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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1

Title and Affiliation

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2

Disclosure

- Nothing to disclose

3

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

4

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

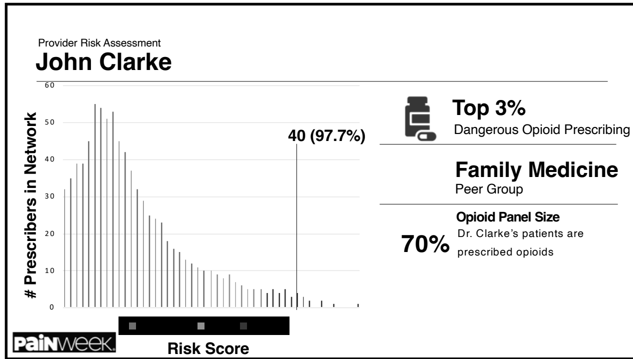
5

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

6



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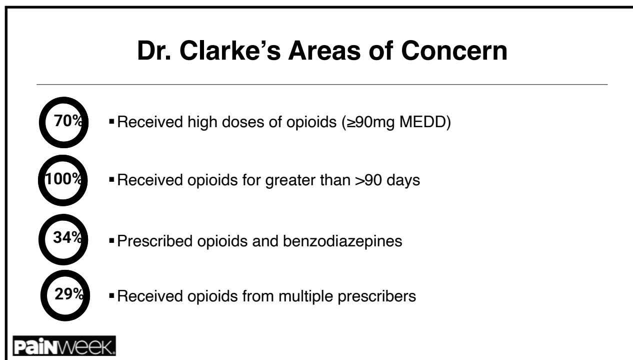


8

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:

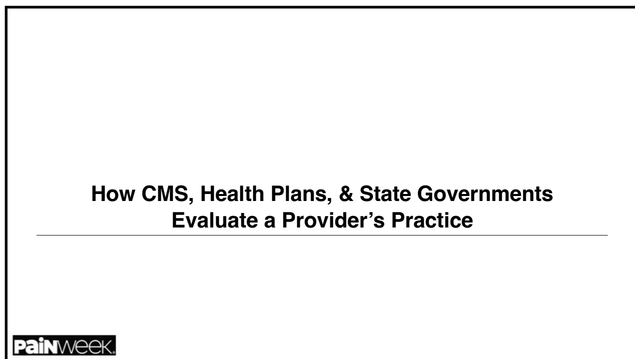
- *"They have no idea what they're talking about!"*
- *"How dare they question my professional judgement!"*

..And finally:

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

PainWeek

9



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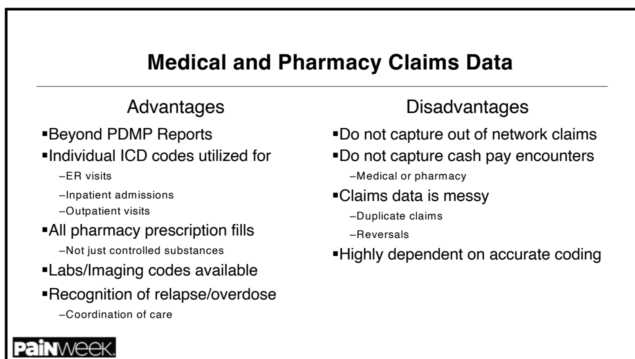

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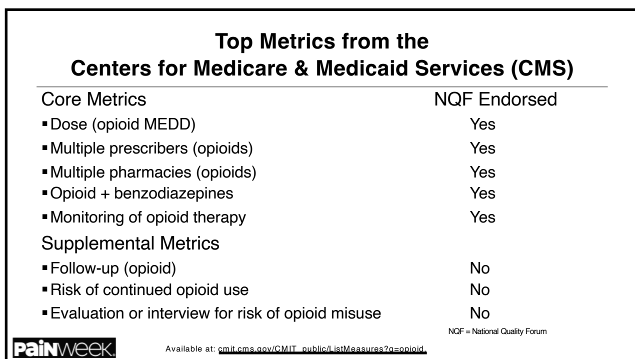


12

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)

13

#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 19.28/1000]

≥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 et al. *JAMA*. 2014;174(5):796-801.
Dunn et al. *Ann Intern Med*. 2010;152(2):85-92.
Gomes et al. *Open Med*. 2011;5(1):E13-E22.
Bohnert et al. *JAMA*. 2011;305(13):1315-1321.
Bohnert et al. *Med Care*. 2016;54:435-441.

14

#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 a 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 et al. *JAMA*. 2014;174(5):796-801.
Dunn et al. *Ann Intern Med*. 2010;152(2):85-92.
Gomes et al. *Open Med*. 2011;5(1):E13-E22.
Bohnert et al. *JAMA*. 2011;305(13):1315-1321.
Bohnert et al. *Med Care*. 2016;54:435-441.

15

#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. *Pain Med.* 2012;13:87-95.
Dilokthornsakul et al. *J Pain.* 2016;17(4):436-443.
Gwira et al. *JAMA.* 2014;174(5):796-801.
Paulozzi et al. *MMWR.* 2015 64(9):1-14.
Hall et al.. *JAMA.* 2008;300(22):2613-2620.

16

#2 Multiple Prescriber Summary

Summary:

- Multiprescriber 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?

