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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

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Learning Objectives

- Describe how payers now measure and address patient risk
- Discern individualized exposure to adverse regulatory or legal action
- Outline strategies discussed to ensure decrease in documented patient risk

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

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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

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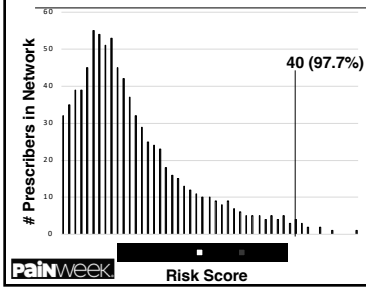
Provider Risk Assessment

John Clarke



Top 3%
Dangerous Opioid Prescribing

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Opioid Panel Size
70% Dr. Clarke's patients are prescribed opioids

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Dr. Clarke's Areas of Concern

- **70%** ▪ Received High Doses of Opioids (≥90mg MEDD)
- **100%** ▪ Received opioids for greater than >90 days
- **34%** ▪ Prescribed Opioids and Benzodiazepines
- **29%** ▪ Received Opioids from Multiple Prescribers

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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"*

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

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Medical and Pharmacy Claims Data

Advantages	Disadvantages
▪Beyond PDMP Reports	▪Do not capture out of network claims
▪Individual ICD codes utilized for	▪Do not capture cash pay encounters
–ER visits	–Medical or pharmacy
–Inpatient admissions	▪Claims data is messy
–Outpatient visits	–Duplicate claims
▪All pharmacy prescription fills	–Reversals
–Not just controlled substances	▪Highly dependent on accurate coding
▪Labs/Imaging codes available	
▪Recognition of relapse/overdose	
–Coordination of care	

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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

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

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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)

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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

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

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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

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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

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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)

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.

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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

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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)

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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

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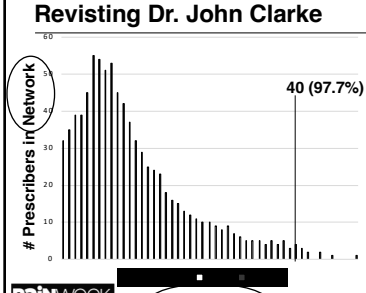
Provider Risk Assessment

Revisting Dr. John Clarke



Top 3%
Dangerous Opioid Prescribing

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Peer Group

Opioid Panel Size

70% Dr. Clarke's patients are prescribed opioids

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Revisting Dr. Clarke's Areas of Concern

- 70% ▪ Received High Doses of Opioids (≥90mg MEDD) → Pain specialist? Inherited patients?
- 100% ▪ Received opioids for greater than >90 days → Suspicious if a Surgeon
- 34% ▪ Prescribed Opioids and Benzodiazepines →Hard to Justify; Worse if co-prescribed
- 29% ▪ Received Opioids from Multiple Prescribers → So What?

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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*

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Strategic Response When Claims Data Becomes Adverse Regulatory or Legal Action

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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.

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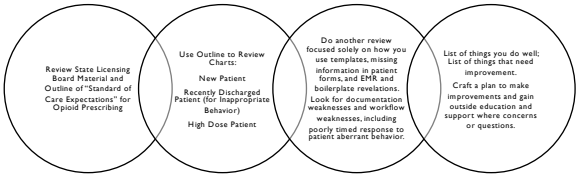
Critical Self Audit Steps



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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

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

Opioid Panel	Opioid Therapy Duration	Opioid Dose (MEDD) metrics
• 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.	• 0-12 mos. • > 1 yr. to <3 yrs. • >3 yrs.	• NMT 50mg MEDD • 51-90mg MEDD • >90mg but <120mg MEDD • >120mg MEDD

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

Risk Domains	Objective Measures of Risk and Timely Review and Intervention	Combination Prescribing and Accountability

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

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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)	

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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?

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