MANAGEMENT OF LONG-TERM OPIOID THERAPY

The Role of Urine Drug Screens and Prescription Drug Monitoring Programs

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Prescription Opioids and the Opioid Crisis

- As many as **one in four patients** receiving long-term opioid therapy in a primary care setting struggles with opioid use disorder.
- In 2022, nearly **9 million Americans** reported misusing prescription opioids in the past year.
- Risk of opioid overdose and death **increases** at higher dosages and when taken for longer periods of time or more often than prescribed.
- While prescription opioids are not a primary driver of drug overdose in the United States, **they do currently contribute** to opioid-related deaths.
- In 2022, the Opioid Dispensing Rate in Kentucky was 61.6 prescriptions per 100 persons, **higher** than the national rate of 39.5

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Urine Drug Screens

- Why do we utilize Urine Drug Screens (UDS) in the course of prescribing/dispensing long-term controlled substances?

1. **Kentucky Regulatory Requirement**
    - 201 KAR 9:260
        - This is the Kentucky administrative regulation that establishes professional standards for prescribing and dispensing of controlled substances.
2. **Clinical Tool**
    - Part of a comprehensive pain management treatment plan
    - Can assist in facilitating safe and appropriate long-term opioid therapy.

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1. Kentucky Regulatory Requirement

- What does the regulation **state**?
  - 201 KAR 9:260 language:
  - SECTION 4 - PROFESSIONAL STANDARDS FOR **COMMENCING LONG TERM USE** OF PRESCRIBING OR DISPENSING OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN AND RELATED SYMPTOMS ASSOCIATED WITH A PRIMARY MEDICAL COMPLAINT:
    - Before a licensee commences to prescribe, dispense or administer any controlled substance to a patient sixteen (16) years or older for pain or other symptoms associated with the same primary medical complaint for a total period of longer than three (3) months
    - **Shall obtain and document a baseline drug screen**

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1. Kentucky Regulatory Requirement

- What does the regulation **state**?
  - 201 KAR 9:260 language:
  - SECTION 5 – PROFESSIONAL STANDARDS FOR **CONTINUING LONG-TERM** PRESCRIBING OR DISPENSING OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN AND RELATED SYMPTOMS ASSOCIATED WITH A PRIMARY MEDICAL COMPLAINT:
    - During the course of long-term prescribing, dispensing, or administering of a controlled substance, the licensee **shall utilize drug screens, appropriate to the controlled substance and the patient's condition, in a random and unannounced manner at appropriate times.**

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In Summary

- Per 201 KAR 9:260, during the course of long-term prescribing, dispensing, or administering of controlled substances, drug screens shall be utilized:

    1. Before initiating treatment, as a baseline screen

    2. During continuation of treatment, “appropriate to the controlled substance and the patient’s condition, in a random and unannounced manner at appropriate times.”

- **What constitutes “in a random and unannounced manner at appropriate times”?**

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Kentucky Board of Medical Licensure Guidance for UDS:

- Recommendations are based on risk stratification
- Suggested Intervals for Urine Drug Screens:
  - At least once a year if the patient is considered “low risk” based on upon the screening done by the physician and other factors.
  - At least twice a year if the patient is considered “moderate risk” based upon the screening done by the physician and other factors.
  - At least three to four times a year if considered “high risk” based on the screening done by the physician and other factors.
  - At each office visit if the patient has exhibited aberrant behavior such as multiple lost prescriptions, multiple requests for early refills, opioids from multiple providers showing up on KASPER, unauthorized dose escalation, and apparent intoxication.

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Risk Stratification for Patients on Long-Term Opioid Therapy

- Assesses risk of adverse outcomes of opioid therapy
- Best performed using professionally developed and clinically recommended screening tools
- Assigns patients to a category of risk
- Factors include:
  - Medical comorbidities: Sleep apnea, COPD, age, Substance Use Disorder
  - Current dose of Opioids
  - Behavioral comorbidities: Substance misuse, history of overdose, depression, anxiety
  - Aberrant behavior
  - Concurrent medications

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Risk Stratification for Patients on Long-Term Opioid Therapy *(cont.)*

- Examples of Screening Tools:
  - ORT-OUD: Evaluates risk of developing Opioid Use Disorder
  - ORT: Evaluates risk of opioid misuse in patients using opioid therapy
  - DAST: Assesses for substance use, not including alcohol or tobacco in the past 12 months.
- Per CDC: If these tools are used, they should be supplemented with other assessments, such as discussions with patients, family, and caregivers; clinical records; PDMP data (see Recommendation 9); and toxicology screening data (see Recommendation 10). Clinicians should always use caution when considering or prescribing opioids and should not overestimate the ability of available risk stratification tools to rule out risks of long-term opioid therapy.

