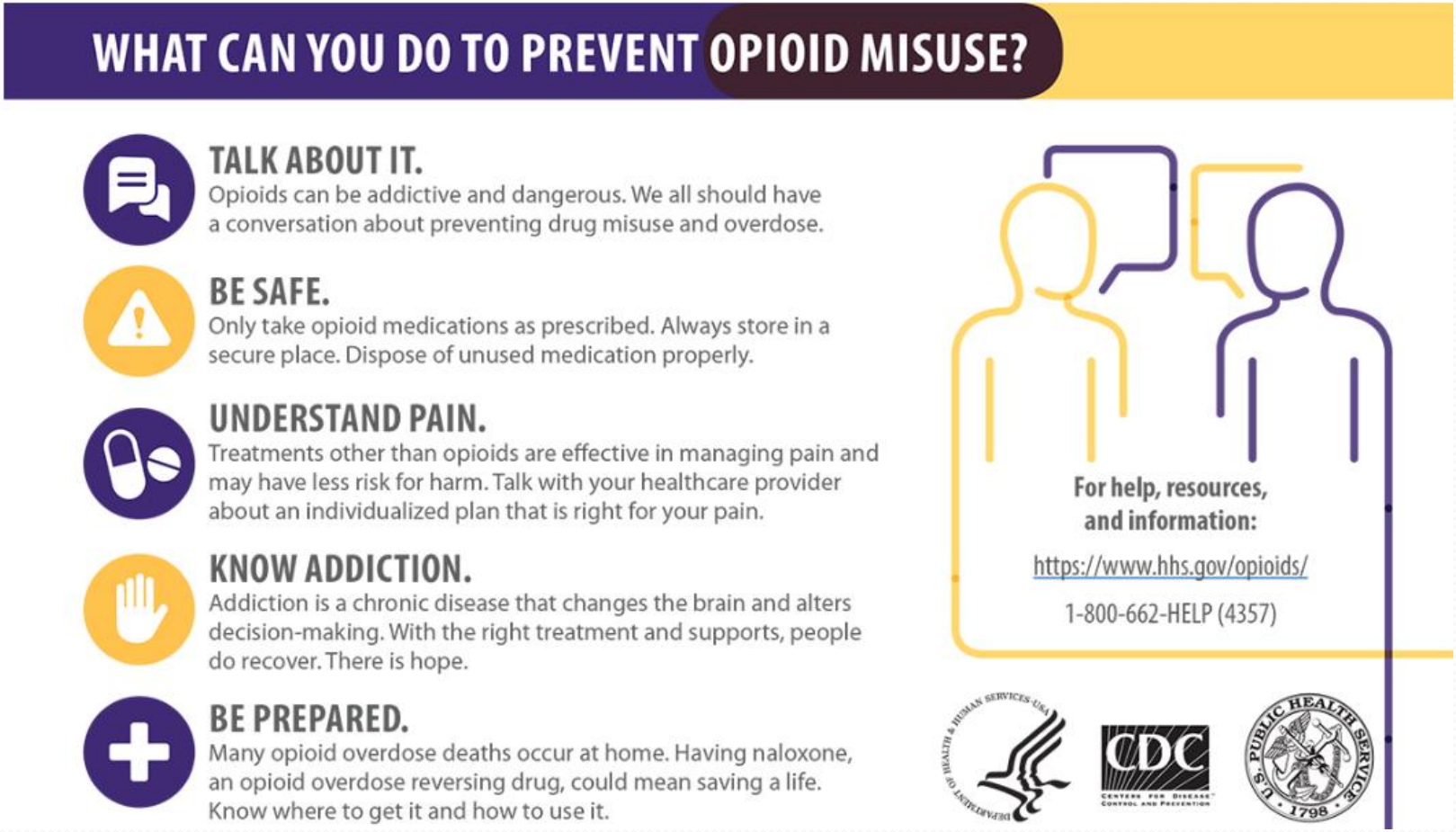
American National Coalition
for Responsible Pain Care:

- American Academy of Pain Medicine
- American Pain Society
- American Society of Anesthesiologists

Jerome Adams, MDA Sept 2018



Surgeon General Postcard Sept 2018



US Dept of Health and Human Services: 5-Point Strategy to Combat the Opioid Crisis

