State and Federal Legislative Update

TPF 11TH Annual Scientific Meeting

10.27.2019

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 over 40 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.

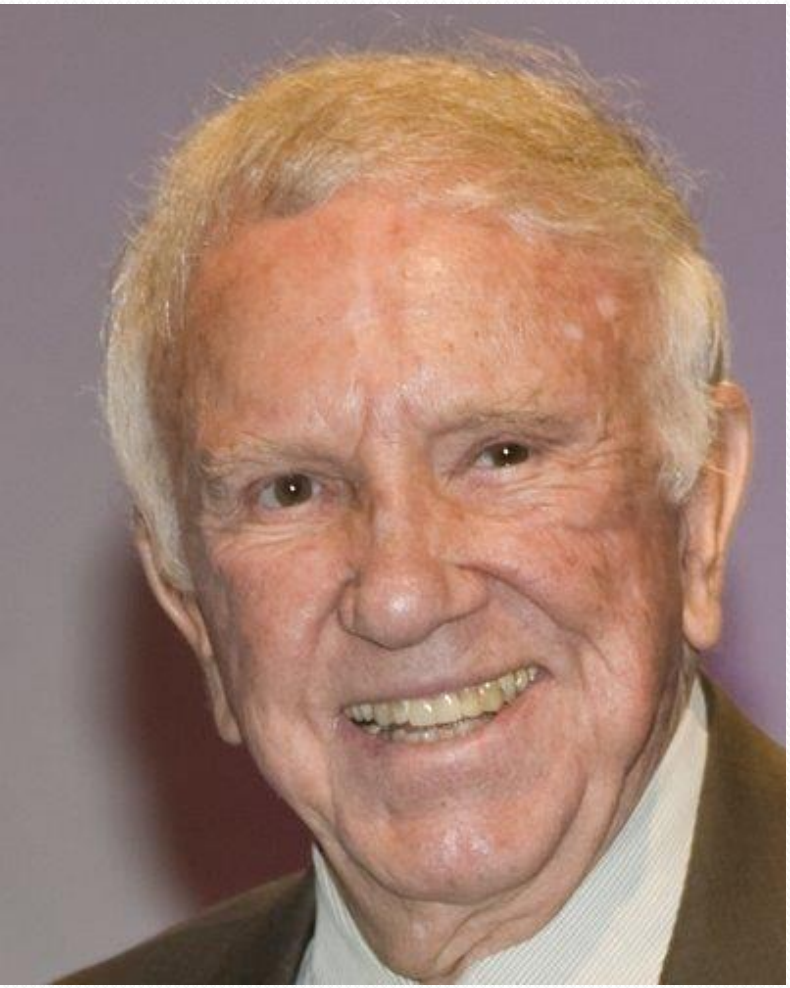
Dr. Schade has a PhD in Electrical Engineering and Computer Science from Stanford University and is a Licensed Professional Engineer.
Colonel Schade also served 10 years with the US Air Force as a Flight Surgeon and served as the Air Force Surgeon General's Consultant in Chemical Warfare.
He is a pioneer 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 Inter-specialty 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

Carey Stratton Hill, Jr., M.D., 1928-2015

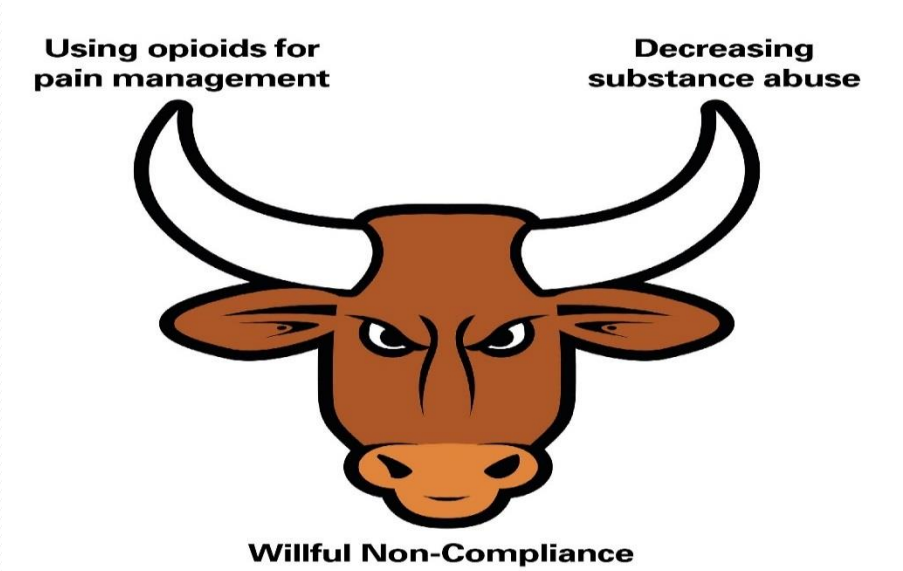
Professor Emeritus



My “Medico-Political” Mentor.

