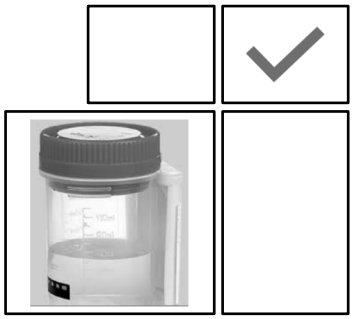
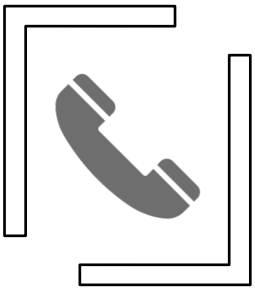


Get Your Specimens in Order:
The Importance of Individualized Test Orders and Timely Test Utilization

Prepared and presented by
Jennifer Bolen, JD



Disclosures for Jennifer Bolen, JD

- Consultant - Generation Partners
- Consultant - Abbott/Alere Toxicology
- Consultant - MTL Solutions, LLC
- Consultant - MyMOMD
- Consultant -Paradigm Labs
- Consultant - Pernix Therapeutics
- Consultant - ReCept Pharmacy
- Consultant - Westox Labs

10/9/18

Learning Objectives

Identify	Describe	Design	Create
• **1A.** Identify the core elements of medical necessity for drug testing using current payor policy, and • **1B.** Consider these policies in light of the questions providers want answered through drug testing.	• **2.** Describe the key elements of "individualized" testing for patients by comparing clinical standards with payor policy.	• **3.** Review the use of a protocol and template for capturing provider rationale for drug test orders and action steps to facilitate improved utilization of drug test reports in the medical practice.	• **4.** Explain how to create a due diligence checklist to ensure proper considerations for drug test menus and test methods/test partners.

Background: Moving Pieces

Payor Response to Fraud

Changes to Medical Necessity Policies

Ongoing audits of drug testing utilization

Ongoing investigations pertaining to inappropriate business relationships between physicians and independent clinical laboratories and related business entities

Enforcement – Who's Looking at Drug Testing and Prescribing Decisions? Why?

1. Licensing Boards and DEA (for Prescribing Issues)
2. Commercial and Government Payors (for Fraud and Abuse)
3. Criminal Prosecutions (for Drug Dealing and Fraud)

Drug Testing Standards – Whose Standards Govern Your Decision-Making?

Clinical Standards	Payor Standards	Licensing Standards
• Peer-reviewed Literature • Professional Society Guidance Documents and Position Papers	• Medical Policies • Billing and Reimbursement Standards	• Licensing Board Rules • Licensing Board Guidelines/Position Statements

Quick Refresher – Pressure Points for Getting Drug Testing Right

Test platform and billing framework; Cost-Effective

Two Broad Categories of Drug Testing

Presumptive	Definitive
• "Screen" • Results are generally + or - • **Typically EIA/IA** (limited test menu, less specificity/sensitivity) **unless sophisticated lab**, then LC-MS/MS, LDTD, or other non-EIA/IA test method	• "Confirm" • Results are generally quantitative (value) • Typically LC-MS/MS or similar

AMA-CPT Descriptors for Presumptive Testing (2018)

CPT/HCPCS Code	Description
Presumptive Drug Testing	
80305	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; capable of being read by direct optical observation only (e.g., utilizing immunoassay [e.g., dipsticks, cups, cards, or cartridges]), includes sample validation when performed, per date of service
80306	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; read by instrument assisted direct optical observation (e.g., utilizing immunoassay [e.g., dipsticks, cups, cards, or cartridges]), includes sample validation when performed, per date of service
80307	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; by instrument chemistry analyzers (e.g., utilizing immunoassay [e.g., EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (e.g., GC, HPLC), and mass spectrometry either with or without chromatography, (e.g., DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service

AMA-CPT Descriptors for Definitive Testing (2018)

