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From the Ivory Tower: The Data-Driven Strategy CMS, Health Plans, and State Governments Use to Review a Provider's Clinical Practice

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Title and Affiliation

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Disclosure

Dr. Atkinson's Disclosures:

- Consulting Fee (e.g., Advisory Board): Purdue Pharma LP

Jennifer Bolen's Disclosures:

- Consultant to Paradigm Healthcare

Learning Objectives

- Describe how payers now measure and address patient risk
- Explain claims analysis to evaluate care including strengths and weaknesses
- Review literature supporting monitored outcomes
- Discern individualized exposure to adverse regulatory or legal action
- Outline strategies discussed to ensure decrease in documented patient risk

CMS, Health Plans, & State Government Communication to Providers When Initiating Administrative or Regulatory Action

Timothy J Atkinson, PharmD, BCPS

Dear Dr. John Clarke,

- This letter serves to notify you of our quality of care concerns based on the inherent risk for morbidity, mortality, addiction and diversion for patients to whom you prescribe opioid medication.
- Based on our claims data, you have several frightening and potentially dangerous prescribing trends
- You have 30 days from receipt of this letter to fax a corrective opioid prescribing action plan to XXX-XXX-XXXX
- If we do not receive your action plan within the next 30 days
  - You will be placed on probation where claims will be paid at reduced rate for 12 months
  - If after probationary period we are not satisfied, we reserve the right to terminate you from the network

Sincerely,
Your Health Plan Partner

Provider Risk Assessment

John Clarke

60
50
40
30
20
10
0

Prescribers in Network

40 (97.7%)

Moderate High Severe

Risk Score

Top 3%

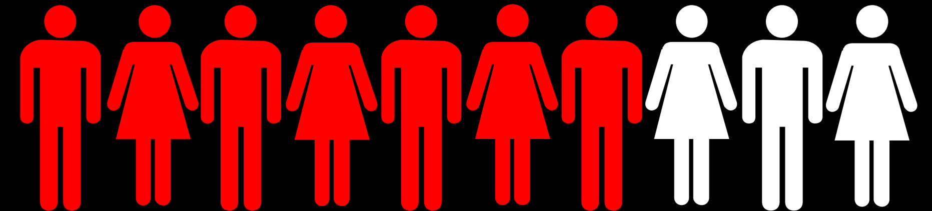
Dangerous Opioid Prescribing

Family Medicine

Peer Group

Opioid Panel Size

70% Dr. Clarke's patients are prescribed opioids



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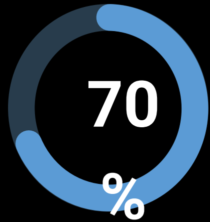
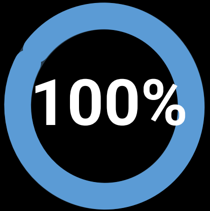
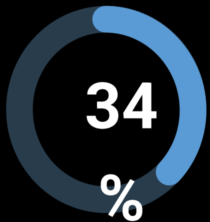
Dr. Clarke's Areas of Concern



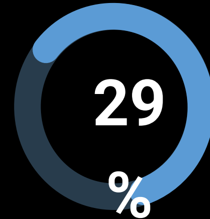
- Received High Doses of Opioids (≥90mg MEDD)



- Received opioids for greater than >90 days



- Prescribed Opioids and Benzodiazepines



- Received Opioids from Multiple Prescribers

How Bad Is It?

Your initial reaction:

- *"Wow, that looks pretty bad! Even I want to kick myself out of practice!"*

Then:

- *This isn't accurate, how are they coming up with this?*

Then:

- *"They have no idea what they're talking about!"*
- *"How dare they question my professional judgement!"*

..And Finally:

- *"I'm going to write them an angry letter"*
- *"I'm going to sue them"*

How CMS, Health Plans, & State Governments Evaluate A Provider's Practice

Timothy J Atkinson, PharmD, BCPS

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Medical and Pharmacy Claims Data

Advantages

- Beyond PDMP Reports
- Individual ICD codes utilized for
  - ER visits
  - Inpatient admissions
  - Outpatient visits
- All pharmacy prescription fills
  - Not just controlled substances
- Labs/Imaging codes available
- Recognition of relapse/overdose
  - Coordination of care

Disadvantages

- Do not capture out of network claims
- Do not capture cash pay encounters
  - Medical or pharmacy
- Claims data is messy
  - Duplicate claims
  - Reversals
- Highly dependent on accurate coding

Top Metrics From the Centers for Medicare & Medicaid Services (CMS)