I met Dr. Hill when he was working on the Texas Chronic Intractable Pain Treatment Act. He founded the MD Anderson Pain management Clinic in 1981. He spearheaded the passage of the Nations First Chronic Intractable Pain Treatment Act in 1989. He was featured on 60 Minutes in 1992 after creating the film "My Word Against Theirs – Narcotics for Cancer Pain Control" which depicted the under-medication of pain. He won the Patient Care and Heart of Wisdom Award for the most humanitarian entry at the 1990 Muir Medical Film Festival. He founded the Texas Cancer Pain Initiative in 1991. He was the recipient of the American Cancer Society’s Humanitarian Award in 1995, and of the National Drug Policy Foundation’s Norman Zinberg Award for Excellence in Medicine in 1997

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."

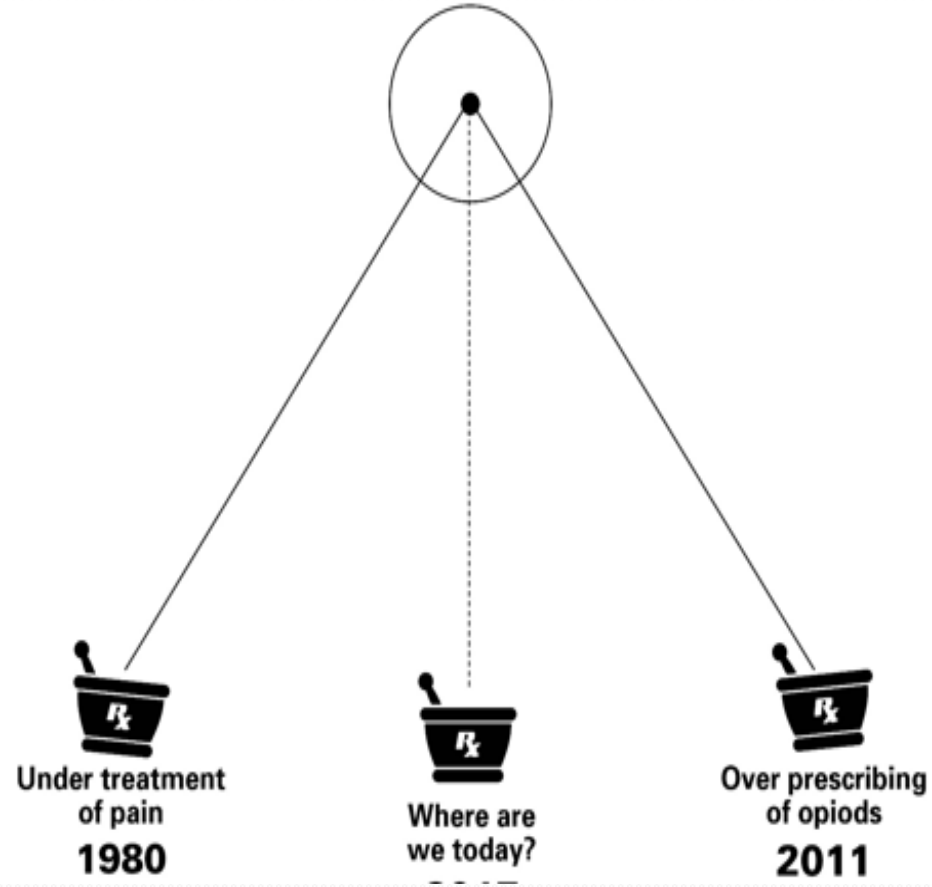
- CMS Opioid Misuse Strategy 1-5-2017

"What can you do to prevent opioid misuse?"