CPT/HCPCS Code	Description
Definitive Drug Testing	
G0659	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem), excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase), performed without method or drug-specific calibration, without matrix-matched quality control material, or without use of stable isotope or other universally recognized internal standard(s) for each drug, drug metabolite or drug class per specimen; qualitative or quantitative, all sources, includes specimen validity testing, per day, any number of drug classes

CPT® is a registered trademark of the American Medical Association

2018 Reimbursement for Drug Testing

Test Category	Type of Test	CPT/HCPCS Code	Medicare's CLFS 2018 Reimbursement Fee
Presumptive	Cassette, Cup, Dipstick	80305 or 80305QW	$13.46
Presumptive	Test w/reader	80306	$17.96
Presumptive	Chemistry Analyzer (EIA)	80307	$71.83
Presumptive	DESI, DART, LC-MS/MS, LDTD, MALDI, TOF	80307	$71.83
Definitive POL	Definitive GC or LC with Mass Spectrometry in the Physician Office Lab	G0659 (# of classes irrelevant)	$71.83
Definitive	GC or LC with Mass Spectrometry or similar NON-EIA/IA test subject to additional lab standard parameters	G0480 (1 to 7 drug classes)	$114.43
		G0481 (8 to 14 drug classes)	$156.59
		G0482 (15 to 21 drug classes)	$198.74
		G0483 (22 or more drug classes)	$246.92

Pain-Related Definitive Drug Class Descriptors (2018)

Class #	Class Descriptor	Class #	Class Descriptor	Class #	Class Descriptor
1	Alcohol	12	Buprenorphine	23	Opioids and Opiate Analogs
2	Alcohol Biomarkers	13	Cannabinoids, Natural	24	Oxycodone
3	Alkaloids	14	Cannabinoids, Synthetic	25	PCP
4	Amphetamines	15	Cocaine	26	Pregabalin
5	Anti-depressants (serotonergic)	16	Ecstasy (MDMA)	27	Propoxyphene
6	Anti-depressants (tricyclic)	17	Fentanyl	28	Sedative Hypnotics
7	Anti-depressants (other)	18	Gabapentin	29	Skeletal Muscle Relaxants
8	Anti-epileptics	19	Heroin	30	Stimulants, Synthetic
9	Anti-psychotics	20	Ketamine	31	Tapentadol
10	Barbiturates	21	Methadone	32	Tramadol
11	Benzodiazepines	22	Opiates	33	Other unspecified

Medical Necessity and the Reasons Providers Drug Test

Objectives 1A and 1B

IDENTIFY

Medical Necessity – What is it?

- Payor definitions of medical necessity include reference to "prevailing standards of care" or "generally accepted standards of medical practice."
  - It is the responsibility of every ordering provider to ensure each drug test ordered is medically necessary for the treatment of the patient.

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Cigna HealthCare Definition of Medical Necessity for other Healthcare Providers

Except where state law or regulation requires a different definition, "Medically Necessary" or "Medical Necessity" shall mean health care services that a Healthcare Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

a. in accordance with the generally accepted standards of medical practice;
b. clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease; and
c. not primarily for the convenience of the patient or Healthcare Provider, a Physician or any other Healthcare Provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "generally accepted standards of medical practice" means:

- standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community,
- Physician and Healthcare Provider Specialty Society recommendations,
- the views of Physicians and Healthcare Providers practicing in relevant clinical areas and
- any other relevant factors.

Preventive care may be Medically Necessary but coverage for Medically Necessary preventive care is governed by terms of the applicable Plan Documents.

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Medicare and Test Utilization

Clinical laboratory services must be ordered and used promptly by the physician who is treating the beneficiary as described in 42 C.F.R. § 410.32(a).

Resource:
MPBM, Ch. 15, § 80.1.