Core Metrics	NQF Endorsed
Dose (Opioid MEDD)	Yes
Multiple Prescribers (Opioids)	Yes
Multiple Pharmacies (Opioids)	Yes
Opioid + Benzodiazepines	Yes
Monitoring of Opioid Therapy	Yes
Supplemental Metrics	
Follow-up (Opioid)	No
Risk of Continued Opioid Use	No
Evaluation or Interview for Risk of Opioid Misuse	No

NQF = National Quality Forum

Available at: https://cmit.cms.gov/CMIT_public/ListMeasures?q=opioid

Metrics Developed by Commercial Health Plans

Core Metrics + New Metrics:

- Opioid Panel Size
- Duration of Opioid Therapy
- Early Refill
- ER + IR Opioids
- Substance Use Disorder (history)
- Psychiatric History
- ED visits (while on opioids)

#1 Dose Evidence

≥50-99mg MEDD:

- HR 3.73[4] (all overdoses); HR 4.63[7,8]
- Moderate dose opioid-related mortality 1.63/1000 [All-cause mortality 19028/1000]

≥100-199mg MEDD:

- HR 8.87[4] (all overdoses); HR 7.18
- 34% more likely to overdose

≥200-399mg MEDD:

- High Dose opioid –related mortality 7.92/1000 [All-cause mortality 42.2/1000]
- 48% more likely to overdose

≥400mg MEDD:

- Very High Dose opioid-related mortality 9.94/1000 [All-cause mortality 44.9/1000]
- 1% of patients in the very high dose opioid category died over a 2 year period

Gwira Baumblatt J et al. High-Risk Use by Patients Prescribed Opioids for Pain and Its Role in Overdose Deaths. *JAMA.* 2014; 174(5):796-801.
Dunn K, Saunders K, Rutter C et al. Overdose and prescribed opioids: Associations among chronic non-cancer pain

Gomes T et al. Trends in opioid use and dosing among socio-economically disadvantaged patients. *Open Med.* 2011; 5(1):E13-E22.

Bohnert A et al. Association Between Opioid Prescribing Patterns and Opioid Overdose-Related Deaths. *JAMA.* 2011; 305(13): 1315-1321.
Bohnert A, Logan J, Ganoczy D, Dowell D. Opioid Dosage and Overdose Deaths Among Patients with Chronic Pain. *Med Care.* 2016; 54:435-441.

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#1 Dose Summary

Summary:

- Majority of overdose events occurred in those receiving low to moderate doses of opioids.
- Incidence rates of overdose increased across all MEDD levels
  - Sharpest increases up to 200mg MEDD.
- Odds ratios increased until 200mg MEDD and tended to level off.
- Odds ratios of overdose incidence increases in fairly linear fashion until 400mg MEDD.

Pearls for Practice:

- Ask how MEDD is calculated
  - (rolling average vs 90 windows vs days supply)
  - Conversion methodology

Gwira Baumblatt J et al. High-Risk Use by Patients Prescribed Opioids for Pain and Its Role in Overdose Deaths. *JAMA*. 2014; 174(5):796-801.
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Bohnert A, Logan J, Ganoczy D, Dowell D. Opioid Dosage and Overdose Deaths Among Patients with Chronic Pain. *Med Care*. 2016; 54:435-441.

#2 Multiple Prescriber Evidence

Core Metrics:

- ≥3 prescribers within 6 months (OR 1.7) among cases of overdose deaths
  - 43% of case (overdose) patients had seen 3 or more prescribers
- ≥4 prescribers within 12 months (OR 2.4) among cases of overdose deaths
  - Duration of opioid therapy not significant
- ≥4 prescribers within 1 year ~90% of overdose cases vs 4.3% of controls < 4 prescribers
- CDC Prescription Behavior Surveillance System (PBSS)
  - defines multiple prescriber episodes as ≥5 prescribers at ≥5 pharmacies within a 6 month period
- Men – twice as likely to die of drug overdose death compared to women
  - Women twice as likely to have evidence of doctor shopping

Paulozzi et al. A History of Being Prescribed Controleld Substances and Risk of Overdose Death. *Pain Med.* 2012; 13:87-95.
Dilokthornsakul P et al. Risk factors of prescription opioid overdose among Colorado Medicaid beneficiaries. J Pain. 2016; 17(4):436-443.
Gwira B et al. High-risk Use by Patients Prescribed opioids for pain and its role in overdose deaths. JAMA. 2014; 174(5):796-801.
Paulozzi et al. Controlled substance prescribing patterns-prescription behavior surveillance system, eight states, 2013. MMWR; 2015; 64(9):1-14.
Hall A et al. Paterns of Abuse Among Unintentional Pharmaceutical overdose fatalities. JAMA. 2008; 300(22):2613-2620.

