PainWeek

Who's Looking at you, Doc?
A Rational Response to 2022 Perspectives on Controlled Substance Prescribing

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Title & Affiliation

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Disclosures

Ms. Bolen serves as a Consultant to Paradigm Healthcare

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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 2022 challenges and beyond.
- Documentation is key!

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Learning Objectives

OBJECTIVE 1
- **Summarize** current stakeholder perspectives and oversight trends for opioid prescribing in 2022.

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.

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Objective 1

Opioid Prescribing: Whose Perspective Matters in 2022?

Oversight trends and documentation challenges

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YOURS

(but make sure it's current and informed)

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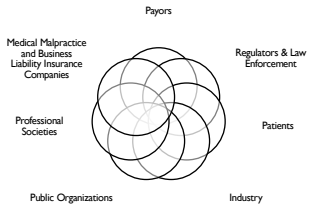
THE "ARMCHAIR" PERSPECTIVES



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CMS OPIOID SAFETY ACTIVITY AND 2022 PERSPECTIVES

Centers for Medicare and Medicaid Services

Just sitting here thinking about the life choices that led me to be here...

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The latest – CDC Draft 2022 Opioid Prescribing Guidelines

- Public comment period ended 4/11/22.
- Draft Guidelines available at https://www.regulations.gov/document/CDC-2022-0024-0005.
- REVISION:
  - Moves away from suggested dosing ranges
  - Emphasizes Physician Discretion and Decision-Making
  - Highlights concerns over misapplication of earlier CDC guidance

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The latest – CDC Draft 2022 Opioid Prescribing Guidelines

- What you should do to stay current:
  - Review Draft
  - Review Comments
  - Check CDC website for final version – expected soon!
  - Evaluate FINAL REVISED CDC Guidelines along side of CMS Materials, which rely heavily on dosing ranges.
  - Watch for CMS updates FOLLOWING RELEASE OF FINAL CDC GUIDELINES

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CMS and Influence on Opioid Prescribing Practices
(Continued Drug Utilization Review Controls in Part D Medicare)

Drug Management Program (DMP)	Opioid Safety Alerts
• Establish DMPs for beneficiaries at risk for misuse/abuse of frequently abused drugs. Tracking beneficiaries at risk for using multiple prescribers and pharmacies. • Part D Plan Sponsors NOW required to have DMP and to track beneficiaries with a Hx of opioid-related overdose.	• At time of dispensing. • Multiple points of information available; See Resource below.

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

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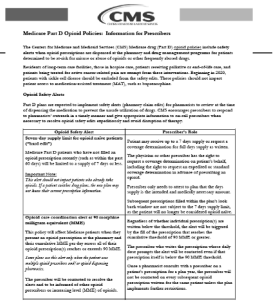
Perspectives – CMS and Payor Opioid Safety Edits



Medicare Part D Opioid Policies: Information for Prescribers

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

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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

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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

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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.

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

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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

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Co-Prescribing of Opioids + Benzodiazepines

BOARDS, LAW ENFORCEMENT, AND PAYORS ARE ALL WATCHING THIS CRITICAL RISK MITIGIATION AREA

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Who's Looking at Patients who receive Opioids + Benzodiazepines? Co-Prescribing Issues?

Boards	Law Enforcement	Payors
• Pain Management Rules and Guidelines • Unprofessional Conduct Investigations	• Federal • State	• Commercial • Government

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

mln MATTERS®
KNOWLEDGE • RESOURCES • TRAINING

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 04/21/22).See also top of page for more insight on CMS identification of OPHBZO prescriber-outliers.

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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]

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Available online at https://www.cms.gov/About-CMS/Story-Page/prescribing-opioids. (bottom of page); accessed 04/21/22).

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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]

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Available online at https://www.cms.gov/About-CMS/Story-Page/prescribing-opioids, (bottom of page); accessed 04/21/22).

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

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

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Available online at https://www.cms.gov/About-CMS/Story-Page/prescribing-opioids, (bottom of page); accessed 04/21/22).

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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.

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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.

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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."

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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.

FDA U.S. Food and Drug Administration | 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).

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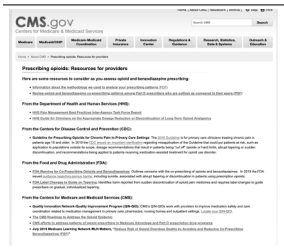
CMS and Resources on Prescribing Opioids for Providers



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

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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.

