PainWeek®

Who's Looking at you, Doc?
A Rational Response to 2021 Perspectives on Controlled Substance Prescribing.

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Disclosures

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Overview

- Recent litigation against opioid manufacturers and prescribers, and the uptick in drug overdose cases, behavioral health needs, and access to pain management solutions during the COVID-19 pandemic, continues to present frontline practitioners with daily practice challenges.
- Frontline practitioners cannot control healthcare access barriers resulting from the controlled substance prescribing and utilization choices of others, but they can control their response to them.
- Understanding stakeholder perspectives and applicable guidance materials is necessary to formulating a rationale response to 2021 challenges and beyond.
- Documentation is key!

Learning Objectives

OBJECTIVE 1

- **Summarize** current stakeholder perspectives and oversight trends for opioid prescribing in 2021.

OBJECTIVE 2

- **Compare** the tension between payor review of opioid prescribing patterns and risk mitigation and law enforcement or licensing board litigation of these topics.

OBJECTIVE 3

- **List** three areas of medical record documentation ripe for improvement and necessary to communicate an appropriate and rationale approach to opioid prescribing.

Objective 1

Opioid Prescribing: Whose Perspective Matters in 2021?

Oversight trends and documentation challenges

YOURS

(but make sure it's current and informed)

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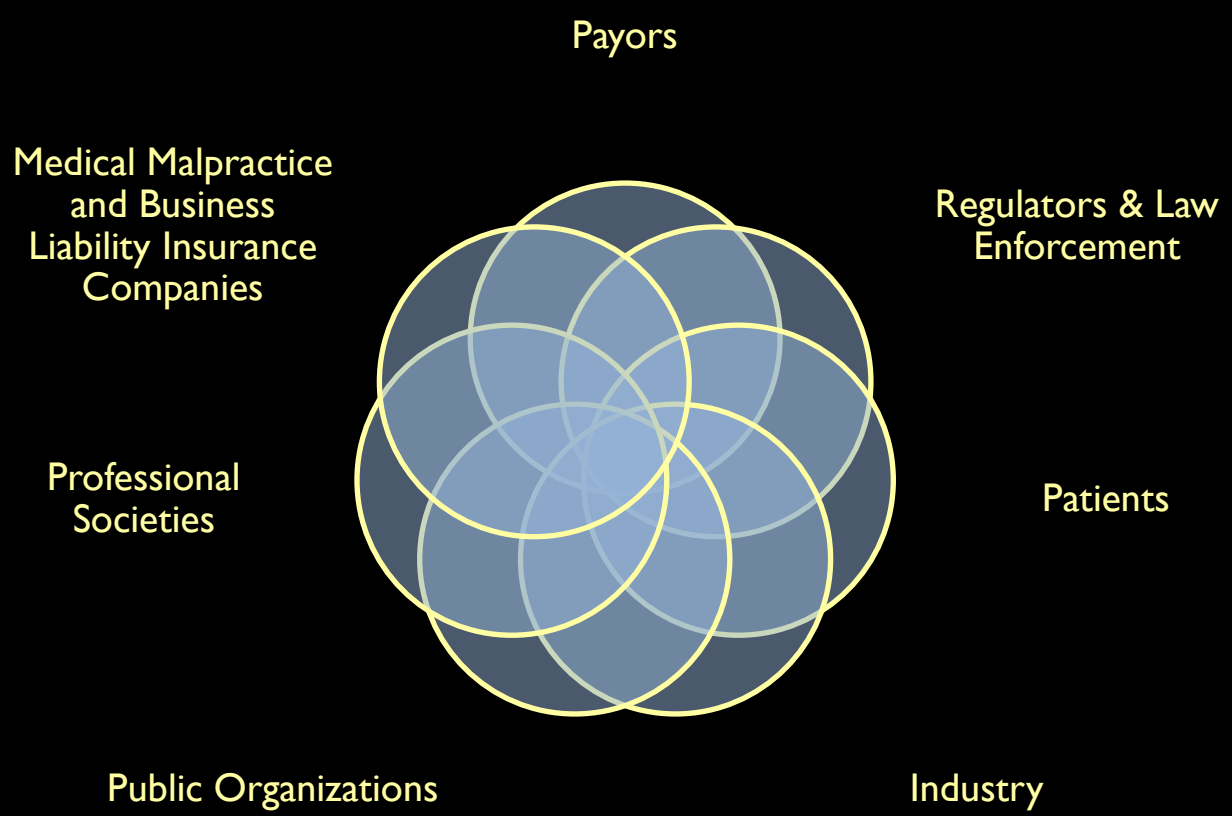
THE “ARMCHAIR” PERSPECTIVES



CMS OPIOID SAFETY ACTIVITY AND 2021 PERSPECTIVES

Centers for
Medicare and Medicaid Services

PAINWEEK

2021 Perspectives – CMS and Payor Opioid Safety Edits

Background

Medicare Part D sponsors must have concurrent drug utilization review (DUR) systems, policies, and procedures designed to ensure that a review of the prescribed drug therapy is performed before each prescription is dispensed to an enrollee in a sponsor's Part D plan, typically at the point-of-sale (POS) or point of distribution as described in 42 CFR 423.153(c)(2). To help prevent and address prescription opioid overuse through improved concurrent DUR, sponsors can fulfill 42 CFR 423.153(c)(2) by implementing opioid safety edits at the POS,[1] including:

- Care coordination edit at 90 morphine milligram equivalents (MME) per day,
- Hard edit at 200 MME per day or more (optional),
- Hard edit for 7 day supply limit for initial opioid fills (opioid naïve),
- Soft edit for concurrent opioid and benzodiazepine use, and
- Soft edit for duplicative long-acting (LA) opioid therapy.

https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization

2021 Perspectives – CMS and Payor EDITS – PURPOSE IS TO PROMPT PRESCRIBERS & PHARMACISTS TO CONDUCT ADDITIONAL SAFETY REVIEWS; EDITS ARE NOT PRESCRIBING LIMITS

- The purpose of the opioid safety edits is to prompt prescribers and pharmacists to conduct additional safety review to determine if the enrollee's opioid use is appropriate and medically necessary. Plan sponsors are expected to implement the edits in a manner that minimizes any additional burden on prescribers, pharmacists, and beneficiaries.

- The opioid safety edits should not be implemented as prescribing limits or as a substitute for clinical judgment. Rather, the opioid safety edits aim to strike a better balance between identifying potential opioid overuse without a negative impact on the patient-doctor relationship, preserving access to medically necessary drug regimens, and reducing the potential for unintended consequences.

https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization

2021 Perspectives – CMS and Payor EDITS – TAPERS SHOULD NOT BE RAPID; CERTAIN BENEFICIARIES EXCLUDED FROM EDITS

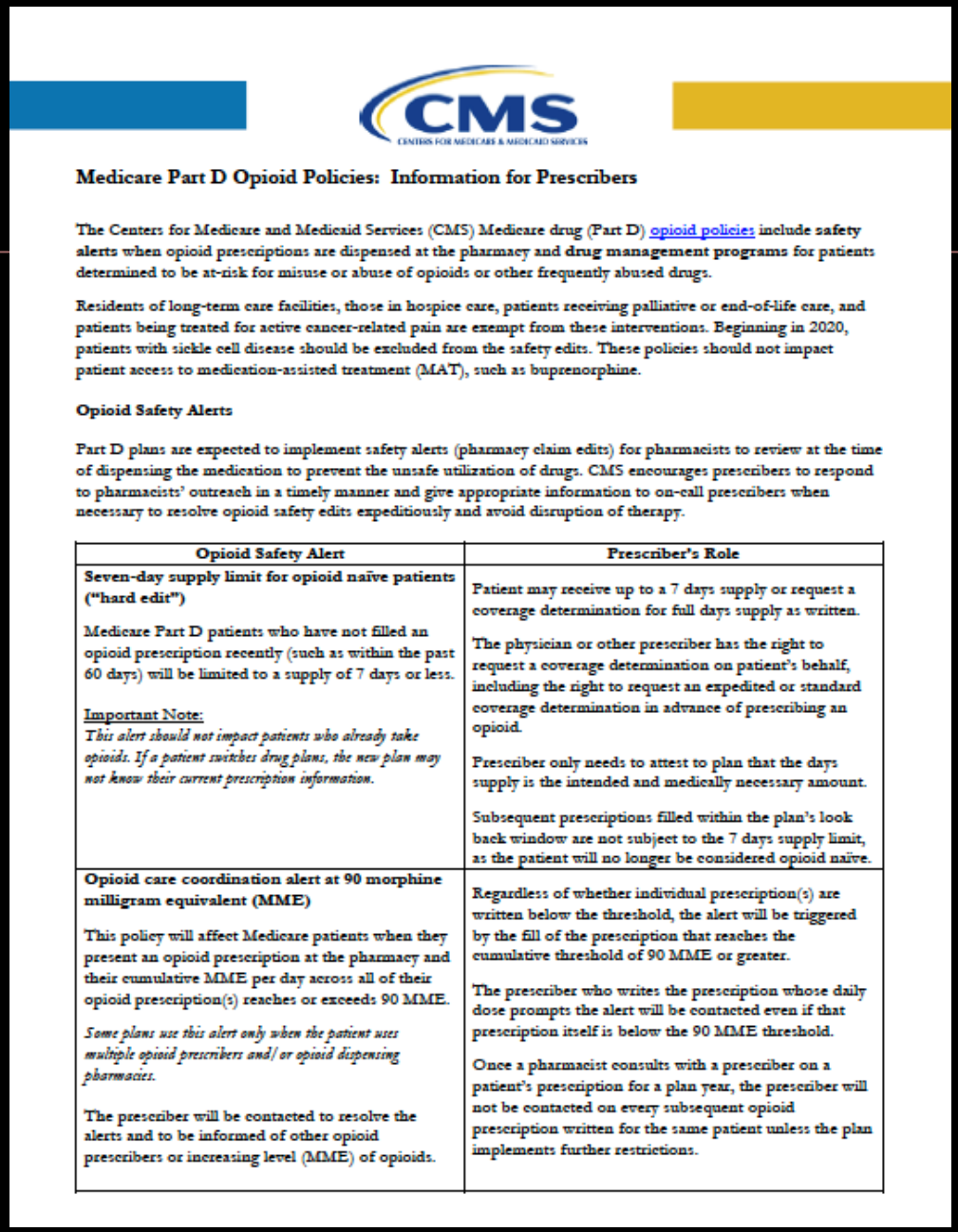
- Decisions by clinicians to taper opioid dosages should be carefully considered and individualized, if appropriate. Opioids should not be tapered rapidly or discontinued suddenly due to the significant risks of opioid withdrawal, unless there is a life-threatening issue confronting the individual patient. Tapering is most likely to be effective when there is patient buy-in and collaboration, tapering is gradual, and clinicians provide support.[2]

- Part D sponsors are expected to develop opioid safety edit specifications that exclude beneficiaries who are residents of a long-term care facility, are in hospice care or receiving palliative or end-of-life care, have sickle cell disease, or are being treated for active cancer-related pain. Sponsors are encouraged to work with their P&T committees to identify other vulnerable patient populations for exclusion from the opioid safety edits.

https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization

2021 Perspectives – CMS and Payor Opioid Safety Edits

https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization



CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Medicare Part D Opioid Policies: Information for Prescribers

The Centers for Medicare and Medicaid Services (CMS) Medicare drug (Part D) opioid policies include safety alerts when opioid prescriptions are dispensed at the pharmacy and drug management programs for patients determined to be at-risk for misuse or abuse of opioids or other frequently abused drugs.

Residents of long-term care facilities, those in hospice care, patients receiving palliative or end-of-life care, and patients being treated for active cancer-related pain are exempt from these interventions. Beginning in 2020, patients with sickle cell disease should be excluded from the safety edits. These policies should not impact patient access to medication-assisted treatment (MAT), such as buprenorphine.