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#2 Multiple Prescriber Summary

Summary:

- Multi-prescriber is consistently predictive of higher risk outcomes
  - Associated with hospital admissions, addiction, and overdose
- Timeframes in literature vary from 6 months to 1 year
  - ≥4 prescribers within 6 month period highly predictive of doctor shopping behavior
  - ≥4 prescribers within 12 months loses specificity but captures more potential cases

Pearls for Practice:

- Ask how providers covering for each other within the same practice is counted
- What timeframe?
  - 3 months, 6 months, 1 year
- Rx length?
  - Does 3 day supply count the same as 30 day supply?

#3 Multiple Pharmacies Evidence

Core Metrics:

- Mean of 2.4 pharmacies (OR 2.3) within 6 months in overdose cases
- ≥4 Pharmacies (OR 3.5) within 1 year of overdose event
  - Duration of opioid therapy not significant
- ≥4 Pharmacies within 1 year in ~95% of overdoses vs 1.7% controls (<4 per year)
- ≥3 Pharmacies within 6 months caught 69% of overdose cases
  - Extending the interval to 12 months increased by only 1% (70%)
- CDC Prescription Behavior Surveillance System (PBSS)
  - defines multiple prescriber episodes as ≥5 prescribers at ≥5 pharmacies within a 6 month period

Paulozzi et al. A History of Being Prescribed Controleld Substances and Risk of Overdose Death. *Pain Med.* 2012; 13:87-95.
Dilokthornsakul P et al. Risk factors of prescription opioid overdose among Colorado Medicaid beneficiaries. J Pain. 2016; 17(4):436-443.
Gwira B et al. High-risk Use by Patients Prescribed opioids for pain and its role in overdose deaths. JAMA. 2014; 174(5):796-801.
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Hall A et al. Paterns of Abuse Among Unintentional Pharmaceutical overdose fatalities. JAMA. 2008; 300(22):2613-2620.

#3 Multiple Pharmacy Summary

Summary:

- Multi-pharmacy is MORE predictive of higher risk outcomes than Multiple Prescribers
  - Relies heavily on PDMP access
- Timeframes in literature vary from 6 months to 1 year
  - ≥4 pharmacies within 6 month period highly predictive of doctor shopping behavior
  - ≥4 pharmacies within 12 months loses specificity but captures more potential cases

Pearls for Practice:

- What timeframe?
  - 3 months, 6 months, 1 year
- Easier to justify multiple prescribers than multiple pharmacies
  - Pain clinic, dentist, surgery etc
  - Less likely to be convenient to use a different pharmacy

CDC's Definition of Multiple Prescribers?

Prescription Behavior Surveillance System (PBSS)

- Funded by CDC and FDA

- Multiple Prescriber Episode Defined as:
  - ≥5 prescribers
  - ≥5 pharmacies
  - Within a 6 month period

Paulozzi et al. Controlled substance prescribing patterns - prescription behavior surveillance system, eight states, 2013. MMWR; 2015;64(9):1-14.

#4 Opioid + Benzodiazepine Evidence

Core Metrics:

- 80% of opioid overdose deaths were prescribed a benzodiazepine
  - Rate of death 10 times higher with concomitant therapy
- Benzodiazepines involved in 60.4% opioid overdoses
  - 38.8% involved multiple opioids
  - 18.4% involved alcohol
- Combination of opioids + benzodiazepines increased risk of overdose 4 times
- 48% of opioid overdose deaths had a prescription benzodiazepine dispensed in the month prior to death

Dasgupta N et al. Cohort Study of the Impact of High-Dose Opioid Analgesics on Overdose Mortality. Pain Med. 2016; 17:85-98.
Gomes T et al. Opioid Dose and Drug-Related Mortality in Patients with Non-Malignant pain. Arch Intern Med. 2011; 171(7):686-691.
Park T et al. Benzodiazepine prescribing patterns and deaths from drug overdose among US veterans receiving opioid analgesics: case-cohort study. British Med J. 2015; 350:h2698.
Fulton-Kehoe D et al. Opioid poisonings in Washington State Medicaid: Trends, dosing, and guidelines. Med Care. 2015; 53(8):679-685.