- 1. Improving access to both addiction treatment and recovery services
- 2. Promoting the use of medications such as naloxone to reverse overdose
- 3. Strengthening the understanding of the epidemic through better public health surveillance
- 4. Providing support for cutting-edge research on pain and opioid addiction
- 5. Advancing better pain management practices

5-15-2018

US Dept of Health and Human Services: Pain Management Task Force

- 1. Working Draft Report-Gaps and Recommendations (20 pgs) public comment
- 2. Vanila Singh, MDA Chief Medical Officer and Committee Chair
- 3. Clinical Best Practices: Approaches to pain management, medication, physical therapy, interventional procedures, special populations, and psychological approaches
- 4. Cross-Cutting Clinical and Policy Best Practices: Risk assessment, stigma, complementary, alternative and integrative therapies (CAIT), education, and access to pain care
- 5. Review of CDC Guidelines: Study long-term efficacy of COT and specific diseases, study optimal opioid dosing, tapering, and escalation, recommend maintaining long-term COT and co-prescribing of benzodiazepines if indicated when the benefits outweigh the risks, discourage the use of arbitrarily defined MME and daily dosing limits

One Hundred Fifteenth Congress
of the
United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Wednesday,
the third day of January, two thousand and eighteen

An Act

To provide for opioid use disorder prevention, recovery, and treatment, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act" or the "SUPPORT for Patients and Communities Act".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

HR-6 SUPPORT FOR PATIENTS AND COMMUNITIES ACT

AP

Trump signs bipartisan measure to confront opioid crisis

1 of 5

President Donald Trump holds a pen up after signing bipartisan legislation to confront the opioid crisis in the East Room of the White House, Wednesday, Oct. 24, 2018, in Washington. (AP Photo/Evan Vucci)

HR-6 SUPPORT FOR PATIENTS AND COMMUNITIES ACT

- WASHINGTON (AP) — President Donald Trump pledged on Wednesday to put an "extremely big dent" in the scourge of drug addiction in America as he signed legislation intended to help tackle the opioid crisis, the deadliest epidemic of overdoses in the country's history.
- H.R. 6—The Substance-Use Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act—is a comprehensive law that combined more than 70 bills from both chambers of Congress. It was passed by the House and the Senate in September before the President signed it on Wednesday, October 24
- The final piece of legislation was 660 pages and contains provisions for the Centers for Disease Control, the Center for Medicare & Medicaid Services (CMS), Drug Enforcement Agency, the FDA, the U.S. Postal Service and other agencies that are impacted by the opioid crisis.

HR-6 SUPPORT FOR PATIENTS AND COMMUNITIES ACT

- • H.R. 3528—Every Prescription Conveyed Securely Act, which requires Schedule II, III, IV or V controlled substances covered under Part D or Medicare Advantage Drug Plans (MA-PD) to be transmitted using an electronic prescription drug program starting Jan. 1, 2021.
- • H.R. 4275—The Empowering Pharmacists to Fight Opioid Abuse Act, which directs the Department of Health and Human Services to develop and disseminate materials that clarify circumstances where pharmacists are allowed to decline to fill prescriptions that they think may be fraudulent or questionable.
- • H.R. 4841—Standardizing Electronic Prior Authorization for Safe Prescribing Act of 2018, which requires the HHS secretary to establish a standard, secure electronic prior authorization system for use by Part D plans no later than Jan. 1, 2021.
- • HR 5676—Senior Communities Protection Act of 2018, which permits Part D plans and Medicare Advantage plans to suspend payment for any fraudulent claim and require reporting of suspensions to HHS.

H.R. 6: SUPPORT for Patients and Communities Act

"This comprehensive bill provides critical support to desperate communities all across the country and gives those fighting on the front line new tools to help treat addiction and slow the flow of illicit drugs across our borders." Energy and Commerce Committee

Key Provisions

- Technical Expert Panel (TEP) on reducing surgical setting opioid use
- "ALTO"— Grants for alternatives to opioids
- Prescribing Limits Study and Report
- NIH research
- FDA Opioid Analgesic Prescribing Guidelines
- Access to increased drug disposal
- Enhanced Flexibility Related to MAT

Combating Opioid Abuse for Care in Hospitals

- Technical expert panel on reducing surgical setting opioid use;
- Data collection on perioperative opioid use.
- This provision requires the Secretary, within six months, to convene a TEP consisting of medical and surgical specialty societies and hospital organizations to provide recommendations on best practices for pain management in surgical settings.
- Within one year of enactment, the Secretary is required to issue a public report on recommendations for broad implementation of pain management protocols that limit the use of opioids in the perioperative setting, while also analyzing perioperative opioid prescribing data for high-volume surgeries.