Opioid Safety Alerts

Part D plans are expected to implement safety alerts (pharmacy claim edits) for pharmacists to review at the time of dispensing the medication to prevent the unsafe utilization of drugs. CMS encourages prescribers to respond to pharmacists' outreach in a timely manner and give appropriate information to on-call prescribers when necessary to resolve opioid safety edits expeditiously and avoid disruption of therapy.

Opioid Safety Alert	Prescriber's Role
Seven-day supply limit for opioid naïve patients ("hard edit") Medicare Part D patients who have not filled an opioid prescription recently (such as within the past 60 days) will be limited to a supply of 7 days or less. Important Note: *This alert should not impact patients who already take opioids. If a patient switches drug plans, the new plan may not know their current prescription information.*	Patient may receive up to a 7 days supply or request a coverage determination for full days supply as written. The physician or other prescriber has the right to request a coverage determination on patient's behalf, including the right to request an expedited or standard coverage determination in advance of prescribing an opioid. Prescriber only needs to attest to plan that the days supply is the intended and medically necessary amount. Subsequent prescriptions filled within the plan's look back window are not subject to the 7 days supply limit, as the patient will no longer be considered opioid naïve.
Opioid care coordination alert at 90 morphine milligram equivalent (MME) This policy will affect Medicare patients when they present an opioid prescription at the pharmacy and their cumulative MME per day across all of their opioid prescription(s) reaches or exceeds 90 MME. *Some plans use this alert only when the patient uses multiple opioid prescribers and/or opioid dispensing pharmacies.* The prescriber will be contacted to resolve the alerts and to be informed of other opioid prescribers or increasing level (MME) of opioids.	Regardless of whether individual prescription(s) are written below the threshold, the alert will be triggered by the fill of the prescription that reaches the cumulative threshold of 90 MME or greater. The prescriber who writes the prescription whose daily dose prompts the alert will be contacted even if that prescription itself is below the 90 MME threshold. Once a pharmacist consults with a prescriber on a patient's prescription for a plan year, the prescriber will not be contacted on every subsequent opioid prescription written for the same patient unless the plan implements further restrictions.

Three Critical Edits And Tie To Documentation

Consider and record your thoughts and efforts at coordinating care over chronic opioid therapy and dose, treatment alternatives, potential adverse conditions (behavioral and substance abuse-focused).

Respond to communications you receive relative to each edit. Individualized and timely patient care must show in your records.

Hard edits will involve a more in-depth interaction with the prescriber.

Medical decision-making documented in detail; Examine licensing board directives; peer literature.

90mg MME	Care coordination edit at 90mg MME
200mg MME	Hard edit and 200mg MME
BZO + OPI	Soft edit for concurrent benzodiazepine and opioid use

2021 Perspectives – CMS and Payor Opioid Safety Edits – Prescriber Information 90mg MME Edit

Opioid care coordination alert at 90 morphine milligram equivalent (MME)

This policy will affect Medicare patients when they present an opioid prescription at the pharmacy and their cumulative MME per day across all of their opioid prescription(s) reaches or exceeds 90 MME.

Some plans use this alert only when the patient uses multiple opioid prescribers and/or opioid dispensing pharmacies.

The prescriber will be contacted to resolve the alerts and to be informed of other opioid prescribers or increasing level (MME) of opioids.

Regardless of whether individual prescription(s) are written below the threshold, the alert will be triggered by the fill of the prescription that reaches the cumulative threshold of 90 MME or greater.

The prescriber who writes the prescription whose daily dose prompts the alert will be contacted even if that prescription itself is below the 90 MME threshold.

Once a pharmacist consults with a prescriber on a patient's prescription for a plan year, the prescriber will not be contacted on every subsequent opioid prescription written for the same patient unless the plan implements further restrictions.

https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization

Vignette to Demonstrate Documentation Idea (90mg MME Alert Edit)

- Dr. Joe received an alert on a Medicare Part D beneficiary alerting him to the fact that Jane Smith, a relatively new patient in his office, crossed the 90mg MME threshold because of his last prescription to her.
- Dr. Joe wants to resolve the alert by making a short entry in Mrs. Smith's medical record.
- What are the key points Dr. Joe should cover in his documentation?

Some plans use this alert only when the patient uses multiple opioid prescribers and/or opioid dispensing pharmacies.

The prescriber will be contacted to resolve the alerts and to be informed of other opioid prescribers or increasing level (MME) of opioids.

Important Note:
This is not a prescribing limit. Decisions to taper or discontinue prescription opioids are individualized between the patient and prescriber.

On the patient's behalf, the physician or other prescriber has the right to request a coverage determination for a drug(s), including the right to request an expedited or standard coverage determination in advance of prescribing an opioid.

https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization

Vignette to Demonstrate Documentation Idea (90mg MME Alert Edit)

- On ABC date, I learned from Medicare's opioid MME alert system that patient Jane Smith is receiving 90mg MME or greater of an opioid medication.
- Our records show that Mrs. Smith is only receiving 50mg MME of hydrocodone from me. The reasons for this medication are well documented in her file.
- To reconcile the MME reported for Mrs. Smith, I have asked my staff to contact Mrs. Smith and determine whether she has received opioid medication from another prescriber and to schedule her to come into the office to discuss this matter with me.

Some plans use this alert only when the patient uses multiple opioid prescribers and/or opioid dispensing pharmacies.

The prescriber will be contacted to resolve the alerts and to be informed of other opioid prescribers or increasing level (MME) of opioids.

Important Note:
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https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization

2021 Perspectives – CMS and Payor Opioid Safety Edits – Concurrent Opioids and Benzodiazepine Use or Multiple Long-Acting Opioids

A couple of months after Dr. Joe handled the 90mg MME alert for Mrs. Smith, Dr. Joe receives a call from a local pharmacist, alerting him to the fact that Mrs. Smith is now receiving opioids from him and a benzodiazepine from a local psychiatrist, Dr. Green Life.

What should the pharmacist do to fulfill the requirement that Mrs. Smith's opioid use is safe and clinically appropriate?

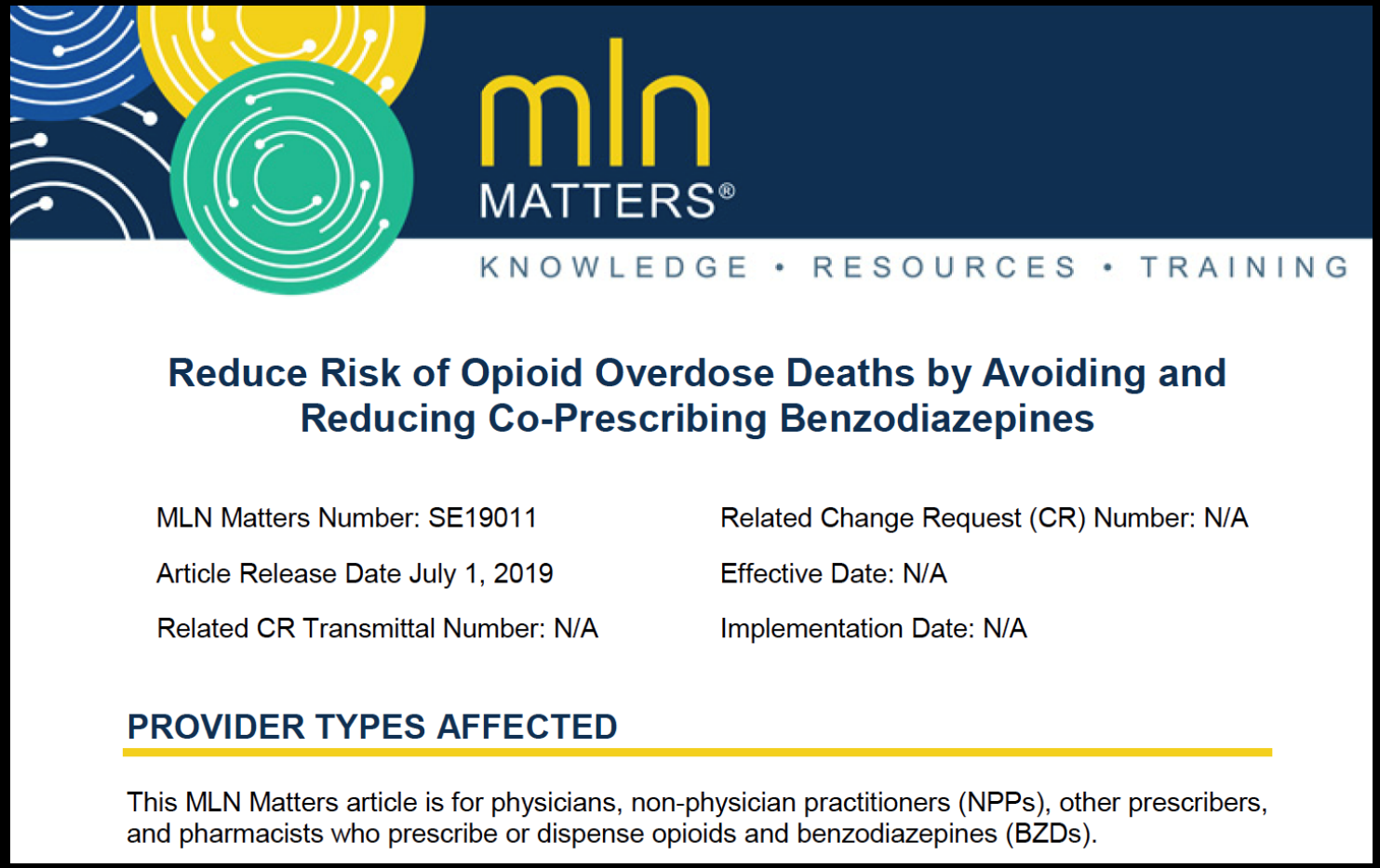
What should Dr. Joe do and document?

Concurrent opioid and benzodiazepine use or duplicative long-acting opioid therapy ("soft edits")

The alerts will trigger when opioids and benzodiazepines are taken concurrently or if on multiple duplicate long-acting opioids.

The pharmacist will conduct additional safety reviews to determine if the patient's opioid use is safe and clinically appropriate. The prescriber may be contacted.

CMS Educational Resource on Reducing Risk of Opioid Overdose Deaths by Avoiding and Reducing Co-Prescribing of Benzodiazepines



mln MATTERS®

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Reduce Risk of Opioid Overdose Deaths by Avoiding and Reducing Co-Prescribing Benzodiazepines

MLN Matters Number: SE19011

Related Change Request (CR) Number: N/A

Article Release Date July 1, 2019

Effective Date: N/A

Related CR Transmittal Number: N/A

Implementation Date: N/A

PROVIDER TYPES AFFECTED

This MLN Matters article is for physicians, non-physician practitioners (NPPs), other prescribers, and pharmacists who prescribe or dispense opioids and benzodiazepines (BZDs).

Available online at https://www.cms.gov/About-CMS/Story-Page/prescribing-opioids, (bottom of page); accessed 08/11/21).

CMS Educational Resource on Reducing Risk of Opioid Overdose Deaths by Avoiding and Reducing Co-Prescribing of Benzodiazepines

There are five central principles for co-prescribing BZDs and opioids:

1. ***Avoid initial combination by offering alternative approaches***
2. ***If new prescriptions are needed, limit the dose and duration***
3. ***Taper long-standing medications gradually and, whenever possible, discontinue***
4. ***Continue long-term co-prescribing only when necessary and monitor closely***
5. ***Provide rescue medication (for example, naloxone) to high-risk patients and their caregivers***

Carefully discuss the risks and benefits with your patients, including legal representatives if needed, before making changes to medication regimens. This can be challenging as often patients want to continue medications that they feel help them stay stable. You are more likely to succeed when you take an individualized, person-centered approach, and create treatment plans that involve your patients' support networks, including friends, family, and caregivers.[7]

Available online at https://www.cms.gov/About-CMS/Story-Page/prescribing-opioids, (bottom of page); accessed 08/11/21).