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DEA Administrative Case – Co-Prescribing Opioids and Benzodiazepines

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

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CMS Outlier Data

Part D Prescribers of Opioids and Benzodiazepines

Aggregate Data of Outlier Part D Prescribers of Opioids and Benzodiazepines

Consistent with section 6065 of the SUPPORT for Patients and Communities Act (SUPPORT Act), CMS has developed a methodology for determining outlier Part D prescribers when concurrently prescribing benzodiazepines and opioid medications. Based on this analysis, CMS sends annual letters to notify identified Part D prescribers that they are in the highest 10th percentile of Part D prescribers in their specialty and state. Individuals who take benzodiazepines and opioids together are at higher risk for adverse events and overdose. As a collaborative partner, CMS strives to provide meaningful and informative data, and believes sharing this data along with current prescribing guidelines will help Part D prescribers provide the best possible care to prevent and relieve pain and maximize function for patients with pain.

As required by section 6065 of the SUPPORT Act, CMS is making this aggregate Part D outlier prescriber information available on the CMS website. This effort is part of our data driven efforts to combat the nation's opioid crisis. Included below are aggregated outlier prescriber data by state for each Calendar Year (CY) for which the analysis was conducted to date.

Link to opioid prescribing and SUPPORT Act section 6065 methodology:
go.cms.gov/prescribing-opioids

https://www.cms.gov/About-CMS/Story-Page/prescribing-opioids (see entry at top of page under **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)**

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CMS Outlier Data Continued from Previous Slide

Methodology for Comparative Analysis:

Co-Prescribing Patterns for Benzodiazepines with Opioids and Average Morphine Milligram Equivalents (MME)

Consistent with section 6065 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act (P.L. 115-271), this methodology is intended to identify Part D prescribers who are outliers as compared to their peers for the percent of their patients concurrently prescribed benzodiazepines and opioids, and for the average MME dose prescribed to those patients.

Analysis Criteria

- Methodology analyzed 12 months of Medicare Part D claims data from July 1, 2020 – June 30, 2021 using Prescription Drug Event (PDE) files.
- Analysis identified beneficiaries with an opioid PDE who received both opioids and benzodiazepines from the same prescriber for a consecutive 30 days.
- Every prescriber was associated with a total count of beneficiaries who were co-prescribed opioids and benzodiazepines.
- Analysis **excludes a beneficiary** who:
  - Was not enrolled in Part D between January 2020 – June 2020, or
  - Had a diagnosis of cancer or sickle cell disease between July 2019 – June 2021, or
  - Was enrolled in long-term care between July 2020 – June 2021, or
  - Was enrolled in hospice care between July 2019 – June 2021
- Analysis **excludes a prescriber** that:
  - Had less than 5 beneficiaries who were co-prescribed opioids and benzodiazepines, or
  - Had less than 10 total beneficiaries who received opioids, or
  - Had less than 10 peers within their specialty and state, or
  - Prescribers who are the subject of an investigation by the Centers for Medicare & Medicaid Services or the Inspector General of the Department of Health and Human Services.
- All buprenorphine products were excluded from the analysis.
- Only opioid National Drug Codes (NDCs) that were associated with a MME conversion factor were included in the analysis.

Comparative Analysis

- MMEs per day were calculated for the opioids received by Medicare beneficiaries for each prescriber.
- The MME was calculated based upon the strength of the drug prescribed, the number of doses dispensed, the days' supply issued, and the respective conversion factor for the opioid prescribed. The conversion factors were derived from the Centers for Disease Control and Prevention's (CDC) 2018 oral MME conversion factors.[1]
- Prescribers were compared to their peers within the same specialty as identified through the National Plan and Provider Enumeration System (NPPES) and in the same state. Outliers were identified using two metrics:
  - Percentage of beneficiaries who were co-prescribed opioids and benzodiazepines
  - Average Daily MME prescribed to those patients
- Outlier prescribers were identified based upon the percentage of beneficiaries who were co-prescribed opioid and benzodiazepines greater than 90th percentile and an average daily MME greater than 90th percentile prescribed to those patients as compared to their peers.