Alternatives to Opioids in Acute Care Settings

- Establishes demonstration program for purposes of establishing grants to test alternative pain management protocols to limit the use of opioids in emergency departments or hospitals, or other acute care settings

-Provides technical assistance on best practices on alternatives to opioids for pain management.

- Use of funds for training providers; promoting evidence based practices and disseminating information aiming at best practices for pain management protocols

Study of Prescribing Limits

Requires HHS, in consultation with the Attorney General (AG) to submit to Congress, a report on the impact of federal and state laws and regulations that limit the length, quantity, or dosage of opioid prescriptions

Research

Advancing Cutting Edge Research

- Allows the National Institutes of Health (NIH) to use its "other transactions authority" for high impact cutting-edge research projects that respond to public health threats, including the opioid crisis and finding new, non-addictive drugs for pain management.

Pain Research

- Updates the scope of the Interagency Pain Research Coordinating Committee to identify risk factors for, and early warning signs of, substance use disorders, and summarize advances in pain care research supported or conducted by the federal government, including information on best practices for the utilization of non-pharmacologic treatments, non-addictive medical products, and other drugs approved, or devices approved or cleared, by the FDA

Evidence-based opioid analgesic prescribing guidelines and report

- Requires FDA to develop evidence-based opioid analgesic prescribing guidelines for the indication-specific treatment of acute pain where such guidelines do not exist.

- FDA will consult with public stakeholders, and other relevant federal agencies in developing such guidelines, and report on how the agency will use the guidelines to protect public health.

- Intended to inform clinical decisions by prescribers and patients and are not intended to restrict, limit, delay or deny coverage or access by individual health care professionals

Grant Program to Increase Drug Disposal Programs

- Allows the Attorney General to award grants to five states to increase participation of eligible collectors as authorized collectors for drug-disposal programs

- Outlines the requirements that a state must meet when submitting an application for a grant and limit the use of the grant that a state receives to the costs associated with drug disposal participation

Expansion of providers that can administer medication assisted treatment (MAT) for opioid use disorders

- Will increase the number of waivered health care providers that can prescribe or dispense medication-assisted treatment (MAT) by authorizing clinical nurse specialists, certified **nurse midwives**, and **certified registered nurse anesthetists** to prescribe MAT for five years.

Also of note:

- It also makes permanent the prescribing authority for physician assistants and nurse practitioners and allows waivered practitioners to immediately treat 100 patients at a time if the practitioner is board certified in addiction medicine or addiction psychiatry; or if the practitioner provides MAT in a qualified practice setting.
- This provision codifies the ability for qualified physicians to prescribe MAT for up to 275 patients. The Secretary of HHS, in consultation with the Drug Enforcement Administration, will be required to submit a report that assesses the care provided by physicians treating over 100 patients and non-physician practitioners treating over 30 patients.

Other Provisions of Interest

- Better data sharing to combat the opioid crisis; prescription drug monitoring programs (PDMPs); also requires Medicaid providers to check PDMPs before prescribing a Schedule II controlled substances; encourages integrations into clinical workflow and establishes standard criteria for PDMPs.

- Several Provisions to enhance "lock-in" programs for Medicare beneficiaries

- Clarifying FDA regulation of non-addictive pain products: requires FDA to hold public meeting to address challenges and barriers of developing non-addictive medical products intended to treat pain or addiction and issue new or updated guidance documents; FDA will assess opioid sparing data for use in the labeling of non-addictive medical products that are as effective at controlling pain and able to reduce patient need of opioids to control pain.

- Safety enhancing packaging and disposal: clarifies FDA's authority to require drug manufacturers to package certain opioids to allow for a set treatment duration (e.g. "blister packs") and takes into consideration patients function limitations; clarifies FDA's authority to require manufacturers to give patients safe options to dispose of unused opioids such as safe disposal packaging or safe disposal systems

CMS 2019 CALL LETTER 04.02.2018

- **Definitions:**
- **Hard reject** - Stops the pharmacy from processing a claim unless or until an override is entered or authorized by a plan representative
- **Soft reject** - Stops the pharmacy from processing a claim unless or until a pharmacist-submitted drug utilization review (DUR)/prospective payment system (PPS) code is entered.