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

AMA: "Inappropriate Use" of CDC Guideline Should Stop, November 14, 2018

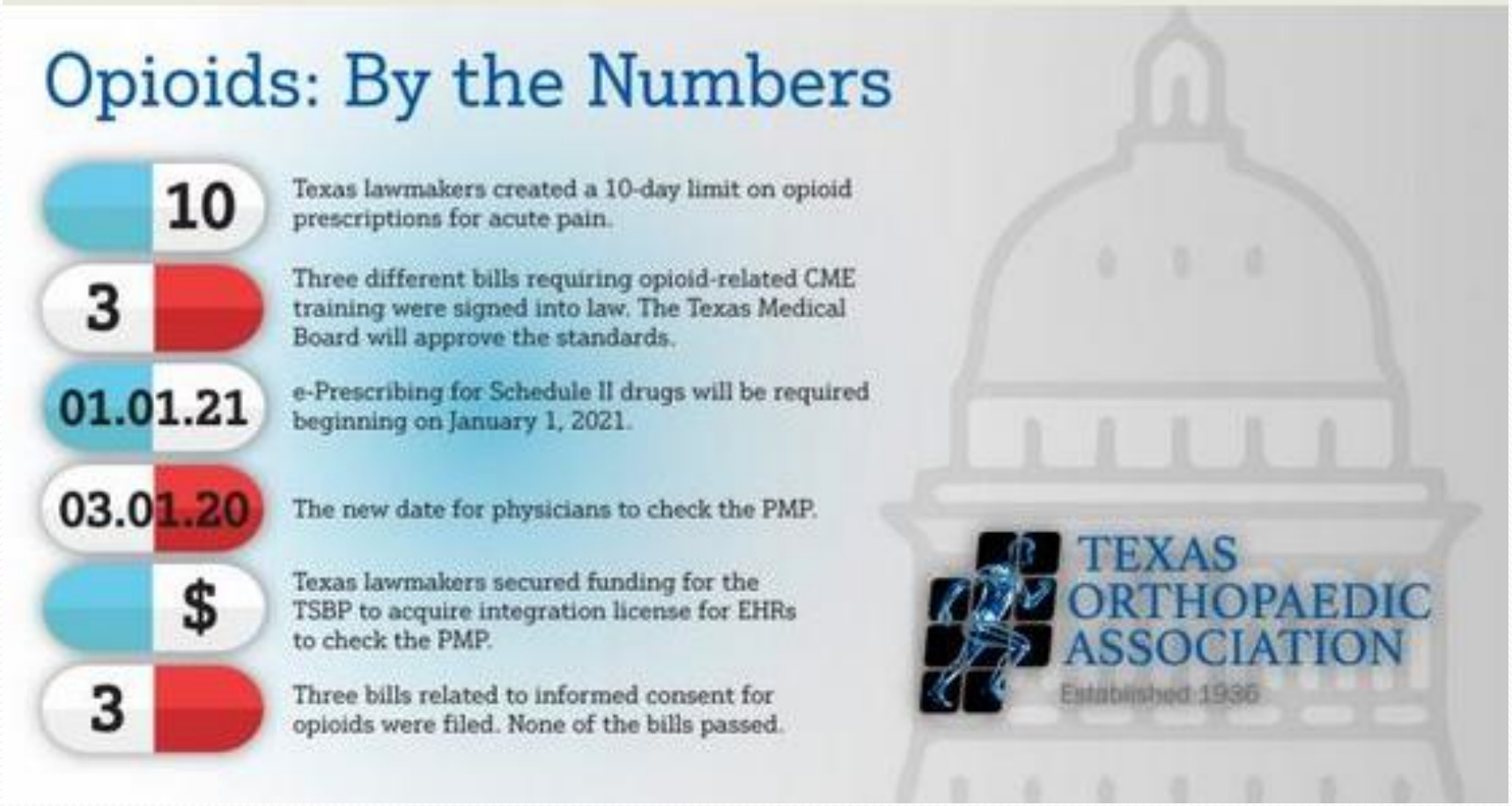
The Opioid Pendulum



After increasing every year for more than a decade , annual opioid prescriptions in the United States peaked at 255 million in 2012 and then decreased to 191 million in 2017.