#4 Opioid + Benzodiazepine Summary

Summary:

- The opioid + benzodiazepine combination is considered a red flag or contraindication to most health plans and population management systems
  - One provider co-prescribing both medications to a high percentage of patients
    - Utilized as a simple method to identify pill mill activities
- CDC's PBSS categorizes prescription drugs primarily into 3 categories
  - Opioids
  - Benzodiazepines
  - Stimulants

Pearls for Practice:

- Benzodiazepine tapers take much longer than opioid tapers so the combination may occur while tapering for months to years
  - Documentation about risk and taper plan is key

#5 Opioid Panel Size Evidence

Common Metrics:

- Opioid Panel Size monitors the percentage of a providers patients are on opioids compared to their peers
- Top 5% opioid prescribers accounted for 66.59% of opioid volume and 39.99% of opioid prescriptions in the state
  - High risk prescribers (3.97%)
- States use PDMP databases to create algorithms to identify providers with unusual prescribing practices
  - High rate of prescriptions for opioids

Chang et al. Impact of prescription drug monitoring programs and pill mill laws on high-risk opioid prescribers: A comparative interrupted time series analysis. Drug Alcohol Depend. 2016; 165:1-8.
Ringwalt et al. The use of a prescription drug monitoring program to develop algorithms to identify providers with unusual prescribing practices for controlled substances. J Primary Prevent. 2015; 36:287-299.
Paulozzi et al. Controlled substance prescribing patterns – prescription behavior surveillance system, eight states, 2013. MMWR. 2015; 64(9):1-14.

#5 Opioid Panel Size Summary

Summary:

- Epidemiology studies indicating a few prescribers account for majority of opioid prescriptions does NOT:
  - Represent outcomes
  - Correlate with percentage prescribing within a provider's panel of patients

Pearls for Practice:

- Peer groups may be assigned incorrectly
- Percent patients on opioids from ONE health plan may not accurately represent a provider's entire practice
- Wouldn't a pain specialist, surgeon, or primary care provider have different opioid prescribing patterns?

#6 Duration of Opioid Therapy Evidence

Common Metrics:

- Script Length: potentially a stand-alone metric
  - Concept: longer days supply leads to increased risk of long-term opioid therapy
- Duration of Opioid Therapy:
- Duration of opioid therapy NOT significantly associated with addiction
  - Average time on opioid therapy 6-8 years
- Duration of opioid therapy NOT significantly associated with overdose risk
  - Groups with average opioid use 5 years vs 4 years
- Among new opioid starts without history of substance abuse
  - 4.35% abuse/addiction
  - Addiction rates did not correlate with duration of opioid therapy (range 1-34 months)

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Hojsted J et al. Classification and identification of opioid addiction in chronic pain patients. Europ J Pain. 2010; 14(10):1014-1020.
Fishbain et al. What perdentage of chronic nonmalignant pain patients exposed to chronic opioid analgesic therapy develop abuse/addiction and/or aberrant drug-related behaviors? A structured evidence-based review. Pain Medicine. 2008; 9:444-459.
Gomes T et al. Opioid Dose and Drug-Related Mortality in Patients with Non-Malignant Pain. Arch Intern Med. 2011; 171(7):686-691.

#6 Duration of Opioid Therapy Summary

Summary:

- Duration of opioid therapy is NOT predictive of adverse outcomes
- Many studies use transition from short-term to long-term opioid prescribing as a significant outcome despite lack of evidence
- Long-term opioid therapy ≠ opioid dependence

Pearls for Practice:

- If Duration is a metric, ask for the evidence
- Periodic documentation of risk vs benefits of continuing opioid therapy is key

#7 Opioid Dependence Evidence

Common Metrics:

- Prescribing opioids to a patient with a diagnosis of opioid dependence
- Prescribing opioids to a patient with a history of substance use
  - More likely to develop opioid abuse/dependence (OR 2.34)
- Strongest predictor of future opioid overdose is past overdose or hx opioid dependence (OR 3.9)
  - MEDD is only metric more predictive of future overdose vs hx OUD
- Strongest predictor of future opioid abuse is history of opioid abuse (OR 3.81)

Edlund M et al. Risk factors for clinically recognized opioid abuse and dependence among veterans using opioids for chronic non-cancer pain. *Pain.* 2007; 129:355-362.

Zedler et al. Development of a risk index for serious prescription opioid-induced respiratory depression or overdose in Veterans' Health Administration Patients. Pain Med. 2015; 16:1566-1579.