CMS 2019 CALL LETTER 04.02.2018

- **Lock-in** - Part D sponsors will be able to limit at-risk beneficiaries' coverage for frequently abused drugs to certain prescribers and pharmacies ("lock-in") and apply beneficiary-specific point-of-sale (POS) claim edits.
- **Potentiator Drugs** -A drug potentiator is defined as a chemical, herb, or other drug that is used to increase the effects of a substance and consequently, increasing both the substance and the potentiators abuse potential.
- **Opioid Naive**- No opioid use for the past 60 days

2019 CMS CALL LETTER 04.02.2018 OPIOID OVERUTILIZATION POLICIES

- 1. Opioid naïve patients: To reduce the potential for chronic opioid use or misuse, we expect all Part D sponsors to implement a **HARD SAFETY REJECT** to limit initial opioid prescription fills for the treatment of acute pain to no more than a **7 DAYS SUPPLY**.

2019 CMS CALL LETTER 04.02.2018 OPIOID OVERUTILIZATION POLICIES

2. High Risk Opioid Users:

- Using high levels of opioid(s) from multiple prescribers and pharmacies
- Part D identify and "lock–in"
- Identify and report opioids with potentiator drugs

2019 CMS CALL LETTER 04.02.2018 OPIOID OVERUTILIZATION POLICIES

3. Chronic Opioid Users:

- Educate patients and prescribers about overdose risk and prevention
- Notify prescribers if patients exceed 90MME/day
- High COT- Assess maintaining or decreasing opioid dosing when multi-sourcing or increased suicide risk

2019 CMS CALL LETTER 04.02.2018 OPIOID OVERUTILIZATION POLICIES

4. Edits:

- 90MME/day – Pharmacist must consult with the prescriber. POS Soft reject
- 200MME/day-POS Hard reject

2019 CMS CALL LETTER 04.02.2018 OPIOID OVERUTILIZATION POLICIES

- 5. Opioid users also taking duplicate or **KEY POTENTIATOR** drugs: Lastly, we expect sponsors to implement additional soft safety edits to alert the pharmacist about duplicative opioid therapy and **CONCURRENT USE OF OPIOIDS AND BENZODIAZAPINES.**
- 6. Overall: CMS also uses quality measures to track trends in opioid overuse across the Medicare Part D program. To drive performance improvement among plan sponsors, CMS will implement technical revisions to the Pharmacy Quality Alliance (PQA) opioid overuse measures and add a new PQA measure, Concurrent Use of Opioids and **BENZODIAZAPINES OR GABAPENTOIDS.**

2019 CMS CALL LETTER 04.02.2018 POTENTIALLY HIGH RISK BENEFICIARIES

- During the most recent 6 months, beneficiaries with an average daily MME greater than or equal to 90 mg and received opioids from more than **3 PRESCRIBERS** and more than **3 PHARMACIES**, OR from more than **5 PRESCRIBERS** regardless of the number of opioid dispensing pharmacies. Beneficiaries with cancer diagnoses and beneficiaries in hospice are excluded. Prescribers associated with the same single Tax Identification Number (TIN) are counted as a single prescriber.

SUMMARY

CMS High Risk Opioid Use and the Overutilization Monitoring System (OMS)