CMS Educational Resource on Reducing Risk of Opioid Overdose Deaths by Avoiding and Reducing Co-Prescribing of Benzodiazepines

You should employ strategies to empower patients to actively participate in their treatment and maintain responsibility for their appropriate use of prescribed BZDs and opioids. Evaluate patients who are taking opioids in person at least every 3 to 6 months. Patients who chronically use a BZD are at higher risk and may require monitoring more often, depending on their individual risk factors and comorbidities. For high-risk patients, you should complete a baseline urine test. Use point of care urine testing with lab confirmation at your discretion, including breath alcohol tests if indicated. Be aware that many tests do not screen for or often do not detect:

- Alcohol
- Certain BZDs (for example, alprazolam, clonazepam and lorazepam)
- Recently ingested medications
- Low levels of illicit drugs (for example, cannabis and cocaine)[16]

Familiarize yourselves with sensitivities in urine or saliva samples. Consider sending samples to outside laboratories for confirmation, particularly when the result of the drug test is different from that suggested by the medical history, clinical presentation, or self-report.[17]

Available online at https://www.cms.gov/About-CMS/Story-Page/prescribing-opioids, (bottom of page); accessed 08/11/21).

CMS Educational Resource on Reducing Risk of Opioid Overdose Deaths by Avoiding and Reducing Co-Prescribing of Benzodiazepines – Vignette and Discussion

- George W. Zombie is a patient using opioids and benzodiazepines prescribed to him by Dr. Heretoday Gonetomorrow. Mr. Zombie is being transferred to your patient roster.

- What initial steps should you take to ensure you are taking reasonable steps to evaluate Mr. Zombie based on new directives from CMS and your licensing board regarding co-prescribing of benzodiazepines and opioid?

- If you receive pushback from the payer regarding your decision to perform periodic drug testing on Mr. Zombie as you navigate the BZO+OPI issue and possibly de-prescribing BZO, what should you focus on based on recent CMS guidance and DEA expectations?

Available online at https://www.cms.gov/About-CMS/Story-Page/prescribing-opioids, (bottom of page); accessed 08/11/21).

CMS Educational Resource on Reducing Risk of Opioid Overdose Deaths by Avoiding and Reducing Co-Prescribing of Benzodiazepines

Vignette Considerations

1. Avoid initial combination by offering alternative approaches
   - ✓ Always consider alternatives to opioids for chronic pain
   - ✓ Always consider alternatives to BZDs for anxiety or insomnia
   - ✓ Remember BZDs are not indicated to treat pain
   - ✓ Avoid prescribing BZDs for patients on MATs
   - ✓ Avoid prescribing opioids for patients taking long-term BZDs
2. If new prescriptions are needed, limit the dose and duration
3. Taper long-standing medications gradually and, whenever possible, discontinue
   - ✓ Do not abruptly stop BZDs or opioids
   - ✓ Taper slowly according to guidelines and adjust depending on symptoms
   - ✓ Always work collaboratively with your patients to taper or discontinue
4. Continue long-term co-prescribing BZDs and opioids only when necessary and monitor closely
   - ✓ Clearly explain risks and black box warnings
   - ✓ Closely monitor and consider drug testing at baseline and regularly, especially for high-risk patients
   - ✓ Set clear expectations for what steps will be taken if your patients do not follow the prescribed regimen, including safely discontinuing a medication
   - ✓ Monitor PDMP regularly
5. Provide rescue medication (for example, naloxone) to high-risk patients and their caregivers

Available online at https://www.cms.gov/About-CMS/Story-Page/prescribing-opioids, (bottom of page); accessed 08/11/21).

2021 Perspectives on Opioid Prescribing – Opioids and Benzodiazepines & Deferring Responsibility

Deferring Responsibility

While the project focused on the risk of coprescribing these two medication classes, most prescribers perceived their role as limited to a single medication class. Primary care prescribers reported referring patients to mental health for discontinuing benzodiazepines, while mental health prescribers excused themselves from facilitating management of opioids for chronic pain.

> (MH1) "I mean I think, it's good to do your medication reconciliation, be aware of all their medications that they are on, but I don't make any attempt to manage their pain medications. I think that's good that there's sort of a solid wall there, so they know when they are coming in here, I'm not going to discuss [their] pain regimen."

- Hawkins EJ, Lott AM, Danner AN, Malte CA, Hagedorn HJ, Berger D, Donovan LM, Sayre GG, Mariano AJ, Saxon AJ. Primary Care and Mental Health Prescribers, Key Clinical Leaders, and Clinical Pharmacist Specialists' Perspectives on Opioids and Benzodiazepines. Pain Med. 2021 Jul 25;22(7):1559-1569. doi: 10.1093/pm/pnaa435. PMID: 33661287.

2021 Perspectives on Opioid Prescribing – Opioids and Benzodiazepines & Collaboration

Collaboration

Both primary care and mental health prescribers reported that communication is critical to the comanagement of medications, but it is challenging to do in practice.

> (PC2) "I think the benzos are harder mostly because the co-management between mental health and us can be hard."

Key clinical leaders also noted that communication across service lines is hard to do.

> (KCL1) "No one wants to deal with it because it involves two service lines talking, so it's very hard. Where do you find time to find the mental health provider who's prescribing these and then decide, who's going to wean what drug and get the patient involved? It's a sticky wicket."

- Hawkins EJ, Lott AM, Danner AN, Malte CA, Hagedorn HJ, Berger D, Donovan LM, Sayre GG, Mariano AJ, Saxon AJ. Primary Care and Mental Health Prescribers, Key Clinical Leaders, and Clinical Pharmacist Specialists' Perspectives on Opioids and Benzodiazepines. Pain Med. 2021 Jul 25;22(7):1559-1569. doi: 10.1093/pm/pnaa435. PMID: 33661287.

2021 Perspectives on Opioid Prescribing – Opioids and Benzodiazepines & Time to Address Deprescribing

- Hawkins EJ, Lott AM, Danner AN, Malte CA, Hagedorn HJ, Berger D, Donovan LM, Sayre GG, Mariano AJ, Saxon AJ. Primary Care and Mental Health Prescribers, Key Clinical Leaders, and Clinical Pharmacist Specialists' Perspectives on Opioids and Benzodiazepines. Pain Med. 2021 Jul 25;22(7):1559-1569. doi: 10.1093/pm/pnaa435. PMID: 33661287.

Time

Primary care and mental health prescribers reported lack of time as a major barrier to deprescribing, in terms of both the length and the frequency of visits needed for discussing and performing tapers.

> (PC4) "So we check him frequently, first it was every 2 weeks, now we are out to a month. But if you are having someone come in that frequently, you can't have all your patients be doing that. I think that the other big [issue is] the amount of time it takes to discuss the taper and the rationale for tapering. You can't just be like, 'Well okay we are going to decrease these medications,' it's a longer discussion than that."

Key clinical leaders endorsed the above, while also reporting that the frequency of visits needed to successfully discontinue/taper these medication classes conflicts with increasing access to care, a current priority of VA health care

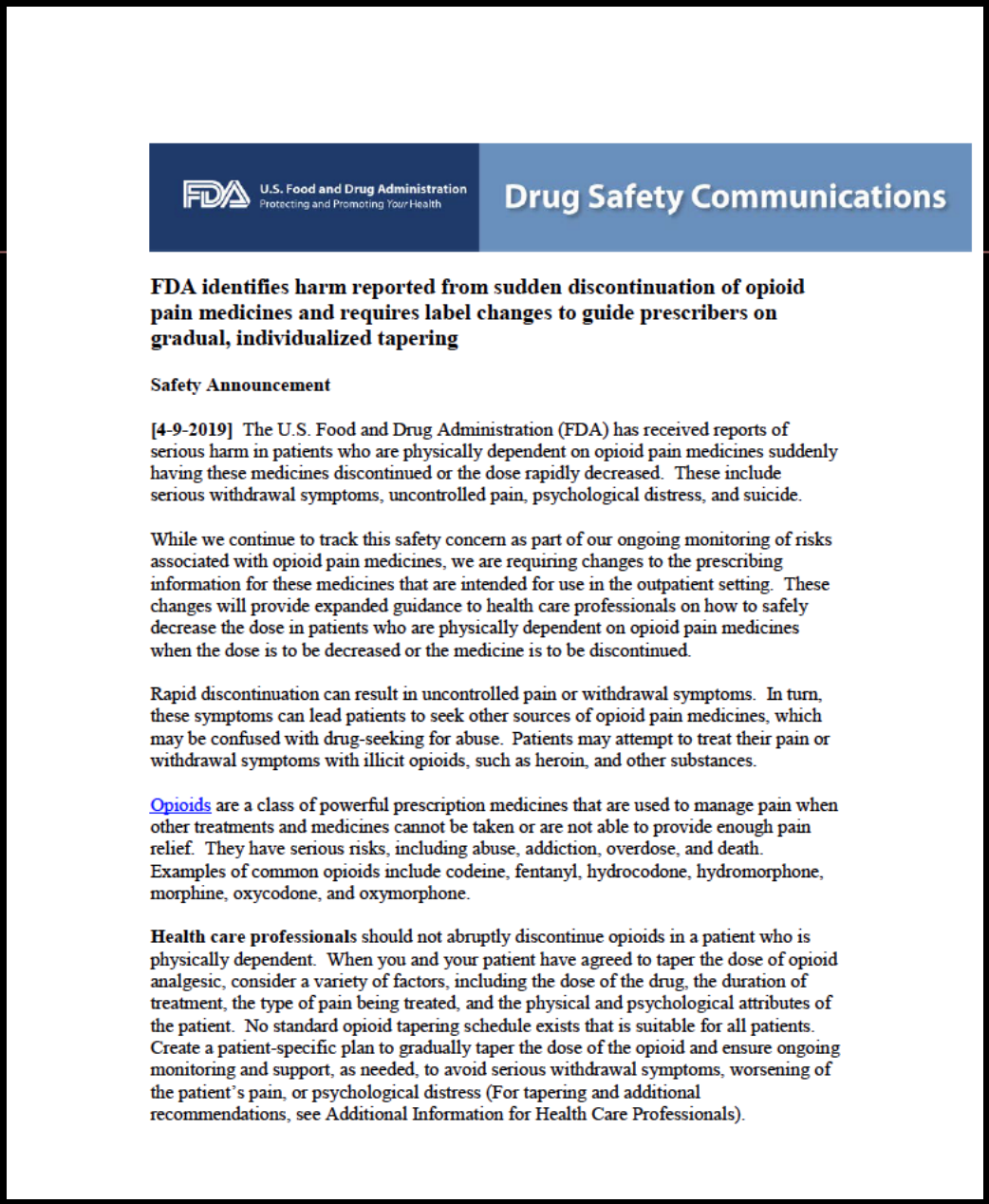
> (KCL3) "It's impossible to do everything that we want to do. . .. I would need to see that patient back frequently, and I would need longer visits, and I don't have either of those things. I can't see them back frequently because the clinics are full. We're trying to achieve access, access is an important goal for the medical center. Properly treating chronic pain and co-morbid mental health, requires more visits than we can do and maintain access. That's a major barrier."

2021 Perspectives – FDA and Gradual, Individualized Tapering

FDA material available on CMS website through links below

https://www.cms.gov/About-CMS/Story-Page/prescribing-opioids

See also https://www.cms.gov/About-CMS/Story-Page/opioid-misuse-resources.



U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Drug Safety Communications

FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering

Safety Announcement

[4-9-2019] The U.S. Food and Drug Administration (FDA) has received reports of serious harm in patients who are physically dependent on opioid pain medicines suddenly having these medicines discontinued or the dose rapidly decreased. These include serious withdrawal symptoms, uncontrolled pain, psychological distress, and suicide.