(CDC 2022 Guideline for Prescribing Opioids for Pain; see Recommendation 8)

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Opioid Risk Tool

This tool should be administered to patients upon an initial visit prior to beginning opioid therapy for pain management. A score of 3 or lower indicates low risk for future opioid abuse, a score of 4 to 7 indicates moderate risk for opioid abuse, and a score of 8 or higher indicates a high risk for opioid abuse.

Mark each box that applies	Female	Male
Family history of substance abuse		
Alcohol	1	3
Illegal drugs	2	3
Rx drugs	4	4
Personal history of substance abuse		
Alcohol	3	3
Illegal drugs	4	4
Rx drugs	5	5
Age between 16—45 years	1	1
History of preadolescent sexual abuse	3	0
Psychological disease		
ADD, OCD, bipolar, schizophrenia	2	2
Depression	1	1
Scoring totals		

Questionnaire developed by Lynn R. Webster, MD to assess risk of opioid addiction.

Webster LR, Webster R. Predicting aberrant behaviors in Opioid-treated patients: preliminary validation of the Opioid risk too. Pain Med. 2005; 6 (6) : 432

Urine Drug Screens

Drug Use Questions (DAST-10)

Using drugs can affect your health and some medications you may take. Please help us provide you with the best medical care by answering the questions below.

Drugs include marijuana, solvents like paint thinners, tranquilizers like Valium, barbiturates, cocaine, stimulants like speed, hallucinogens such as LSD, or narcotics like heroin. Drug use also includes using prescription or over-the-counter medications more than directed.

Scoring

Each response from the DAST has a score of either 0 or 1. All "Yes" responses get a score of 1, all "No" responses get a score of 0. After a patient has completed the DAST, add up the number of "Yes" responses for the patient's score. Below are the scoring guidelines for the DAST.

In the past 12 months...	1	0
1. Have you used drugs other than those required for medical reasons?	○ Yes	○ No
2. Do you abuse more than one drug at a time?	○ Yes	○ No
3. Are you unable to stop using drugs when you want to?	○ Yes	○ No
4. Have you ever had blackouts or flashbacks as a result of drug use?	○ Yes	○ No
5. Do you ever feel bad or guilty about your drug use?	○ Yes	○ No
6. Does your spouse (or parents) ever complain about your involvement with drugs?	○ Yes	○ No
7. Have you neglected your family because of your use of drugs?	○ Yes	○ No
8. Have you engaged in illegal activities in order to obtain drugs?	○ Yes	○ No
9. Have you ever experienced withdrawal symptoms (felt sick) when you stopped taking drugs?	○ Yes	○ No
10. Have you had medical problems as a result of your drug use (such as: memory loss, hepatitis, convulsions, or bleeding)?	○ Yes	○ No

Guidelines for Interpretation for DAST-10

Score	Degree of Problems Related to Drug Abuse	Suggested Action
0	No problems reported	Encouragement and education
1-2	Low level	Brief intervention
3-5	Moderate level	Brief intervention plus brief therapy
6-10	Substantial level	Brief intervention plus referral to chemical dependency treatment

Skinner HA. The Drug Abuse Screening Test. *Addictive Behavior*. 1982, 7(4): 363-371.
Yudko E, Lozhkina O, Fouts A. A comprehensive review of the psychometric properties of the Drug Abuse Screening Test. *J Subst Abuse Treatment*. 2007, 32:189-198.

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2. Clinical Tool for Management of Long-Term Opioid Therapy

- Monitors adherence to prescribed patient treatment plan
- Identify potential misuse, use of illicit substances, diversion
- Comprehensive pain management treatment plans often include urine drug screens, patient agreement or contract, risk stratification, pill counts, and utilization of PDMPs.
- UDS often preferred due to ease of collection
- Intended to improve patient safety
- Not without limitations

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2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain

- Recommendation #10
  - When prescribing opioids for subacute or chronic pain, clinicians should consider the benefits and risks of toxicology testing to assess for prescribed medications as well as other prescribed and nonprescribed controlled substances.
    - **Before starting opioids and periodically (at least annually) during opioid therapy**, clinicians should consider the benefits and risks of toxicology testing to assess for prescribed opioids and other prescription and nonprescription controlled substances that increase risk for overdose when combined with opioids, including nonprescribed and illicit opioids and benzodiazepines.

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2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain

- Recommendation #10
  - Clinicians should consider toxicology screening results as potentially useful data, **in the context of other clinical information**, for all patients and consider toxicology screening whenever its potential limitations can be addressed.