Regulation Time Line

- 1981 Texas Triplicate Prescription for CII
- 1989 Texas Intractable Pain Treatment Act
- 2005 NASPER-National all Schedules Prescription Electronic Reporting Act
- 2007 TMB Pain Management, Rule 170
- 2010 TMB Registration of Pain Management Clinics Rule, 195
- 2011 Opioid prescribing peaked
- 2011 Texas PMP-Prescription Access Texas Pilot
- 2015 Sunset of Texas Controlled Substances registration
- 2016 Texas PMP moved to TSBP PMP Aware
- 2016 CDC guideline for prescribing opioids for chronic pain for PCPs
- 2018 TMB Audits: Service Area, Top 50, Potentiator Drugs
- 2019 HHS Pain Management Task Force Issues Report on Best Practices for Treatment of Pain
- 2019 10 Day Opioid limit
- 2020 Mandatory PMP Checks
- 2021 Mandatory e-Prescribing


Opioids: By the Numbers
10
Texas lawmakers created a 10-day limit on opioid prescriptions for acute pain.
3
Three different bills requiring opioid-related CME training were signed into law. The Texas Medical Board will approve the standards.
01.01.21
e-Prescribing for Schedule II drugs will be required beginning on January 1, 2021.
03.01.20
The new date for physicians to check the PMP.
$
Texas lawmakers secured funding for the TSBP to acquire integration license for EHRs to check the PMP.
3
Three bills related to informed consent for opioids were filed. None of the bills passed.
TEXAS ORTHOPAEDIC ASSOCIATION
Established 1936

Texas Lawmakers created a 10 day limit on opioid prescription for acute pain

- 09.01.2019 10 day limit on opioid Rx for acute pain.

- Ultimately, we are expecting regulatory clarification related to the following laws:

What Happens When a 10-Day Prescription for an Opioid Expires?

- The TMB indicated in its initial August guidance that a face-to-face visit would be required to write a new opioid prescription once the initial 10-day prescription runs out for an episode.

- The TMB is determining whether "telemedicine," such as a telephone call, would be adequate. It appears that the TMB will offer a solution that should satisfy surgeons.

Three different bills requiring opioid –related CME training were signed into law. The Texas Medical Board will approve the standards.

3 different pills created new laws for CME. This has created some confusion for regulators. Can all 3 bills be merged into one three-hour requirement?

One bill required the TSBP to develop its own CME hour for opioids.

TMB might be considering a "bucket" process in which each type of specialty would have a different CME requirement: eg Surgeons vs Radiolgists

E- prescribing for Schedule II drugs will be required beginning on January 1, 2021.

- Texas aligned it e-prescribing laws with the federal laws
- All Medicare prescriptions for controlled substances will be e-prescribed
- Texas requires e-prescribing for all controlled substances

3-1-2020 physicians to check the PMP

There are several regulatory questions related to the PMP that will be answered soon:

- Check when prescribing: opioids, benzodiazepines, barbiturates, and/or Soma
- How will regulators know that a physician checked the PMP? Will work flow integration technology show that the physician checked on the back end (assumed compliant)? Or will it have to be documented into the medical record?
- What about inpatients? Will physicians have to check the PMP every single time that a drug is administered while the patient is in the hospital, extended care, long term care, day surgery, etc?

Texas Lawmakers secured funding for the TSBP to acquire integration license for EHRs to check the PMP

- The state funding offset the $50 charge to access the PMP electronically
- Each practice has to pay for their EHR work flow integration upgrade to check the PMP

Three bills related to informed consent for opioids were filed. None of the bills passed.

- BUT
- The Texas Medical Disclosure Panel has created new forms for patients to sign for certain procedures, and the new forms go into effect on January 1, 2020.
- The MDP places each procedure on one of 2 list: List A or list B. List A require specific disclosures, and list B does not.
- The difference between the new and current form is mainly a change of style and not of substance. The new form makes the consent more clear, divides the sections clearly and emphasizes that additional procedures may be necessary, and requires an initial pertaining to consent for blood products