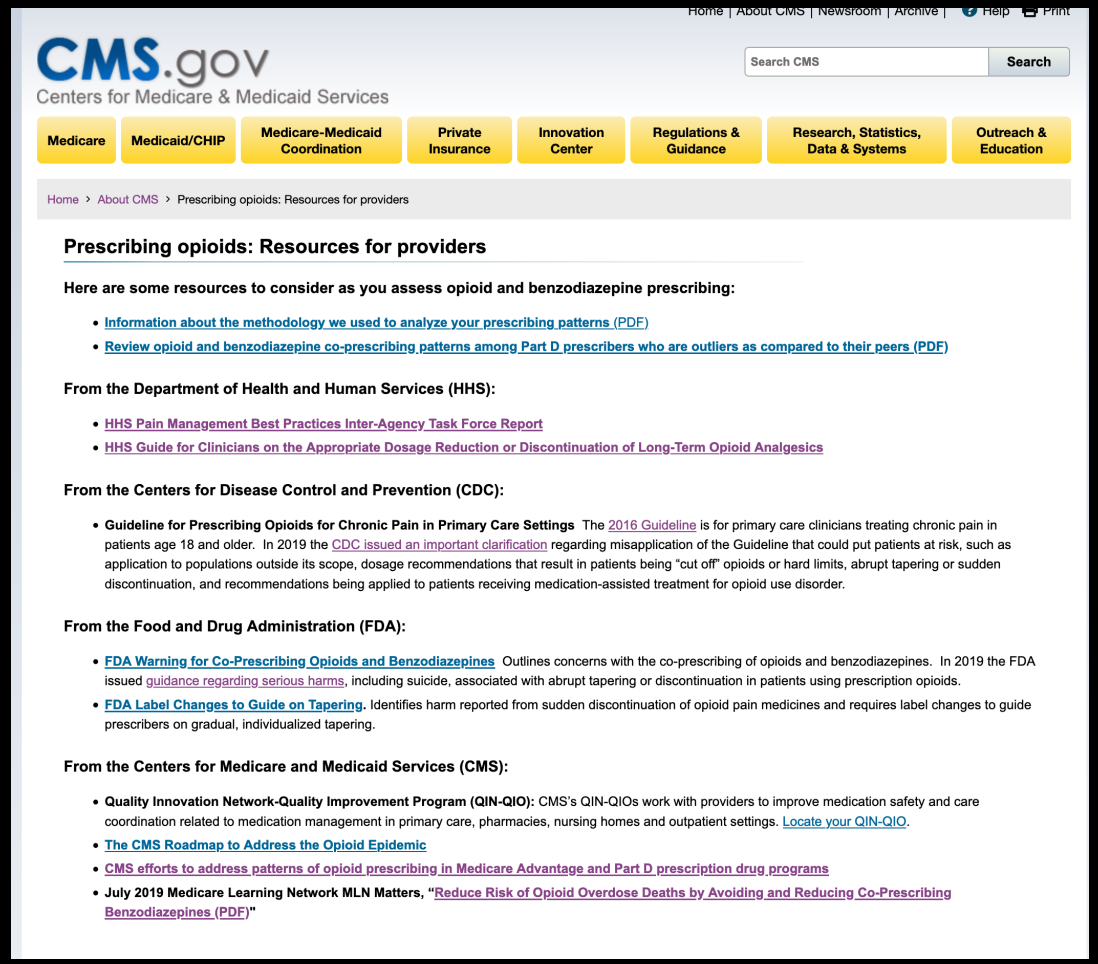
While we continue to track this safety concern as part of our ongoing monitoring of risks associated with opioid pain medicines, we are requiring changes to the prescribing information for these medicines that are intended for use in the outpatient setting. These changes will provide expanded guidance to health care professionals on how to safely decrease the dose in patients who are physically dependent on opioid pain medicines when the dose is to be decreased or the medicine is to be discontinued.

Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms. In turn, these symptoms can lead patients to seek other sources of opioid pain medicines, which may be confused with drug-seeking for abuse. Patients may attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin, and other substances.

Opioids are a class of powerful prescription medicines that are used to manage pain when other treatments and medicines cannot be taken or are not able to provide enough pain relief. They have serious risks, including abuse, addiction, overdose, and death. Examples of common opioids include codeine, fentanyl, hydrocodone, hydromorphone, morphine, oxycodone, and oxymorphone.

Health care professionals should not abruptly discontinue opioids in a patient who is physically dependent. When you and your patient have agreed to taper the dose of opioid analgesic, consider a variety of factors, including the dose of the drug, the duration of treatment, the type of pain being treated, and the physical and psychological attributes of the patient. No standard opioid tapering schedule exists that is suitable for all patients. Create a patient-specific plan to gradually taper the dose of the opioid and ensure ongoing monitoring and support, as needed, to avoid serious withdrawal symptoms, worsening of the patient's pain, or psychological distress (For tapering and additional recommendations, see Additional Information for Health Care Professionals).

CMS and Resources on Prescribing Opioids for Providers



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Home › About CMS › Prescribing opioids: Resources for providers

Prescribing opioids: Resources for providers

Here are some resources to consider as you assess opioid and benzodiazepine prescribing:

- Information about the methodology we used to analyze your prescribing patterns (PDF)
- Review opioid and benzodiazepine co-prescribing patterns among Part D prescribers who are outliers as compared to their peers (PDF)

From the Department of Health and Human Services (HHS):

- HHS Pain Management Best Practices Inter-Agency Task Force Report
- HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics

From the Centers for Disease Control and Prevention (CDC):

- **Guideline for Prescribing Opioids for Chronic Pain in Primary Care Settings** The 2016 Guideline is for primary care clinicians treating chronic pain in patients age 18 and older. In 2019 the CDC issued an important clarification regarding misapplication of the Guideline that could put patients at risk, such as application to populations outside its scope, dosage recommendations that result in patients being "cut off" opioids or hard limits, abrupt tapering or sudden discontinuation, and recommendations being applied to patients receiving medication-assisted treatment for opioid use disorder.

From the Food and Drug Administration (FDA):

- **FDA Warning for Co-Prescribing Opioids and Benzodiazepines** Outlines concerns with the co-prescribing of opioids and benzodiazepines. In 2019 the FDA issued guidance regarding serious harms, including suicide, associated with abrupt tapering or discontinuation in patients using prescription opioids.
- **FDA Label Changes to Guide on Tapering.** Identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering.

From the Centers for Medicare and Medicaid Services (CMS):

- **Quality Innovation Network-Quality Improvement Program (QIN-QIO):** CMS's QIN-QIOs work with providers to improve medication safety and care coordination related to medication management in primary care, pharmacies, nursing homes and outpatient settings. Locate your QIN-QIO.
- The CMS Roadmap to Address the Opioid Epidemic
- CMS efforts to address patterns of opioid prescribing in Medicare Advantage and Part D prescription drug programs
- **July 2019 Medicare Learning Network MLN Matters, "**Reduce Risk of Opioid Overdose Deaths by Avoiding and Reducing Co-Prescribing Benzodiazepines (PDF)**"**

- https://www.cms.gov/About-CMS/Story-Page/prescribing-opioids
- See also https://www.cms.gov/About-CMS/Story-Page/opioid-misuse-resources.

DEA Administrative Case – Co-Prescribing Opioids and Benzodiazepines

https://www.federalregister.gov/documents/2021/06/25/2021-13526/carol-hippenmeyer-md-decision-and-order

Dr. Lynch testified about the applicable standard of care in Arizona for prescribing opioids and benzodiazepines concurrently. Tr. 178–80, 244–45, 275, 299, 300–02, 370–72. He referred to this practice as "co-prescribing." *Id.* at 245. Dr. Lynch testified that "about 1 in 500 patients who take a pain pill will overdose and die every year, which is a very high death rate." *Id.* at 182. When opioids and benzodiazepines are combined, the death rate increases by nine times. *Id.* at 180, 302. Dr. Lynch testified that the "second biggest predictor" of overdose and death is "concomitant benzodiazepine use."[31] *Id.* at 244. In 2014, the Arizona DHS reported that benzodiazepines were involved in thirty to sixty percent of opioid overdose deaths. *Id.*; GX 16, at 19.

DEA Administrative Case – Co-Prescribing Opioids and Benzodiazepines

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https://www.federalregister.gov/documents/2021/06/25/2021-13526/carol-hippenmeyer-md-decision-and-order

patients on both [opioids and benzodiazepines].'' *Id.* at 180. He further stated that if a physician is going to prescribe both, he should ''go to great lengths to document the reasons'' and to document the discussions with the patient about the risks and benefits. *Id.* Dr. Lynch discussed the Arizona DHS's and the CDC's recommendations on co-prescribing. *Id.* at 179. The Arizona DHS recommends that ''[c]ombined use of opioids and benzodiazepines should be avoided if possible. If this combination is used, it should be with great caution and informed consent should be obtained.'' GX 16, at 8. The CDC likewise cautions that ''[c]linicians should avoid prescribing opioid pain medication and benzodiazepines concurrently wherever possible.'' GX 15, at 18. Dr. Lynch testified that the Arizona DHS and the CDC also advise physicians not to prescribe opioids along with carisoprodol,[33] which he described as ''a highly diverted and addictive muscle relaxant.'' Tr. 200; *see also* GX 16, at 8, 19 (stating that carisoprodol ''should be avoided'' and ''[p]articular caution should [ ] be exercised when opioids are used with other sedatives/hypnotics''). Dr. Lynch

2021 Perspectives on Opioid Prescribing – Provider Opioid Knowledge Deficits

Provider Opioid Knowledge Deficit

There are substantial knowledge gaps around appropriate and inappropriate opioid prescribing, including deficits in understanding current research, legislation, and appropriate prescribing practices. Providers often have knowledge deficits that include:

- Understanding of addiction
- At-risk opioid addiction populations
- Prescription vs. non-prescription opioid addiction
- The belief that addiction and dependence on opioids is synonymous
- The belief that opioid addiction is a psychological problem instead related to a chronic painful disease

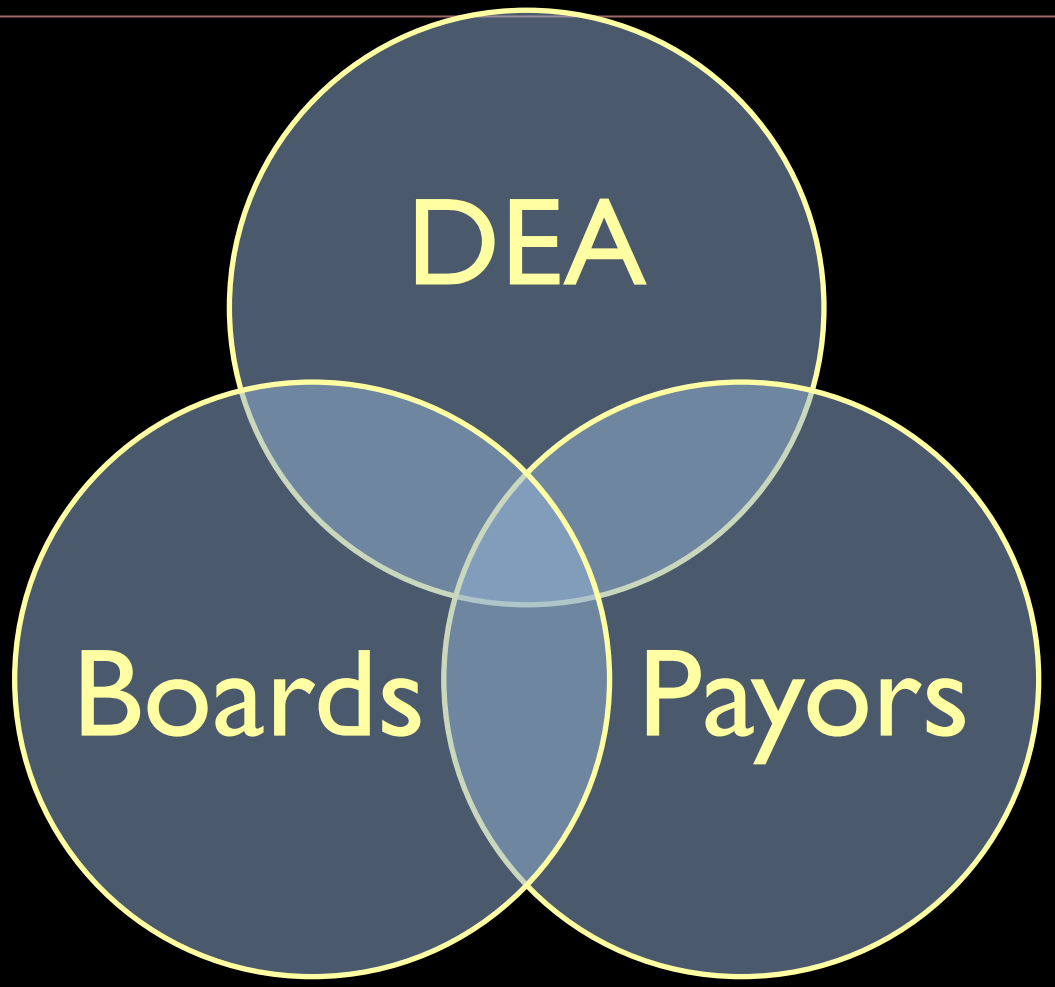
With a long history of misunderstanding, poor society, provider education, and inconsistent laws, the prescription of opioids has resulted in significant societal challenges that will only resolve with significant education and training.