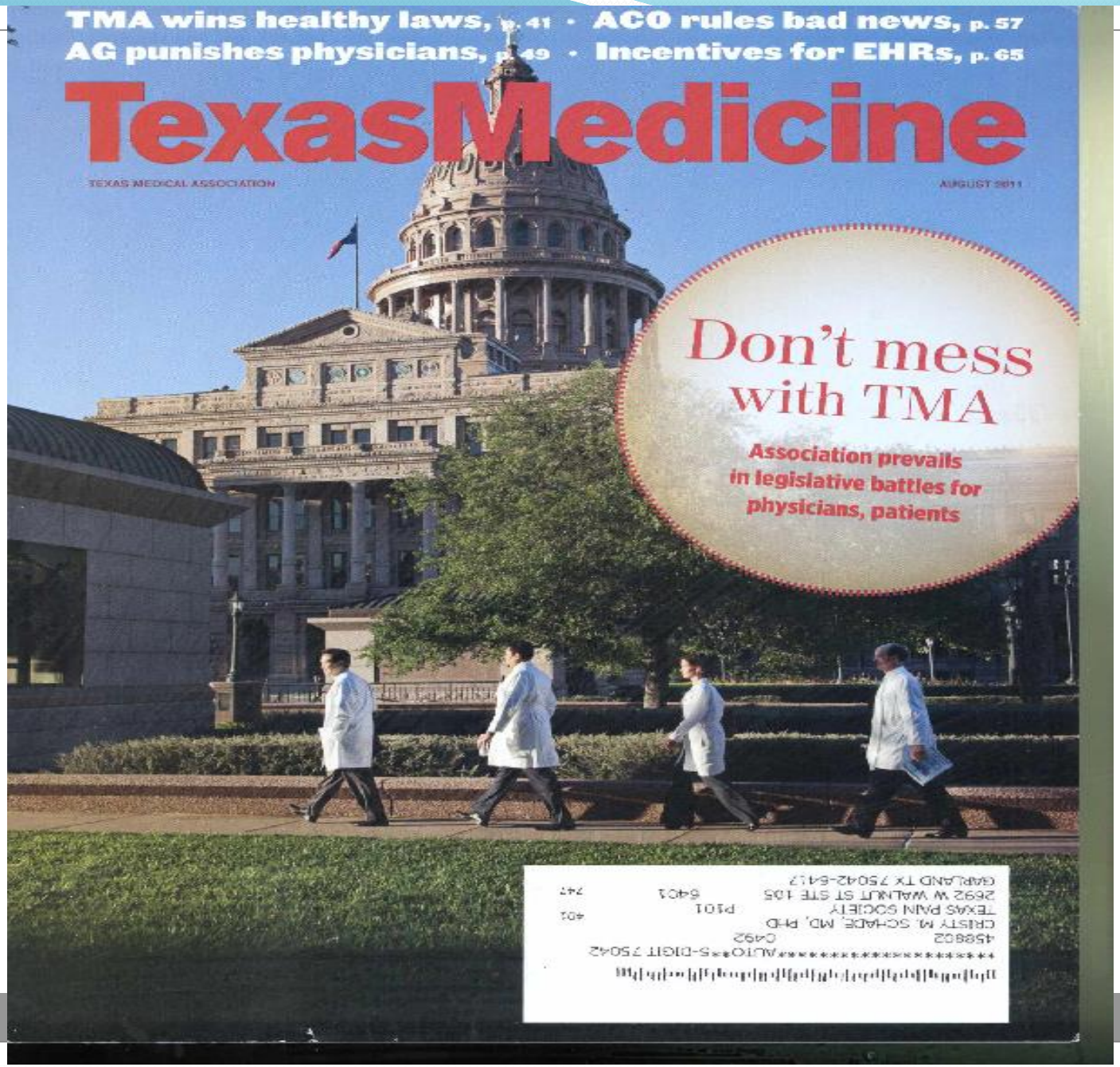
- 3 providers and 3 pharmacies, OR 5 providers - during the most recent 6 months
- More than 2 concordant opioid medications
- Greater than or equal to 90 MME per day---POS Soft Reject
- Greater than or equal to 200 MME per day—POS Hard Reject
- Concurrently taking opioid potentiator drugs

(benzodiazepines and/or gabapentinoids, eg, gabapentin >2400 mg/day)

The United Nations Says Untreated Pain is "Inhumane and Cruel"

Withholding all means of pain treatment goes against the view advocated by the UN, WHO, and Human Rights Watch.
It is past due for each and every one of us, including our pain patients and their families, to use our voices to tell all concerned parties that we support the UN view that untreated pain is tantamount to torture, and is cruel, inhuman, or degrading punishment.

Forest Tennant, MD, DrPH, Editor in Chief


TMA wins healthy laws, p. 41 · ACO rules bad news, p. 57
AG punishes physicians, p. 49 · Incentives for EHRs, p. 65
TexasMedicine
TEXAS MEDICAL ASSOCIATION
AUGUST 2011
Don't mess with TMA
Association prevails in legislative battles for physicians, patients

CONCLUSION

IF YOU AREN'T AT THE TABLE, THEN YOU ARE ON THE MENU