Zedler et al. Validation of a screening risk index for overdose or serious prescription opioid-induced respiratory depression. [Poster] AAPM 2015.

Boscarino et al. Risk factors for drug dependence among outpatients on opioid therapy in a large US healthcare system. Addiction. 2010; 105:1776-1782.

#7 Opioid Dependence Summary

Summary:

- Long-term opioid therapy ≠ opioid dependence
- ICD-10 code opioid dependence ≠ physical dependence
  - Umbrella term indicating opioid addiction
  - Correct ICD-10 code for long-term opioid use and physical dependence
    - *Z79.891 Long term (current) use of opiate analgesic*

Pearls for Practice:

- Beware of mislabeling opioid dependence
  - May lead to appearance of prescribing opioids to large percentage of patients with opioid use disorder

#8 Follow-up

CMS Metric: Opioid Therapy Follow-up Evaluation

- Description: All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.

- Rationale: Clinicians should periodically reassess all patients on chronic opioid therapy (COT). Regular monitoring is critical because therapeutic risks and benefits do not remain static…Monitoring is essential to identify patients who are benefiting from COT, those who might benefit from restructuring treatment…and those whose benefits from treatment are outweighed by harms.

CMS Measures Inventory Tool. Opioid Therapy Follow-up Evaluation. Updated 6/30/21. Accessed 7/28/21. Available at: https://cmit.cms.gov/CMIT_public/ListMeasures.

#8 Follow-up

Summary:

- Calculated:
  - Numerator = Patients who had a follow-up evaluation conducted at least every 3 months during opioid therapy
  - Denominator = All patients 18 and older prescribed opiates for longer than six weeks duration

Pearls for Practice:

- Doesn't capture:
  - Cash pay visits
  - No shows/cancellations
  - Changes in insurance coverage
- Not an endorsed metric by NQF

CMS Measures Inventory Tool. Opioid Therapy Follow-up Evaluation. Updated 6/30/21. Accessed 7/28/21. Available at: https://cmit.cms.gov/CMIT_public/ListMeasures.

Provider Risk Assessment

Revisting Dr. John Clarke

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Prescribers in Network

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Moderate High Severe

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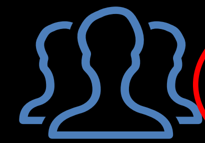
Dangerous Opioid Prescribing

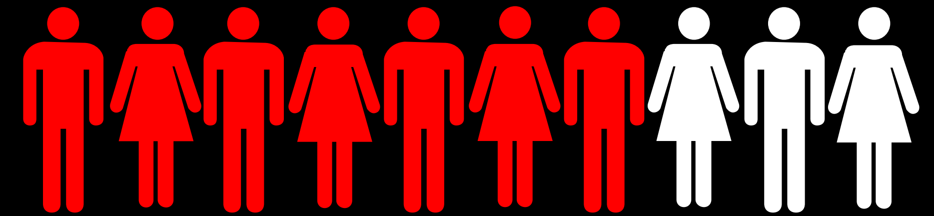


Family Medicine

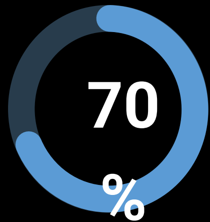
Peer Group

Opioid Panel Size

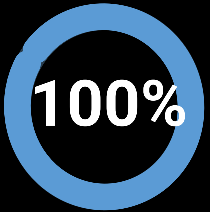
70% Dr. Clarke's patients are prescribed opioids



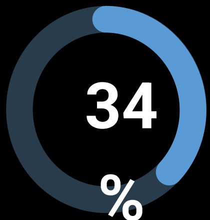
Revisting Dr. Clarke's Areas of Concern



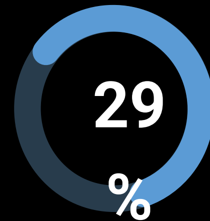
- Received High Doses of Opioids (≥90mg MEDD) → Pain specialist? Inherited patients?



- Received opioids for greater than >90 days → Suspicious if a Surgeon



- Prescribed Opioids and Benzodiazepines →Hard to Justify; Worse if co-prescribed



- Received Opioids from Multiple Prescribers → So What?