Dydyk AM, Sizemore DC, Trachsel LA, Dulebohn SC, Porter BR. Tennessee Controlled Substance Prescribing For Acute and Chronic Pain. 2021 Jul 12. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2021 Jan–. PMID: 33620833.

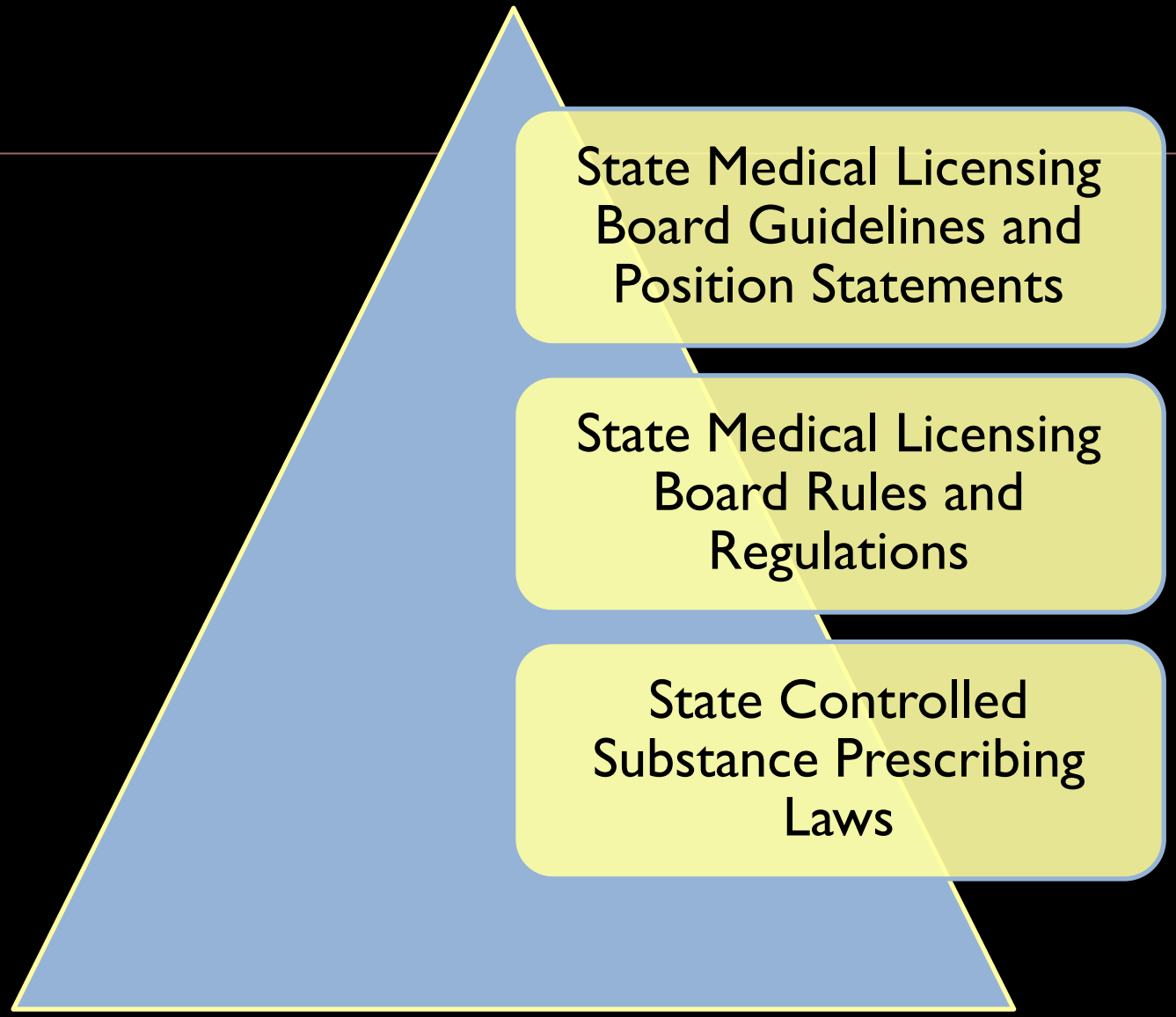
Objective #2

Compare the tension between payor review of opioid prescribing patterns and risk mitigation and law enforcement or licensing board litigation of these topics.

Rationale Response to Stakeholder Enforcement Efforts



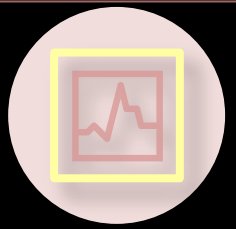
Board


State Medical Licensing Board Guidelines and Position Statements
State Medical Licensing Board Rules and Regulations
State Controlled Substance Prescribing Laws

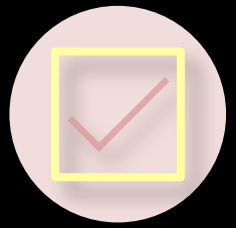
What does a licensing board “generally” expect from a controlled substance prescriber as part of the “Usual Course” process)

History & Physical Examination

Risk Evaluation



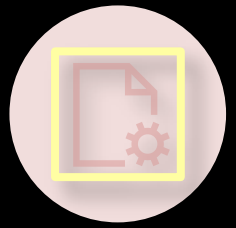
Diagnosis and Treatment Plan



Informed Consent and Treatment Agreement

Periodic Review and Risk Monitoring

Consultations and Referrals



Proper Documentation

PAINWEEK®

DEA Expectations

DEA Administrative Case – Co-Prescribing of Opioids and Benzodiazepines with Insight to Licensing Board Position

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https://www.federalregister.gov/documents/2021/06/25/2021-13526/carol-hippenmeyer-md-decision-and-order

Fifth, the ALJ found that Dr. Lynch's testimony that it was a violation of the standard of care in Arizona to prescribe opioids and benzodiazepines concurrently conflicted with his later testimony that "it's hard to say it's below the standard of care" because it "still continues to happen." RD, at 17 (*comparing* Tr. 275 *with* Tr. 371). The ALJ found that this inconsistency "undermine[d] Dr. Lynch's credibility on the issue of co-prescribing." *Id.* I agree with the ALJ that this testimony was inconsistent, but I do not find that this inconsistency detracted from Dr. Lynch's credibility on co-prescribing because he later clarified. Tr. 370–71; *see also id.* at 244–45 (agreeing that the Arizona DHS Guidelines do not ban co-prescribing, they just "strongly recommend[] that docs not do it"). Additionally, I found that Dr. Lynch's testimony on the standard of care for co-prescribing benzodiazepines was consistent with other record evidence, including guidelines from the Arizona DHS, the Arizona Medical Board, and the Centers for Disease Control and Prevention (hereinafter, CDC). *See infra* II.E.4.

DEA Administrative Case – Core Standard of Care Issues

1. Medical Records
2. Urine Drug Testing
3. Co-prescribing of opioids and benzodiazepines

.

https://www.federalregister.gov/documents/2021/06/25/2021-13526/carol-hippenmeyer-md-decision-and-order

There was significant disagreement at the hearing and in the parties' posthearing briefs on a number of issues: (1) Whether a physician must maintain medical records in order to establish a valid doctor-patient relationship, (2) whether the Arizona standard of care requires physicians to conduct urine drug screens and query the Arizona PMP while prescribing controlled substances, and (3) whether it is a violation of the standard of care to prescribe benzodiazepines and opioids concurrently. In accordance with Dr. Lynch's uncontroverted expert testimony and the record as a whole, I make the following findings regarding the applicable standard of care in Arizona.

DEA Administrative Case – Core Standard of Care Issues – Urine Drug Testing in Chronic Opioid Therapy

https://www.federalregister.gov/documents/2021/06/25/2021-13526/carol-hippenmeyer-md-decision-and-order

Dr. Lynch testified that physicians should also perform "periodic urine drug screening" on patients receiving chronic opioid therapy to "make sure that [the patients are] compliant with therapy." Tr. 182–83, 238–39, 262–63, 271–72. He testified that this requirement is based on guidance from the Arizona DHS and the Arizona Medical Board. *Id.* at 182–83, 238. The Arizona DHS Guidelines provide that "[a]ppropriate monitoring for [chronic opioid therapy] includes, at a minimum, . . . periodic completion of [urine drug screens]." GX 16, at 8. The Arizona Medical Board Guidelines state that "[p]eriodic drug testing may be useful in monitoring adherence to the treatment plan, as well as in detecting the use of non-prescribed drugs." GX 14, at 10. Dr. Lynch testified that "there's disagreement on how often" urine drug screens should be performed," but they should be performed "at some interval." Tr. 198. Dr. Lynch testified that the frequency of drug testing is based on the risk score of the patient. *Id.* at 238. The

DEA Administrative Case –
Core Standard of Care Issues –
Urine Drug Testing in Chronic Opioid Therapy

[28] The Arizona Medical Board also provides guidance on the frequency of drug screening. The Board advises that "clinical judgment trumps recommendations for frequency of testing" for patients being treated for pain, but for patients being treated for addiction, testing should occur "as frequently as necessary to ensure therapeutic adherence." GX 14, at 10.

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https://www.federalregister.gov/documents/2021/06/25/2021-13526/carol-hippenmeyer-md-decision-and-order

DEA Administrative Case – Core Standard of Care Issues – Urine Drug Testing in Chronic Opioid Therapy

Arizona. *See, e.g.*, RD, at 88. The ALJ reached this conclusion primarily because he found that the documents that Dr. Lynch referenced as requiring urine drug screens—the Arizona DHS Guidelines and the Arizona Medical Board Guidelines—do not establish the standard of care. RD, at 27–28, 35–36, 88. The ALJ quotes disclaimers that the guidelines "do[ ] not replace or constrain the Arizona Medical Board's determination of standard of care in individual cases" and "should not be used to establish any standard of care." RD, at 27–28 (citing GX 14, at 1; GX 16, at 2). The ALJ also references Dr. Lynch's testimony that the guidelines influence the standard of care, but they do not establish it. *Id.* (citing Tr. 217, 265, 267).

https://www.federalregister.gov/documents/2021/06/25/2021-13526/carol-hippenmeyer-md-decision-and-order

DEA Administrative Case – Core Standard of Care Issues – Urine Drug Testing in Chronic Opioid Therapy

Although I agree with the ALJ's assessment of Dr. Lynch's testimony that the guidelines do not independently establish the standard of care, I decline to discredit Dr. Lynch's testimony merely because he referenced the guidelines in formulating his opinions.[29] Dr. Lynch testified that all of his opinions at the hearing were based on the minimum standard of care in Arizona. Tr. 216. He testified that the "ultimate guide" for the standard of care is "what [ ] physicians are doing in the marketplace," *id.* at 267, and physicians began conducting urine drug screens in 2011 when "the CDC started releasing data showing that 19 to 40 percent of patients were abusing or misusing" the drugs that they were prescribed. *Id.* at 271. Dr. Lynch testified repeatedly that urine drug screens are part of the minimum standard of care in Arizona.