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

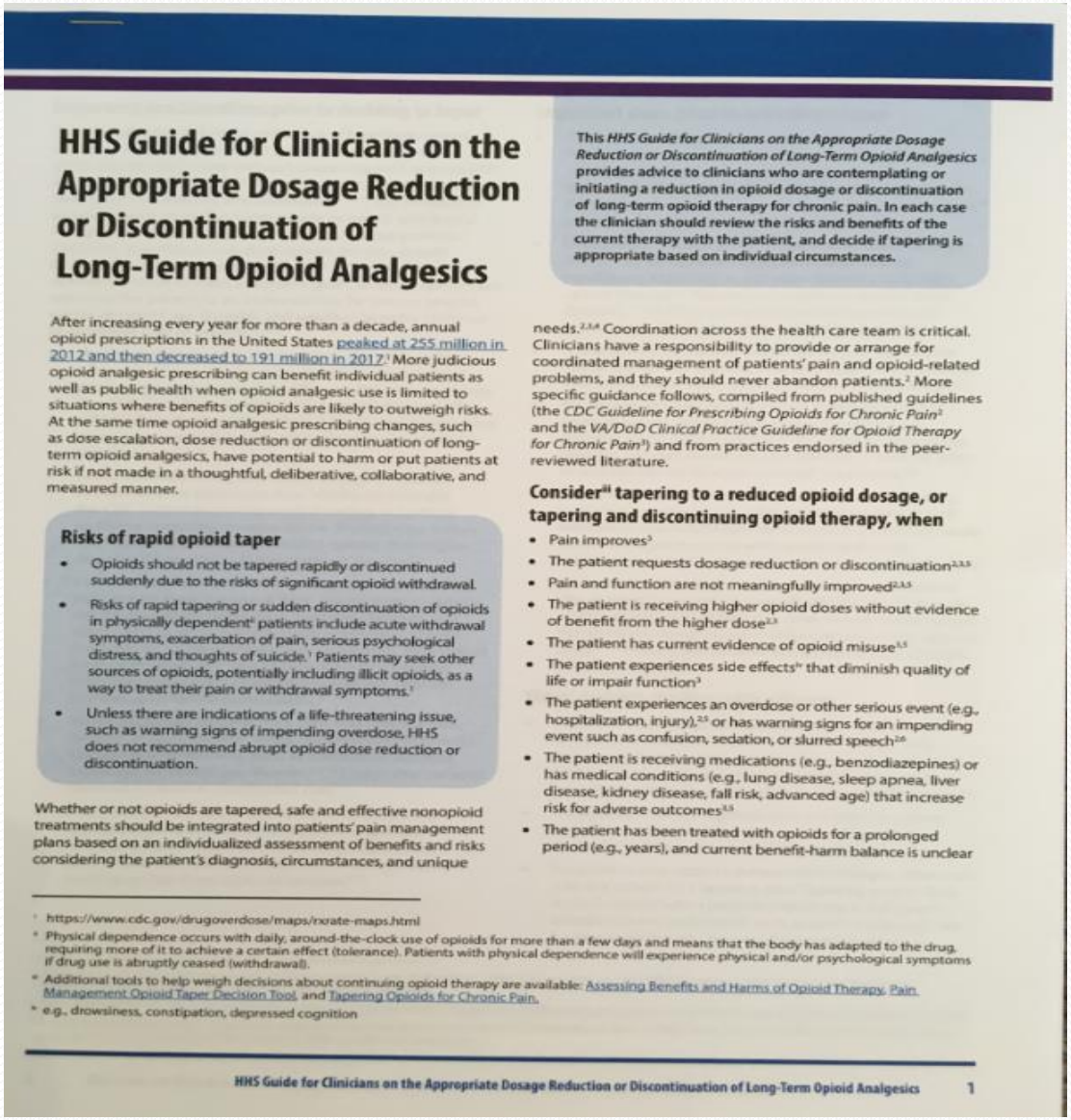
US Dept of Health and Human Services: Pain Management Task Force

- 1. Pain Management Task Force Issued its Final Report on Best Practices for Treatment of Pain on 5-6-2019
- 2. Vanila Singh, MD, APM was the 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

CDC Guidelines Updates

- **April 2019 In a NEJM article, the CDC says that misimplementation the guideline could cause harm, and it does not support stopping opioid use abruptly**
- **4-9-2019 FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering**
- **10-10-19 HHS Announces Guide for Appropriate Tapering or Discontinuation of Long-Term Opioid Use**

HHS GUIDE



HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics

This *HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics* provides advice to clinicians who are contemplating or initiating a reduction in opioid dosage or discontinuation of long-term opioid therapy for chronic pain. In each case the clinician should review the risks and benefits of the current therapy with the patient, and decide if tapering is appropriate based on individual circumstances.