Opioid Metrics Takeaways

Summary:

- Data is NOT Sacred
  - Garbage in = Garbage out
  - Data analytics is imperfect at best
- "A complex proprietary data science algorithm"
  - *"It's a secret and I won't tell you how we came up with that analysis"*
- Common Errors:
  - *MEDD calculation*
  - *Duplicate claims not removed*
  - *Peer group classification*

Pearls for Practice:

- Cooperate to understand their process and definitions
- Ask for a *Peer Review*

Strategic Response When Claims Data Becomes Adverse Regulatory or Legal Action

Jen Bolen, JD

First Things First

- The best time to start a legal strategy is now – NOT AFTER you are under investigation or in litigation.
  - By the time claims data or adverse regulatory or legal action is taken, it often is too late to mount a successful defense in certain types of litigation.
- An honest, internal evaluation is one of the best proactive steps you can take.

Critical Self Audit Steps

Review State Licensing Board Material and Outline of "Standard of Care Expectations" for Opioid Prescribing

Use Outline to Review Charts:

New Patient

Recently Discharged Patient (for Inappropriate Behavior)

High Dose Patient

Do another review focused solely on how you use templates, missing information in patient forms, and EMR and boilerplate revelations. Look for documentation weaknesses and work flow weaknesses, including poorly timed response to patient aberrant behavior.

List of things you do well; List of things that need improvement.

Craft a plan to make improvements and gain outside education and support where concerns or questions.

Proactive Response – An Honest Examination of Medical Record Charting and Review Efforts

- PRIOR RECORDS
- INITIAL EVALUATION, RISK ASSESSMENT, AND DECISION-MAKING
- ONGOING MONITORING AND DECISION-MAKING; PATIENT COUNSELING
- AVOIDANCE OF OVER-RELIANCE ON BOILERPLATE

Proactive Response – How many patients do you have on opioids and for how long?

Opioid Panel

- Percentage referred into the practice for opioid therapy.
- Percentage originated by each prescriber.
- Percentage of patients whose prescribing is primarily handled by NP or PA and related supervisory issues.

Opioid Therapy Duration

- 0-12 mos.
- > 1 yr. to <3 yrs.
- >3 yrs.

Opioid Dose (MEDD) metrics

- NMT 50mg MEDD
- 51-90mg MEDD
- >90mg but <120mg MEDD
- >120mg MEDD

Proactive Response – Evaluating Risk Mitigation and Staying Current – Focus is Understanding and Updating

Risk Domains

- Medication
  - Dose
  - Formulation
  - Combinations
- Medical comorbidities
- Behavioral Risks
  - Substance Use Disorder
  - Psychiatric History
- Abuse/Diversion Potential
  - Questionnaire Scores
  - ED visits
  - Multiple family members receiving treatment with CS

Objective Measures of Risk and Timely Review and Intervention

- PDMP check
- UDT history
- Medication Counts
- Office Visit Frequency

Combination Prescribing and Accountability

- Opioids – LAO + SAO, or SAO + SAO, or LAO + IRO, or SAO + IRO
- Opioids + Benzodiazepines
- Opioids + other CNS depressants
- Behavioral Health medication track record while in chronic opioid therapy

Brainstorm Other Risk Mitigation Areas and Documentation Efforts

Careful evaluation and clear statements of findings, medical decision-making and rationale

Proper Informed Consent Process and Clinical and Behavioral Boundaries for Treatment Plan

(medication – nature and dose; opioid trial period)

Use of Behavioral Health interventions

Follow-through on recommendations for and patient's use of non-opioid and non-drug treatments

Ongoing monitoring tools; dose reductions; medication changes; treatment plan reevaluation

Visit Frequency, Medication Counts and follow-through when patient misses appointments or forgets to bring medication.

Use of Prescription Drug Monitoring Databases and response to multiple provider findings or confusing information.

Use of Drug Testing and TIMELY use of Test Results

Use of referrals for specialty evaluation; Use of consults; Use of peer input.

Exit Strategy (Treatment Failures, Consequences for Non-Compliance)

And if bad things happen, …

1. Get a very good lawyer who speaks "pain." DO NOT represent yourself.

2. Familiarize the lawyer with your practice and your "opioid dossier" of patients, your qualifications, education, and training, your staff's qualifications, education, experience, the risk mitigation strategies you use, and your charting/documentation practices. And many more things.

3. Be prepared to engage a medical expert and/or specialty team.

4. Be prepared to answer questions and admit to your legal counsel where mistakes were made and gaps exist. This will go along way to minimizing the potential of your legal team getting blindsided and it may help you achieve a better result, especially in regulatory actions (Board, DEA Administrative).

5. Blaming the world for problems you created is not a good idea. Many examples in DEA Administrative Case Decisions and Orders.

6. Regulatory and legal actions take time and money.

7. Criminal actions take time, money, and a very experienced team

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Questions?