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https://www.federalregister.gov/documents/2021/06/25/2021-13526/carol-hippenmeyer-md-decision-and-order

DEA Administrative Case – Core Standard of Care Issues – Urine Drug Testing in Chronic Opioid Therapy

Id. at 182–83, 238–39, 262–63, 271–72. Dr. Lynch also testified that regular PMP monitoring became "strong standard in care" in 2014. *Id.* at 181. Therefore, based on the uncontroverted testimony of the expert witness as supported by state guidance, I conclude that the minimum standard of care in Arizona requires that physicians prescribing opioids regularly query the PMP and periodically conduct urine drug screens.[30]

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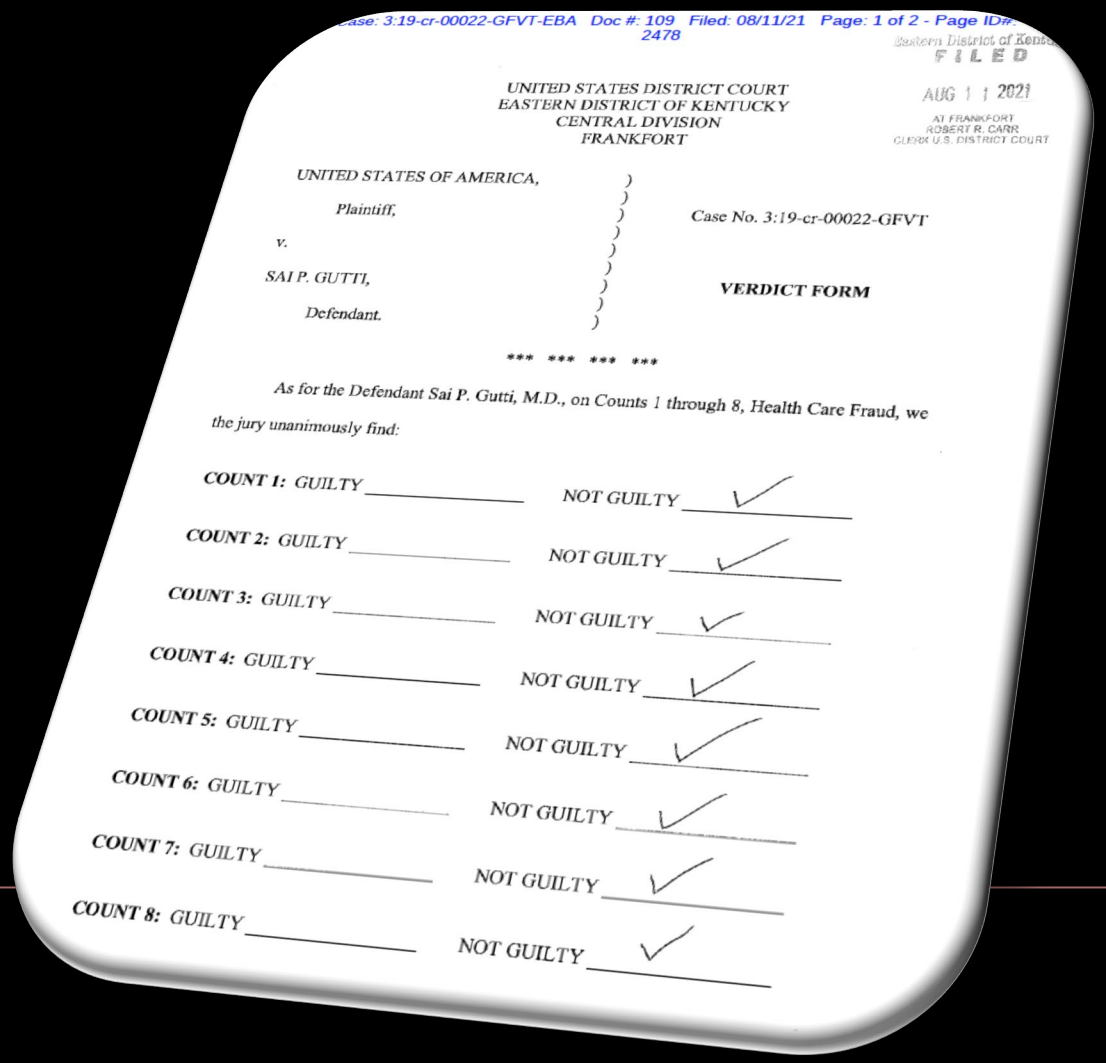
https://www.federalregister.gov/documents/2021/06/25/2021-13526/carol-hippenmeyer-md-decision-and-order

Healthcare Fraud Case involving Urine Drug Testing via Physician Office Laboratory



Case: 3:19-cr-00022-GFVT-EBA Doc #: 109 Filed: 08/11/21 Page: 1 of 2 - Page ID#: 2478

Eastern District of Kentucky
FILED
AUG 11 2021
AT FRANKFORT
ROBERT R. CARR
CLERK U.S. DISTRICT COURT

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
CENTRAL DIVISION
FRANKFORT

UNITED STATES OF AMERICA,
Plaintiff,
v.
SAI P. GUTTI,
Defendant.

Case No. 3:19-cr-00022-GFVT

VERDICT FORM

*** *** *** ***

As for the Defendant Sai P. Gutti, M.D., on Counts 1 through 8, Health Care Fraud, we the jury unanimously find:

COUNT 1:	GUILTY _____	NOT GUILTY ✓
COUNT 2:	GUILTY _____	NOT GUILTY ✓
COUNT 3:	GUILTY _____	NOT GUILTY ✓
COUNT 4:	GUILTY _____	NOT GUILTY ✓
COUNT 5:	GUILTY _____	NOT GUILTY ✓
COUNT 6:	GUILTY _____	NOT GUILTY ✓
COUNT 7:	GUILTY _____	NOT GUILTY ✓
COUNT 8:	GUILTY _____	NOT GUILTY ✓

Case Filed in 2019
Trial in July/Aug. 2021
Dr. Gutti was ACQUITTED OF ALL CHARGES on 08/11/21

PAINWEEK

Payor Policies May Conflict with DEA and Board Standard of Care Expectations

- US v. Gutti, EDKY, NOT GUILTY VERDICT 08/11/21
  - Government, through Medicare Administrative Contractor and a Medical Expert, claimed Dr. Gutti was “over-testing” because he performed and billed for both presumptive (immunoassay)of drug classes and definitive (LC/MS/MS) testing of specific prescribed opioids, benzodiazepines (by a family physician), and gabapentin.
    - Medical expert testified that presumptive testing was sufficient and that Dr. Gutti committed fraud by ordering definitive testing because his patients were on low dose opioid therapy, and some did not show aberrant behavior or problematic histories.
  - Dr. Gutti was NOT charged with inappropriate prescribing.
    - Most of his patients were on low dose opioid therapy (50mg MME or less). However, not all of his patients were “low risk.”

Case Filed in 2019
Trial in July/Aug. 2021
Dr. Gutti was ACQUITTED OF ALL CHARGES on 08/11/21

- The Government's position on presumptive and definitive testing under Medicare and Medicaid coverage policies
- (CGS, Medicare Administrative Contractor)

14. Medicare and Medicaid considered presumptive testing to be medically necessary, and appropriately reimbursable, in the treatment of chronic pain patients, provided the presumptive testing was used in the diagnosis and treatment of beneficiaries and members and the need for the testing was substantiated by documentation in the patient's medical record. Conversely, Medicare and Medicaid specifically excluded from coverage, and did not consider medically necessary, "blanket orders" or routine presumptive testing of substances.

15. Medicare and Medicaid considered definitive testing to be medically necessary, and appropriately reimbursable, in the treatment of chronic pain patients in certain limited circumstances, including when beneficiaries or members had a specific and documented need for definitive testing. Conversely, Medicare and Medicaid specifically excluded from coverage, and did not consider medically necessary, "blanket orders" or routine definitive testing of substances.

Excerpt from the Indictment in US v. Gutti, EDKY.

Case Filed in 2019
Trial in July/Aug. 2021
Dr. Gutti was ACQUITTED OF ALL CHARGES on 08/11/21

- The Government's charged conduct covering presumptive and definitive testing;
- JURY REJECTED THEIR POSITION WITH THE GUILTY VERDICT

Case: 3:19-cr-00022-GFVT-EBA Doc #: 1 Filed: 04/11/19 Page: 10 of 12 - Page ID#: 10

Count	Beneficiary/ Member	Service Date	UDT Date	HCBP Claim Number	Item/ Service Billed	Approx. Claim Date	Claim Amount
1	D.M.	10/10/16	Not Recorded	Medicaid 136697762600	G0479	06/27/17	$160.00
2	D.M.	10/10/16	Not Recorded	Medicaid 136945476500	G0483	11/15/16	$810.00
3	R.G.	09/08/18	09/20/18	Medicare 662818267628340	80307	09/24/18	$160.00
4	R.G.	09/08/18	09/12/18	Medicare 662818268628880	G0480	09/25/18	$260.00
5	D.H.	01/28/19	02/05/19	Medicaid 7519066014353	80307	2/25/19	$160.00
6	D.H.	01/28/19	02/01/19	Medicaid 7519066014374	G0480	2/25/19	$260.00
7	W.P.	01/30/19	02/06/19	Medicare 662819042508780	80307	02/11/19	$160.00
8	W.P.	01/30/19	02/01/19	Medicare 662819042508790	G0480	02/11/19	$260.00

Each of the above in violation of 18 U.S.C. §§ 1347 and 2.

Excerpt from the Indictment in US v. Gutti, EDKY.

Kentucky Medical Board Rule Referencing Drug Testing (Baseline Drug Test)

4. The physician shall obtain and document a baseline drug screen.

5. If, after screening, the physician determines that the controlled substance prescribed to the patient will be used or is likely to be used other than medicinally or other than for an accepted therapeutic purpose, the physician shall not prescribe any controlled substance to that patient.

- 201 KAR 9:260, Sec. 4(h)(4)
- "***shall*** obtain and document a baseline drug screen"

Kentucky Medical Board Rule Referencing Drug Testing (Random Periodic Drug Testing)

(k)1. During the course of long-term prescribing or dispensing of a controlled substance, the physician shall utilize drug screens, appropriate to the controlled substance and the patient's condition, in a random and unannounced manner at appropriate times. If the drug screen or other information available to the physician indicates that the patient is noncompliant, the physician shall:

a. Do a controlled taper;

b. Stop prescribing or dispensing the controlled substance immediately; or

c. Refer the patient to an addiction specialist, mental health pro-

- 201 KAR 9:260, Sec. 5(k)(1)
- "***shall*** utilize drug screens ***appropriate to the [prescribed] controlled substance***"

Kentucky Medical Board Rule Referencing Drug Testing – FAQ on 201 KAR 9:260, Sections 4 and 5

KENTUCKY BOARD OF MEDICAL LICENSURE
201 KAR 9:260 Summary

*Please note this is a summary of 201 KAR 9:260. Physicians should review and refer to the actual regulation, which is available at the Board's website, www.kbml.ky.gov. This summary does not replace 201 KAR 9:260 and should not be considered legal advice or a legal opinion.