After increasing every year for more than a decade, annual opioid prescriptions in the United States peaked at 255 million in 2012 and then decreased to 191 million in 2017.[1] More judicious opioid analgesic prescribing can benefit individual patients as well as public health when opioid analgesic use is limited to situations where benefits of opioids are likely to outweigh risks. At the same time opioid analgesic prescribing changes, such as dose escalation, dose reduction or discontinuation of long-term opioid analgesics, have potential to harm or put patients at risk if not made in a thoughtful, deliberative, collaborative, and measured manner.

Risks of rapid opioid taper

- Opioids should not be tapered rapidly or discontinued suddenly due to the risks of significant opioid withdrawal.
- Risks of rapid tapering or sudden discontinuation of opioids in physically dependent[ii] patients include acute withdrawal symptoms, exacerbation of pain, serious psychological distress, and thoughts of suicide.[1] Patients may seek other sources of opioids, potentially including illicit opioids, as a way to treat their pain or withdrawal symptoms.[1]
- Unless there are indications of a life-threatening issue, such as warning signs of impending overdose, HHS does not recommend abrupt opioid dose reduction or discontinuation.

Whether or not opioids are tapered, safe and effective nonopioid treatments should be integrated into patients' pain management plans based on an individualized assessment of benefits and risks considering the patient's diagnosis, circumstances, and unique needs.[2,3,4] Coordination across the health care team is critical. Clinicians have a responsibility to provide or arrange for coordinated management of patients' pain and opioid-related problems, and they should never abandon patients.[2] More specific guidance follows, compiled from published guidelines (the *CDC Guideline for Prescribing Opioids for Chronic Pain*[3] and the *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*[4]) and from practices endorsed in the peer-reviewed literature.

Consider[iii] tapering to a reduced opioid dosage, or tapering and discontinuing opioid therapy, when

- Pain improves[3]
- The patient requests dosage reduction or discontinuation[2,3,5]
- Pain and function are not meaningfully improved[2,3,5]
- The patient is receiving higher opioid doses without evidence of benefit from the higher dose[2,3]
- The patient has current evidence of opioid misuse[3,5]
- The patient experiences side effects[iv] that diminish quality of life or impair function[3]
- The patient experiences an overdose or other serious event (e.g., hospitalization, injury),[2,5] or has warning signs for an impending event such as confusion, sedation, or slurred speech[2,6]
- The patient is receiving medications (e.g., benzodiazepines) or has medical conditions (e.g., lung disease, sleep apnea, liver disease, kidney disease, fall risk, advanced age) that increase risk for adverse outcomes[4,5]
- The patient has been treated with opioids for a prolonged period (e.g., years), and current benefit-harm balance is unclear

[i] https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html

[ii] Physical dependence occurs with daily, around-the-clock use of opioids for more than a few days and means that the body has adapted to the drug, requiring more of it to achieve a certain effect (tolerance). Patients with physical dependence will experience physical and/or psychological symptoms if drug use is abruptly ceased (withdrawal).

[iii] Additional tools to help weigh decisions about continuing opioid therapy are available: Assessing Benefits and Harms of Opioid Therapy, Pain Management Opioid Taper Decision Tool, and Tapering Opioids for Chronic Pain.

[iv] e.g., drowsiness, constipation, depressed cognition

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)

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

- **DEFINITIONS:**
- **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

All Part D sponsors are to implement a **HARD SAFETY REJECT** to limit initial (opioid niave) 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

- 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

There are additional soft safety edits to alert the pharmacist about duplicative opioid therapy and **CONCURRENT USE OF OPIOIDS WITH BENZODIAZAPINES AND/OR GABAPENTOIDS.**

SUMMARY

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

- POTENTIALLY HIGH RISK BENEFICIARIES:
- 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

When Drug Enforcement Agents Come Knocking

- US Drug Enforcement Administration (DEA) agents from the DEA Diversion Control Program turn up in your office wanting to ask you questions. They announce they have the right to inspect your records without warning…

When Drug Enforcement Agents Come Knocking

- Hopefully this won't happen to you, but if it does and you are caught off guard, you could end up losing your DEA registration for a couple of years, even if you have done nothing wrong.
- See the TMA's Office of General Council's free white paper "DEA Investigations"

When Drug Enforcement Agents Come Knocking

- The TMA Office of General Counsel urges physicians to call their practice's legal counsel immediately after being approached by DEA

There is NO "Miranda Warning"