17

#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. *Pain Med.* 2012;13:87-95.
Dilokthornsakul et al. *J Pain.* 2016;17(4):436-443.
Gwira et al. *JAMA.* 2014;174(5):796-801.
Paulozzi et al. *MMWR.* 2015 64(9):1-14.
Hall et al.. *JAMA.* 2008;300(22):2613-2620.

18

#3 Multiple Pharmacy Summary

Summary:

- Multipharmacy 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

19

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. *MMWR*. 2015;64(9):1-14.

20

#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 et al. *Pain Med*. 2016;17:85-98.
Gomes et al. *Arch Intern Med*. 2011;171(7):686-691.
Park et al. *BMJ*. 2015;350:h2698.
Fulton-Kehoe et al. *Med Care*. 2015;53(8):679-685.

21

#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 coprescribing 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

22

#5 Opioid Panel Size Evidence

Common Metrics:

- Opioid panel size monitors the percentage of a provider's 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. *Drug Alcohol Depend*. 2016;165:1-8.
Ringwalt et al. *J Primary Prevent*. 2015;36:287-299.
Paulozzi et al. *MMWR*. 2015;64(9):1-14.

23

#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?

24

#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:
  - NOT significantly associated with addiction
    - Average time on opioid therapy 6-8 years
  - 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 et al. *Eur J Pain*. 2010;14(10):1014-1020.
Fishbain et al. *Pain Med*. 2008;9:444-459.
Gomes et al. *Arch Intern Med*. 2011;171(7):686-691.

25

#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

26

#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 et al. *Pain*. 2007;129:355-362.
Zedler et al. *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. *Addiction*. 2010 105:1776-1782.

27

#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:

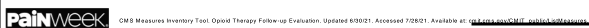
- Beware of mislabeling opioid dependence
  - May lead to appearance of prescribing opioids to large percentage of patients with opioid use disorder

28

#8 Follow-up

CMS Metric: Opioid Therapy Follow-up Evaluation

- Description: All patients 18 and older prescribed opiates for longer than 6 weeks duration who had a follow-up evaluation conducted at least every 3 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: cmit.cms.gov/CMIT_public/ListMeasures.

29

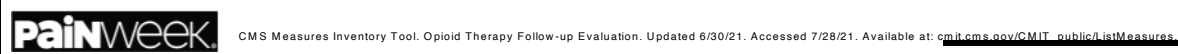
#8 Follow-up

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 6 weeks duration

Pearls for Practice:

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



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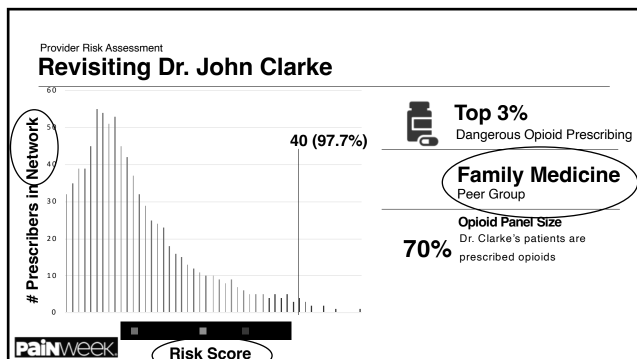

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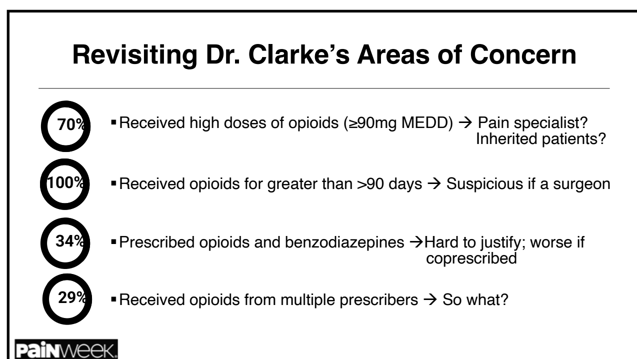

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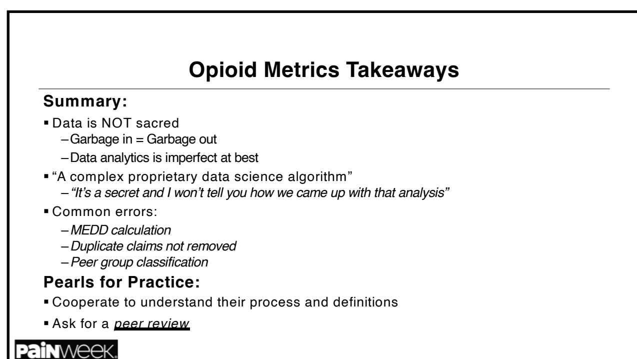


33

Strategic Response When Claims Data Becomes Adverse Regulatory or Legal Action

Provided by Jen Bolen, JD
Legal Side of Pain

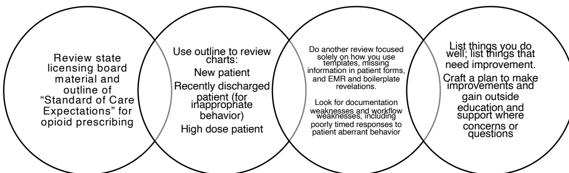
34

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

35

Critical Self Audit Steps



36

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

37

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 a long 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

38

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Questions?

39