Kentucky Medical Board Rule Referencing Drug Testing – FAQ on 201 KAR 9:260, Sections 4 and 5

Section 4 – Commencement of Long-term Prescribing (AFTER 90 Days) to Treat Non-Cancer Pain

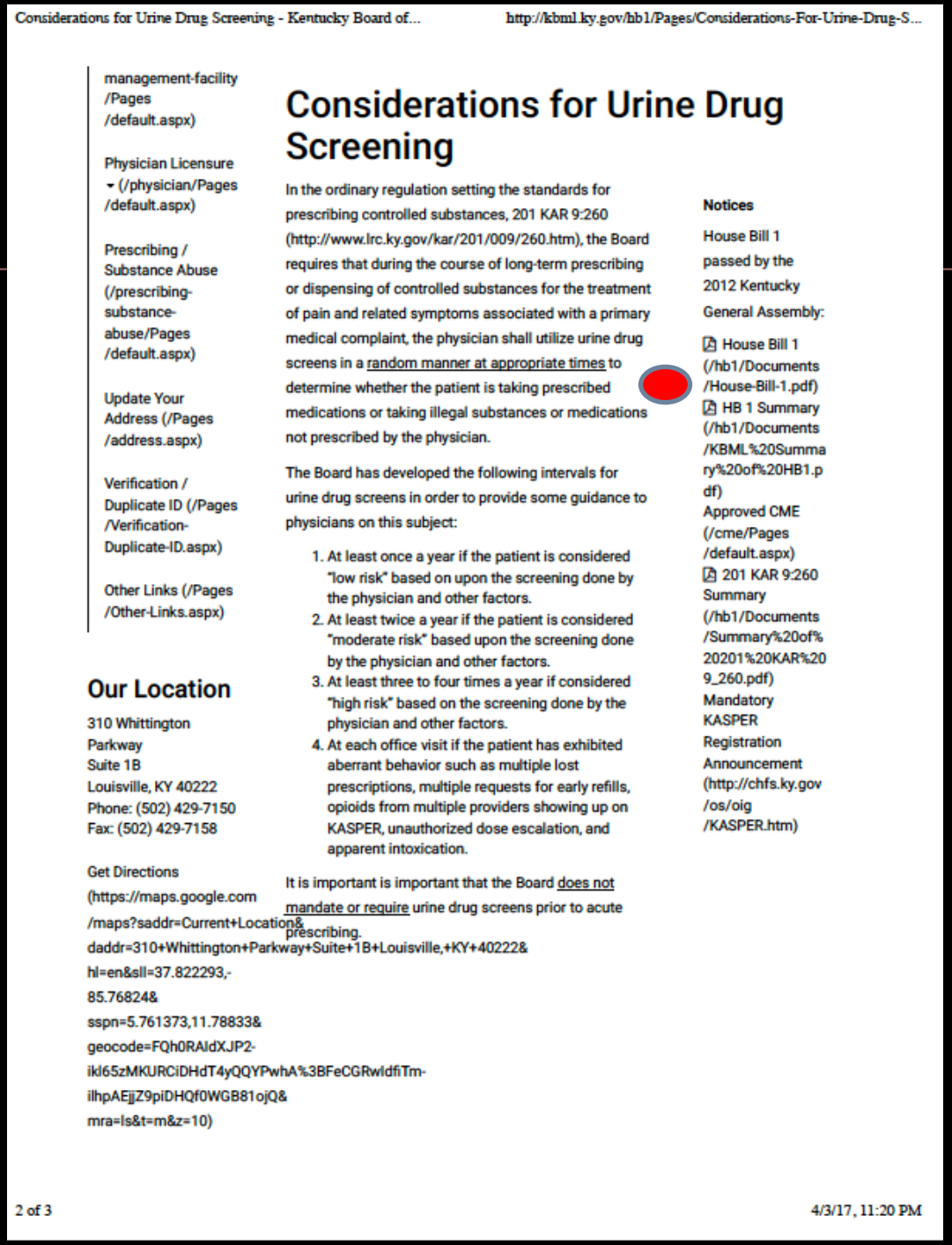
- Different licensed practitioners working in same practice location may perform tasks to meet the required standards so long as in their scope;
- Comprehensive history to include:
  - History of substance abuse/treatment for patient & history of abuse for first degree relatives;
  - Past family history of relevant illness & Psychosocial history;
  - Appropriate Physical Exam to support long-term use of controlled substances;
  - Baseline Assessments to establish & monitor treatment plan;
  - Obtain Prior Medical Records, if needed to justify continued prescribing;
- Formulate Working Diagnosis;
  - Refer if necessary to formulate a working diagnosis;
  - Only prescribe if medically indicated & appropriate if no working diagnosis can be established despite referral;
- Develop and document treatment plan if improvement is medically expected;
- Baseline drug screen – do not prescribe if medication is determined being used/likely to be used for other than medicinal purpose;
- Screen for other conditions that may impact treatment or necessitate a referral;
- Diversion risk – if patient determined to be high risk – prescribing agreement;
- Written Informed Consent;
- Attempt trial of other modalities and lower doses, or document a previous attempt by another;
- KASPER Review.

Kentucky Medical Board Rule Referencing Drug Testing – FAQ on 201 KAR 9:260, Sections 4 and 5

Section 5 – Continued Long-Term Prescribing Non-Cancer Pain in Patients

- Ensure patient is seen monthly, until titrated to appropriate level;
- At appropriate intervals:
  - Update H&P as necessary;
  - Perform Measurable Exams; and
  - Evaluate and update working diagnosis and treatment plan;
- Annual Preventive Health Screening - conduct or ensure is done;
- KASPER review every 3 months; More frequent or immediately if indicated;
- Notify other practitioners if you suspect "doctor shopping";
- Random pill counts if appropriate;
- Random Drug Screens appropriate to the drug prescribed and the patient's condition and if the patient is noncompliant, discontinue prescribing, do a controlled taper or make referral;
- Consultative Assistance – as appropriate;
- Significant Risk of Diversion – discontinue prescribing or document /justify use in record;
- No Significant Improvement Where Expected – obtain consultative assistance;
- Mood, Anxiety or Psychotic Disorders – obtain psychiatric consult if appropriate;
- Document Treatment or Refer to Addiction Management – no improvement where medically expected; significant adverse effects; or patient exhibits inappropriate or behavior/ diversion;
- Breakthrough Pain – Identify triggers – attempt non-controlled substances or if adding controlled substances, take steps to minimize likelihood of improper/illegal use;

KENTUCKY BOARD OF MEDICAL LICENSURE WEBSITE 2017



management-facility /Pages /default.aspx)

Physician Licensure (/physician/Pages /default.aspx)

Prescribing / Substance Abuse (/prescribing-substance-abuse/Pages /default.aspx)

Update Your Address (/Pages /address.aspx)

Verification / Duplicate ID (/Pages /Verification-Duplicate-ID.aspx)

Other Links (/Pages /Other-Links.aspx)

Considerations for Urine Drug Screening

In the ordinary regulation setting the standards for prescribing controlled substances, 201 KAR 9:260 (http://www.lrc.ky.gov/kar/201/009/260.htm), the Board requires that during the course of long-term prescribing or dispensing of controlled substances for the treatment of pain and related symptoms associated with a primary medical complaint, the physician shall utilize urine drug screens in a random manner at appropriate times to determine whether the patient is taking prescribed medications or taking illegal substances or medications not prescribed by the physician.

The Board has developed the following intervals for urine drug screens in order to provide some guidance to physicians on this subject:

1. At least once a year if the patient is considered "low risk" based on upon the screening done by the physician and other factors.
2. At least twice a year if the patient is considered "moderate risk" based upon the screening done by the physician and other factors.
3. At least three to four times a year if considered "high risk" based on the screening done by the physician and other factors.
4. At each office visit if the patient has exhibited aberrant behavior such as multiple lost prescriptions, multiple requests for early refills, opioids from multiple providers showing up on KASPER, unauthorized dose escalation, and apparent intoxication.

It is important is important that the Board does not mandate or require urine drug screens prior to acute prescribing.

Notices

House Bill 1 passed by the 2012 Kentucky General Assembly:

House Bill 1 (/hb1/Documents /House-Bill-1.pdf)
HB 1 Summary (/hb1/Documents /KBML%20Summary%20of%20HB1.pdf)
Approved CME (/cme/Pages /default.aspx)
201 KAR 9:260 Summary (/hb1/Documents /Summary%20of%20201%20KAR%209_260.pdf)
Mandatory KASPER Registration Announcement (http://chfs.ky.gov /os/oig /KASPER.htm)

Our Location

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Louisville, KY 40222
Phone: (502) 429-7150
Fax: (502) 429-7158

Get Directions (https://maps.google.com /maps?saddr=Current+Location&daddr=310+Whittington+Parkway+Suite+1B+Louisville,+KY+40222&hl=en&sll=37.822293,-85.76824&sspn=5.761373,11.78833&geocode=FQh0RAIdXJP2-ikl65zMKURCiDHdT4yQQYPwhA%3BFeCGRwIdfiTm-ilhpAEjjZ9piDHQf0WGB81ojQ&mra=ls&t=m&z=10)

PAINWEEK

FSMB 2017 Model Guidelines for the Use of Controlled Substances to Treat Pain

Guidelines for the Chronic Use of Opioid Analgesics

Adopted as policy by the Federation of State Medical Boards
April 2017

INTRODUCTION

In April 2015, the Federation of State Medical Boards (FSMB) Chair, J. Daniel Gifford, MD, FACP, appointed the Workgroup on FSMB's *Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain* to review the current science for treating chronic pain with opioid analgesics and to revise the Model Policy as appropriate.

To accomplish this charge, the workgroup conducted a thorough review and analysis of FSMB's existing policy document and other state and federal policies on the prescribing of opioids in the treatment of pain, including the March 2016 *CDC Guideline for Prescribing Opioids for Chronic Pain* (https://www.cdc.gov/drugoverdose/prescribing/guideline.html)

FSMB 2017 Model Guidelines for the Use of Controlled Substances to Treat Pain (at PDF pg. 11)

Periodic and Unannounced Drug Testing

Periodic and unannounced drug testing (including chromatography) are useful in monitoring adherence to the treatment plan, as well as in detecting the use of non-prescribed drugs. Drug testing is an important monitoring tool because self-reporting of medication use is not always reliable and behavioral observations may detect some problems but not others. It is strongly recommended that patients being treated for addiction be tested as frequently as necessary to ensure therapeutic adherence, but for patients being treated for pain, clinical judgment trumps recommendations for frequency of testing.

and creatinine should be measured. Initial testing may be done using class-specific immunoassay drug panels (point-of-care or laboratory-based), which typically do not identify particular drugs within a class unless the immunoassay is specific for that drug. If necessary, this can be followed up with a more specific technique, such as gas chromatography/mass spectrometry (GC/MS) or other chromatographic tests to confirm the presence or absence of a specific drug or its metabolites. In drug testing in a pain practice, it is important to identify the specific drug and metabolites, not just the class of the drug.

BALANCING ACT

PainWeek®

Objective 3

List three areas of medical record documentation ripe for improvement and necessary to communicate an appropriate and rationale approach to opioid prescribing.

Three Key Documentation Areas Ripe for Improvement

- Review of Prior Medical Care
- Risk Evaluation, Stratification, Monitoring
- Coordination of Care and Exit Strategies

TEXAS & BASIC MEDICAL RECORD-KEEPING REQUIREMENTS

https://casetext.com/regulation/texas-administrative-code/title-22-examining-boards/part-9-texas-medical-board/chapter-165-medical-records/section-1651-medical-records

(6) The written plan for care should include when appropriate:

(A) treatments and medications (prescriptions and samples) specifying amount, frequency, number of refills, and dosage;

(B) any referrals and consultations;

(C) patient/family education; and

(D) specific instructions for follow up.

(7) Include any written consents for treatment or surgery requested from the patient/family by the physician.

(8) Include a summary or documentation memorializing communications transmitted or received by the physician about which a medical decision is made regarding the patient.

(9) Billing codes, including CPT and ICD-9-CM codes, reported on health insurance claim forms or billing statements should be supported by the documentation in the medical record.

(10) All non-biographical populated fields, contained in a patient's electronic medical record, must contain accurate data and information pertaining to the patient based on actual findings, assessments, evaluations, diagnostics or assessments as documented by the physician.

(11) Any amendment, supplementation, change, or correction in a medical record not made contemporaneously with the act or observation shall be noted by indicating the time and date of the amendment, supplementation, change, or correction, and clearly indicating that there has been an amendment, supplementation, change, or correction.

(12) Salient records received from another physician or health care provider involved in the care or treatment of the patient shall be maintained as part of the patient's medical records.