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CMS Outlier Data Continued from Previous Slide

Annual Aggregate Outlier Data by State:

State	2020 Outliers	2021 Outliers	2022 Outliers
AK	1	0	0
AL	18	12	6
AR	9	7	6
AZ	8	2	1
CA	54	32	26
CO	8	5	2
CT	4	5	1
DE	2	0	1
FL	77	44	32
GA	31	14	16
HI	2	2	0
IA	5	1	2
ID	1	2	1
IL	19	16	13
IN	15	8	14
KS	8	6	2
KY	4	9	5
LA	21	10	5
MA	5	7	6
MD	8	0	2
ME	2	1	1
MI	27	16	16
MN	2	3	2
MO	14	16	10
MS	3	2	3
MT	2	0	1
NC	25	25	15
ND	1	2	0
NE	2	3	1
NH	2	1	1
NJ	13	8	7
NM	4	2	3
NV	7	3	2
NY	31	21	10
OH	13	9	11
OK	8	6	4
OR	4	4	2
PA	26	14	16
PR	6	0	0
RI	1	2	1
SC	16	6	8
SD	1	1	1
TN	30	16	16
TX	47	35	29
UT	8	4	2
VA	13	12	4
VT	1	0	0
WA	8	6	8
WI	7	4	4
WV	4	1	2
WY	0	1	1
Total	628	406	322

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CMS Education to Patients – OPI + BZO and CMS efforts to "mitigate risks"

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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.

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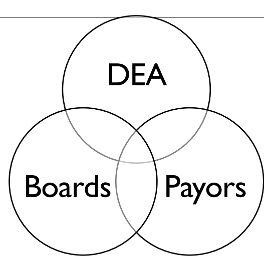
Rationale Response to Stakeholder Enforcement Efforts



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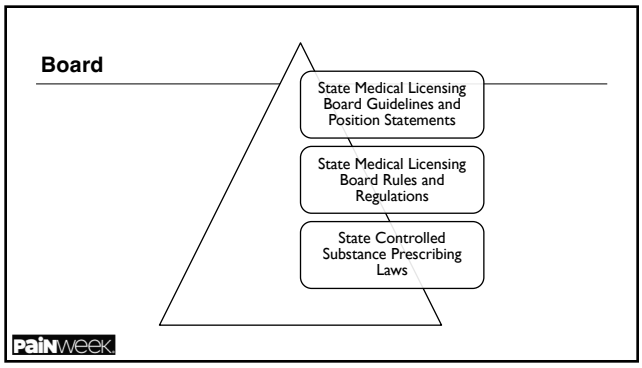

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LOUISIANA STATE BOARD OF MEDICAL EXAMINERS

- http://www.lsbme.la.gov/
- http://www.lsbme.la.gov/licensure/laws
- http://www.lsbme.la.gov/licensure/rules
- http://www.lsbme.la.gov/content/statements-position
- http://www.lsbme.la.gov/content/advisory-opinions ***

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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

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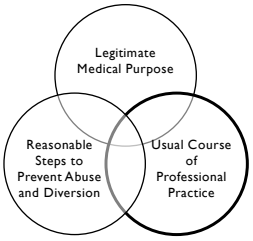
DEA Expectations



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

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.

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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.

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

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

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

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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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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]

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

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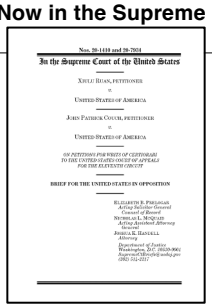
Pending Now in the Supreme Court of the United States



Nos. 20-1410 and 20-7051

In the Supreme Court of the United States

XIULU RUAN, PETITIONER

v.

UNITED STATES OF AMERICA

JOHN PATRICK COUCH, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITIONS FOR WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

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QUESTION PRESENTED

Whether the district court abused its discretion in declining a requested jury instruction on the ground that it would have required acquittal on charges of the unauthorized distribution of controlled substances, in violation of 21 U.S.C. 841, based on petitioners' own "subjective view" of the "usual course of medical practice."

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What could this case mean for opioid prescribers?

- **MAYBE . . .**
  - More clarity in the legal standard for controlled substance prescribing (legitimate medical purpose while acting in the usual course of professional practice).
- **ARGUMENT CENTERS ON . . .**
  - Objective vs. subjective standards.

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From the Government's Supreme Court Brief

While the district court offered to give a different instruction including "good faith language," Pet. App. 136a, it declined to give petitioners' particular proposed instruction, *id.* at 135a. As most relevant here, it determined that the instruction embodied "a subjective view of what is the usual course of professional practice," when "the standard should be an objective one." *Id.* at 134a. The court also concluded that the proposed language requiring proof that a physician operated as a "drug pusher" was legally incorrect. *Id.* at 104a.

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BALANCING ACT

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Objective 3

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

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Three Key Documentation Areas Ripe for Improvement

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

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Case-Based Learning

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Case Study:

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 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.

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Thoughtful Approach:

Which answer reflects a rationale and reasonable approach as you evaluate 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 controlled drugs 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.

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THANK YOU!

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