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PDMP/KASPER Review

- A prescription drug monitoring program (PDMP) is a state-operated electronic database that tracks prescriptions for controlled substances.
- In Kentucky, the PDMP is known as Kentucky All Schedule Prescription Electronic Reporting (KASPER).
- KASPER is a real-time web database that provides a tool to address the misuse, abuse and diversion of controlled substances.
- Kentucky was one of the first states to implement interstate data sharing. Kentucky shares data with 30 other states.

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KASPER CONTRIBUTES: HARM REDUCTION

- First became operational in 1999
- KASPER functions as harm reduction because it monitors factors that help identify a patient who is at high risk for overdose or other adverse consequences of opioid use.
- From 2018-2022 there was an increase of 197.3% in PDMP use
- An increase in PDMP queries from 450 million (2018) to 1.3 billion (2022)
- **In one decade, Physicians and other health care professionals have reduced opioid prescribing by approximately 50% in all 50 states** (2012-2022)

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Prescription Opioids

- Prescription opioids are currently *not a primary driver of drug-related overdoses* in America, but do contribute along with other factors. 3 of 4 persons who have used heroin report that they first used a prescription opioid.
- The increasingly **dangerous illicit drug supply** which is often contaminated with fentanyl, fentanyl analogs, stimulants and other toxic substances is the **primary cause of drug-related overdoses and death.**

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KASPER

- **HIPAA and KASPER:**

1. DISPENSERS ARE REQUIRED TO REPORT CERTAIN INFORMATION TO PDMP, EVEN THOUGH IT IS CONSIDERED HIPAA PROTECTED INFORMATION.
2. KASPER REPORTS CONTAIN HIPAA PROTECTED INFORMATION.
3. THEREFORE, THE **REPORTS SHOULD BE KEPT SECURE** AND **USERS MUST PROTECT AND NOT SHARE ANY OF THEIR LOGIN CREDENTIALS.**

Who can run a KASPER query:

1. Licensing boards when investigating a licensee
2. Practitioners and Pharmacists to review a current patient's CS Rx Hx
3. Law Enforcement Officers, Commonwealth/County attorneys as part of a bonafide drug investigation or prosecution on an active case
4. Judges, probation or parole officer, medical examiners, Medicaid, OIG

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PURPOSE OF THE PDMP

- Helps inform clinical decision-making to improve patient care and safety
- To review patient's history of controlled substance prescriptions for the prior 12 months
- Identify patients at higher risk for overdose due to overlapping prescriptions, high dosages (MME) or co-prescribing of opioids with benzodiazepines
- Alert prescriber to potential aberrant behaviors such as improper use or illegal diversion
- Determine if a patient is taking prescription as directed
- Identify when a patient is taking an opioid prescription with a benzodiazepine (see *CDC recommendation #9 in Guidelines)*

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PURPOSE OF THE PDMP *(continued)*

- Review MME/day (ACME or Active Cumulative Morphine Equivalent)
- KASPER cautions that ACME>90 may warrant clinical vigilance and a Rx for Naloxone. ACME>90 will trigger an alert in KASPER report.
- Confirm that patient is receiving controlled substance prescriptions from *only one source* (alerts provider to multiple provider episodes)
- Confirm that patient is *utilizing the designated pharmacy* as agreed (alerts provider to multiple pharmacy episodes)
- To help clinician when patient medication history is unavailable
- Provide information to clinician when patient is transitioning care

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KY REGULATIONS AND STATUTES

- 201 KAR 9:260-sets professional standards for prescribing and dispensing CS (controlled substances) and emphasizes the use of KASPER.
- House Bill 1- outlines the obligations of healthcare providers in utilizing KASPER to improve monitoring and dispensing to improve patient safety and promote integrated care.
- KRS 218A.205 –specifies operational requirements for electronic prescriptions for CS, including KASPER use for real-time reporting by pharmacies and prescribers.
- For official information on Ky legislation, **visit Kentucky Legislative Research Commission**

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KASPER ELECTRONIC PRESCRIPTIONS

- In January 2021, Kentucky mandated that all controlled substance prescriptions must be transmitted electronically.
- Certain temporary exceptions apply such as technological/electrical failure, natural disasters.