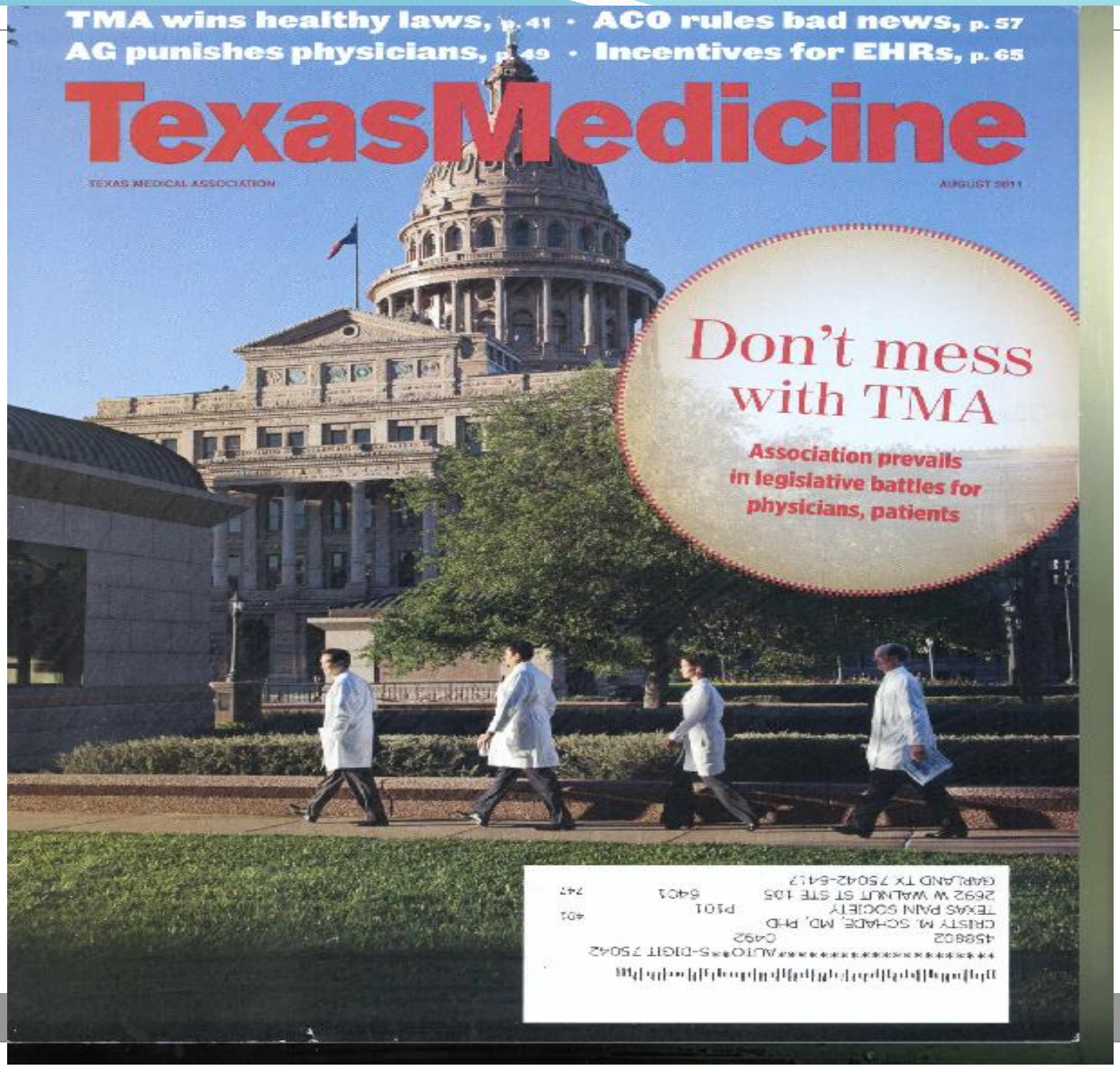
Your Legal counsel will be able to determine:

- If the investigation is routine or related to a complaint.
- If you should reschedule the search for another day.
- Whether to allow DEA agents to talk to staff without advise of counsel
- Which records and communication are appropriate for the investigation, and
- If you should sign a form to voluntarily surrender your controlled substance registration.

When Drug Enforcement Agents Come Knocking

- It does not reflect adversely on you to ask for time to consult with counsel; to reschedule the investigation; and defer making any decision, if needed, without advice from counsel, the paper says.

  The DEA is authorized to "inspect, copy and verify the correctness of records required to be kept". This authority does not, however, include the right to interrogate.


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