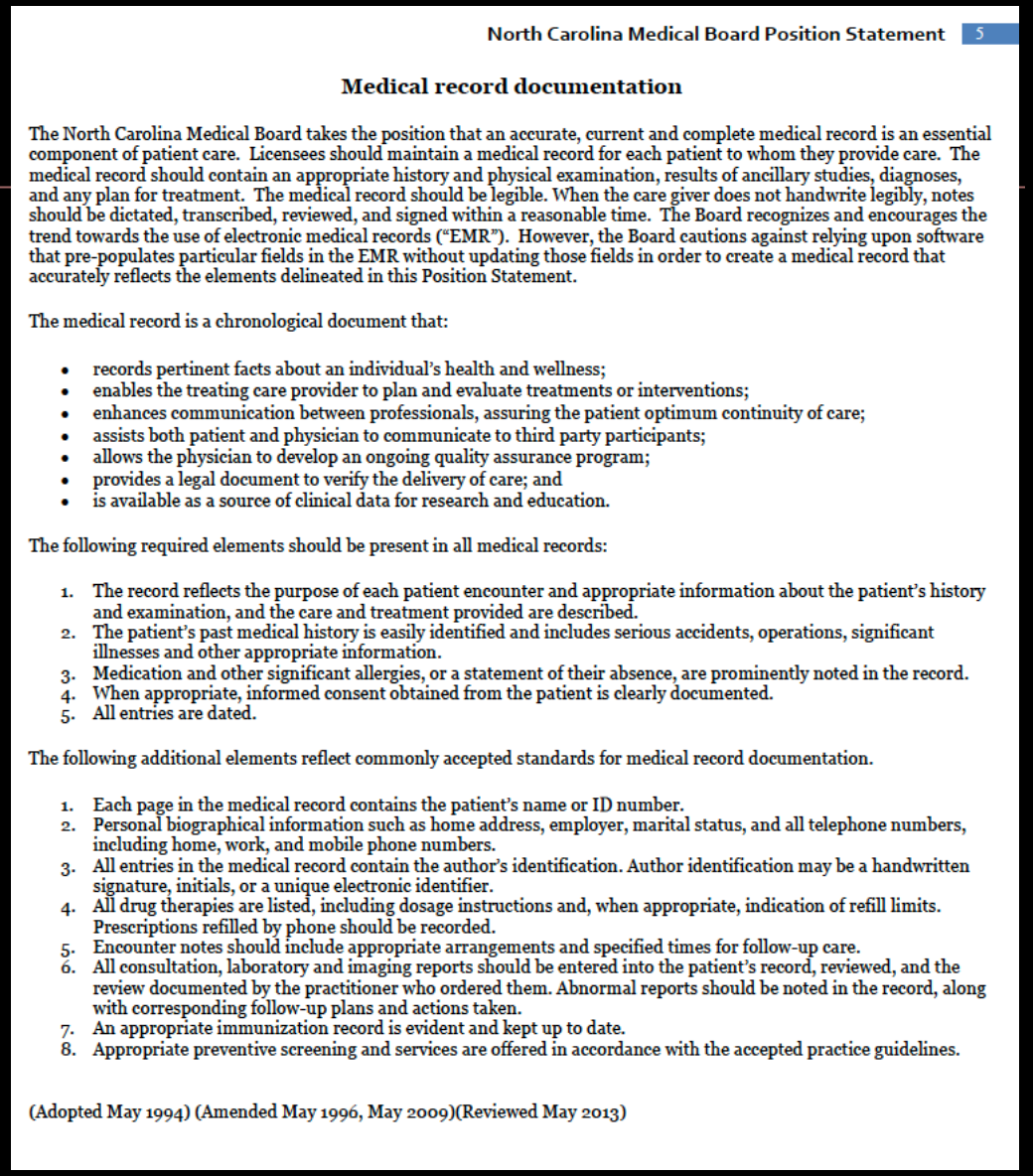
(13) The board acknowledges that the nature and amount of physician work and documentation varies by type of services, place of service and the patient's status. Paragraphs (1) - (12) of this subsection may be modified to account for these variable circumstances in providing medical care.

NORTH CAROLINA

Basic Medical Record Documentation

Must also look to the state's pain-specific rule or guideline on documentation associated with opioid prescribing.

NOTE: Caution about EMR pre-populating certain fields without updating information to reflect the medical record charting requirement of the board.



Medical record documentation

The North Carolina Medical Board takes the position that an accurate, current and complete medical record is an essential component of patient care. Licensees should maintain a medical record for each patient to whom they provide care. The medical record should contain an appropriate history and physical examination, results of ancillary studies, diagnoses, and any plan for treatment. The medical record should be legible. When the care giver does not handwrite legibly, notes should be dictated, transcribed, reviewed, and signed within a reasonable time. The Board recognizes and encourages the trend towards the use of electronic medical records ("EMR"). However, the Board cautions against relying upon software that pre-populates particular fields in the EMR without updating those fields in order to create a medical record that accurately reflects the elements delineated in this Position Statement.

The medical record is a chronological document that:

- records pertinent facts about an individual's health and wellness;
- enables the treating care provider to plan and evaluate treatments or interventions;
- enhances communication between professionals, assuring the patient optimum continuity of care;
- assists both patient and physician to communicate to third party participants;
- allows the physician to develop an ongoing quality assurance program;
- provides a legal document to verify the delivery of care; and
- is available as a source of clinical data for research and education.

The following required elements should be present in all medical records:

1. The record reflects the purpose of each patient encounter and appropriate information about the patient's history and examination, and the care and treatment provided are described.
2. The patient's past medical history is easily identified and includes serious accidents, operations, significant illnesses and other appropriate information.
3. Medication and other significant allergies, or a statement of their absence, are prominently noted in the record.
4. When appropriate, informed consent obtained from the patient is clearly documented.
5. All entries are dated.

The following additional elements reflect commonly accepted standards for medical record documentation.

1. Each page in the medical record contains the patient's name or ID number.
2. Personal biographical information such as home address, employer, marital status, and all telephone numbers, including home, work, and mobile phone numbers.
3. All entries in the medical record contain the author's identification. Author identification may be a handwritten signature, initials, or a unique electronic identifier.
4. All drug therapies are listed, including dosage instructions and, when appropriate, indication of refill limits. Prescriptions refilled by phone should be recorded.
5. Encounter notes should include appropriate arrangements and specified times for follow-up care.
6. All consultation, laboratory and imaging reports should be entered into the patient's record, reviewed, and the review documented by the practitioner who ordered them. Abnormal reports should be noted in the record, along with corresponding follow-up plans and actions taken.
7. An appropriate immunization record is evident and kept up to date.
8. Appropriate preventive screening and services are offered in accordance with the accepted practice guidelines.

(Adopted May 1994) (Amended May 1996, May 2009)(Reviewed May 2013)

Position statements available online at https://www.ncmedboard.org/images/uploads/other_pdfs/PS_October2015.pdf.

Question:

Dr. Adams agreed to see Marcie Meddle as a favor to his good friend, Dr. Sneed, who is a general practitioner who treats some of his patients with chronic opioid therapy.

Ms. Meddle has been receiving opioids from Dr. Sneed for two years, apparently for chronic pain associated with a fall off of a golf cart during a golf tournament.

Ms. Meddle is asking you for a higher dose of opioid, complaining that Dr. Sneed never really believed her pain was real and limited her to 2 hydrocodone tablets per day.

Answer: Which answer reflects a reasonable and rationale step to take prior to deciding whether to take Ms. Meddle on as a patient?

A. Check the Prescription Drug Monitoring Database and Perform a Urine Drug Screen prior to prescribing to Ms. Meddle.
B. Ask Dr. Sneed to send over Ms. Meddle's records and evaluate her file prior to making any prescribing decisions.
C. Prescribe Ms. Meddle 3 hydrocodone tablets per day and see her back in two weeks to see if she is experiencing better pain control.
D. Change Ms. Meddle's medication from hydrocodone to oxycodone and continue her at two tablets (10/325) per day. Reassess her in three to four weeks.

Case-Based Learning

Case Study

- BigBox Health Plan has sent you several letters alerting you to opioid dosing levels for a patient of yours who has been on a stable dose of the below-listed opioid for the past three years:

- Hydrocodone/APAP at 10/325, take 1 tablet every 6 to 8 hours, #120 every 30 days. You have authorized the patient to receive multiple prescriptions at a time because the patient is believed to be at “low risk” for abuse and diversion of controlled medication. You write them as shown below and see the patient once every two months or so.

- Rx # 1 is dated today, signed today, fill immediately.
- Rx #2 is dated today, signed today, do not fill until 10/7/21.
- Rx #3 is dated today, signed today, do not fill until 11/7/21.

- The patient has been compliant in terms of keeping office appointments, only using one physician and one pharmacy for obtaining and filling his opioid prescriptions, is working, and has only had a couple of “aberrant” drug test results involving a positive result for THC x 2 in the last 18 months and a couple of results where the quantitative opioid values show higher levels of hydromorphone over hydrocodone and Norhydrocodone.

- The letter sent by the Health Plan encourages you to make a more concerted effort to reduce the patient’s morphine equivalent daily dose (MEDD) and to submit an updated treatment plan reflecting this and other efforts to minimize the patient’s reliance on opioids. Because you know that health plans have nurse case reviewers identifying high dose opioid prescribers, you recognize that you should make some effort to respond.

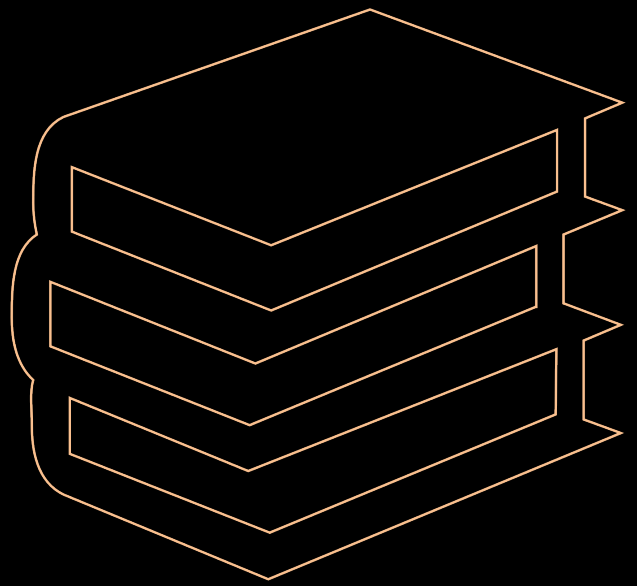
- Which answer best illustrates a reasonable and rationale approach to dealing with the health plan’s letter and re-evaluating medical record documentation of your prescribing rationale?

- A. Write the health plan back and tell them that you are unable to reduce the patient's dose of hydrocodone any further and that changing the patient to a different opioid or otherwise changing the patient's medication does not make sense in light of the long-term relationship you have with the patient; Tell the health plan that they have records on the patient and should be able to determine the patient's daily dose, risk ranking, and current compliance status by consulting their existing patient file; .

- B. Ignore the health plan's request for information and simply place a copy of the letter in the patient's chart, believing that you have everything in order regarding your evaluation and monitoring of the patient.

- C. Consult your licensing board's current opioid prescribing guidelines/rules; Use these materials to review the patient's chart and determine whether there are any steps you can take to reduce the patient's reliance on opioids and ensure clarity in your prescribing rationale; Consider whether the use of "do not fill until _____" prescriptions remain indicated for the patient and whether it is medically advisable to prescribe the long-acting version of hydrocodone in lieu of the frequent dosing of short-acting formulations; Update your chart notes and treatment plan and submit these materials and a factual summary supporting the ongoing use of opioids with the patient and your reasonable efforts to minimize risk to the patient.

- D. Send the letter to your local pain society and ask others whether they too are receiving such letters and whether it might be advisable to write a letter on the society's letter head suggesting that the health plan should not be practicing medicine.



Additional Resources (Attendee Library)

Faculty Contact Information

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865-755-2369 (please text first due to call scheduling)
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THANK YOU!