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CDC RECOMMENDATIONS Re: PDMP

- The CDC recommends checking the PDMP:
- **When initiating opioid therapy** for acute, subacute or chronic pain (*recommendation #9 in the 2022 Clinical Practice Guidelines for Prescribing Opioids for Pain*).
- **Every 3 months** or more frequently when continuing opioid therapy.
- **Ideally, a PDMP should be reviewed before every opioid prescription.**

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Initial Prescription:
KBML Summary of 201 KAR 9:260

SECTION 3 OF SUMMARY 201 KAR 9:260 (on KBML website)

UPDATED 11/15/2017

Prior to the initial prescribing or dispensing of any controlled substance for pain or other symptoms associated with the primary complaint, the first physician prescribing or dispensing shall:

Obtain and review a KASPER report for the patient for previous 12 months

*only prescribe Schedule II controlled substances in accordance with the standards established in Section 9 of this regulation

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KBML Summary 201 KAR 9:260

- **Kentucky regulation 201 KAR 9:260 Section 9 (Additional Standards for prescribing or dispensing Schedule II controlled substances) states that:**
- If the course of treatment *goes beyond 3 months*, the physician shall:

1. **Query KASPER no less than once every 3 months** for all available data on the patient for the preceding 12-month period
2. Review KASPER data before issuing a new prescription or refills for the patient

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KASPER UNAVAILBLE OR INDICATES MANUAL PROCESS,NO REPORT GENERATED

- Sometimes, KASPER is unavailable. If that is the case, it is recommended to record the date, time and circumstances that prevented querying the report and document in your chart note.
- If KASPER is “down”, record the date and time and document in your chart note.
- If KASPER indicates “manual process” and a report is not generated using manual process, it is recommended to document the request number in the chart.

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Exceptions to Standards of 201 KAR 9:260 Section 1

- Patient's hospice and end of life treatment
- Patient admitted to hospital inpatient, outpatient or observation
- Cancer patients or pain related to cancer treatment
- Patients in long-term care facilities
- In a single dose prescribed or dispensed to relieve anxiety, pain or discomfort for a diagnostic test or procedure (e.g. patient who is claustrophobic scheduled for an MRI)

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Exceptions to KAR 9:260 *(continued)*

- Any scheduled V controlled substance;
- That is a Schedule II as part of a narcotic treatment program licensed by the Cabinet for Health and Family Services
- That is a Schedule II immediately prior to, during, or within 14 days following a major surgery, being any operative or invasive procedure or a delivery, or significant trauma, being an acute blunt, blast or penetrating bodily injury that has risk of death or physical disability or impairment, and the usage does not extend beyond 14 days

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House Bill 1 Regarding: KASPER and THE MEDICAL RECORD

- KASPER REPORTS CAN BE PLACED IN THE PATIENT'S MEDICAL RECORD, AND ACQUIRES THE STATUS OF AN ORDINARY COMPONENT OF THAT MEDICAL RECORD.
- "Expanded Use of KASPER Info - Practitioner may share KASPER report with patient or patient's agent
- Practitioner may place KASPER report in patient's medical record, subject to disclosure on same terms as ordinary medical record"

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House Bill 1 Regarding: KASPER and THE MEDICAL RECORD

- Always use your professional judgement when caring for your patients.
- Follow CDC, Kentucky regulations and KBML guidance when prescribing CS, particularly opioids.
- Utilize KASPER (PDMP) to its full potential. Check out useful functions including Findhelpnow, daily med graph, CourtNet drug conviction data, and remember to check your Reverse KASPER/Prescriber Report.

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Helpful Resources

- Considerations on urine drug screens : https://kbm.ky.gov/hb1/Pages/Considerations-For-Urine-Drug-Screening.aspx
- Fact Sheet: Kentucky's oversight of opioid prescribing and monitoring of opioid use:

  https://www.ojp.gov/pdffiles1/ondcp/pdmp.pdf
- 2022 CDC Clinical Practice Guideline at a Glance | Overdose Prevention | CDC https://www.cdc.gov/overdose-prevention/hcp/clinicalguidance
- Kentucky Board of Medical Licensure Summary of 201KAR9:260 https://kbml.ky.gov/hb1/Documents/Summary of 201KAR9-260.pdf
- KBML Summary of HB1 at www.kbml.ky.gov
- Guidance on Risk Stratification https://familymedicine.uw.edu/improvingopioidcare/wp-content/uploads/sites/9/2019/09/Risk-Stratification-and-Opioid-Prescribing-w-attribution.pdf
- Screening and Assessment Tools Chart | National Institute on Drug Abuse (NIDA) (nih.gov)

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Additional References

- Resources SAWashington State Interagency Guideline on Opioid Dosing for Chronic Non-Cancer Pain Urine Drug Testing Guidance.pdf (ky.gov)
- American Family Physician (aafp.org)
- Title 201 Chapter 9 Regulation 260 • Kentucky Administrative Regulations • Legislative Research Commission
- Urine Drug Screening: Practical Guide for Clinicians (mayoclinicproceedings.org)
- CDC-DUIP-UrineDrugTesting_FactSheet-508.pdf (uw.edu)
- Opioid Dispensing Rate Maps | Overdose Prevention | CDC
- KASPER Website includes the KASPER TRAINING CENTER: https://chfs.ky.gov/agencies/os/oig/dai/deppb/Pages/kasper.aspx

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