To Prevent Denials

The following conditions must be met:

- Urine drug screenings must be ordered by the physician who is treating the beneficiary, that is, the physician and other eligible professionals who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary.
- All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered for the treatment of the individual patient. Criteria to establish medical necessity for drug testing must be based on patient-specific elements identified during the clinical assessment and documented by the clinician in the patient's medical record. Tests used for routine screening of patients without regard to their individual need are not usually covered by the Medicare Program, and therefore are not reimbursed.
- The physician or other eligible professionals who ordered the test must maintain documentation of medical necessity in the beneficiary's medical record.
- Entities submitting a claim must maintain documentation received from the ordering physician or non-physician practitioner. (See 42 Code of Federal Regulations 410.32.)

Medicare and Medical Necessity
(Medicare Learning Network Item - ICN 909412 September 2016)

A look at how some laboratories characterize testing:
Their menu on your test order form (Looks like Tier 2 – G0481)

STIMULANTS (1)	MUSCLE RELAXANTS (2)	Opiates/Synthetics (3)	Opioids (4)
Amphetamines, Methylphenidate, Ritlanic Acid, Phentermine	Carisoprodol, Gabapentin, Ketamine, Norketamine, Meprobamate, Pregabalin, Zolpidem	Codeine, Morphine, Hydrocodone, Norhydrocodone, Hydromorphone, Oxycodone, Noroxycodone, Oxymorphone, Buprenorphine, Meperidine	Norbuprenorphine, Fentanyl, Nor Fentanyl, Methadone, EDDP, Tapentadol, Tramadol, O-desmethyltramadol, Propoxyphene
AMPHETAMINES (5)	BARBITURATES (6)	ILLICITS/OTHERS (7)	TOBACCO (8)
Methamphetamine	Butalbital, Phenobarbital, Pentobarbital, Amobarbital, Secobarbital	6-MAM, Benzoylecognine, MDA, MDMA, PCP, THC-COOH	Cotinine
Benzodiazepines (9)		TRICYCLIC ANTIDEPRESSANTS (10)	
7-aminoclonazepam, Alprazolam, a-OH-Alprazolam, Diazepam, Nordiazepam, Oxazepam, Temazepam, Lorazepam, a-OH-Midazolam		Amitriptyline, Nortriptyline	

What their test menu translates to in $$$ (Tier 4 – G0483)

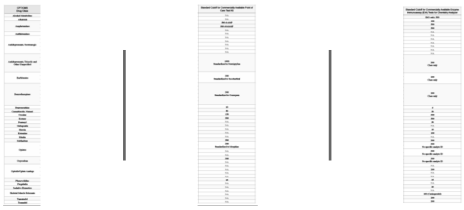
Alkaloids (1)	Amphetamines (2)	Antidepressants (TCA) (3)	Barbiturates (4)	Benzodiazepines (5)
Buprenorphine (6)	Cannabinoids, Natural (7)	Cocaine (8)	Ecstasy (9)	Fentanyls (10)
Gabapentin (11)	Heroin (12)	Ketamine (13)	Methylphenidate (14)	Opiates (15)
Oxycodone (16)	Opioids and Opiate Analogs (17)	PCP (18)	Pregabalin (19)	Skeletal Muscle Relaxants (20)
Methadone (21) EDDP	Sedative Hypnotics (22) Zolpidem	Tapentadol (23)	Tramadol (24) O-desmethyltramadol	

Presumptive Method	Definitive Method	Cost Category	Challenges
EIA by Independent Lab	LC-MS/MS by Independent Lab	Expensive, depending on scope of "reflex and add testing" rules	Getting sufficient information prior to Rx
POCT Cup or Cassette	LC-MS/MS	Expensive, depending on how Definitive Testing Ordered	Getting timely LC-MS/MS results Using Results in Timely Fashion
POCT Cup and EIA Analyzer by POL	LC-MS/MS by Independent Lab	Expensive	Skipped billing cup to bill for analyzer, but used cup prior to issuing Rx – Payor may see as Fraud/Abuse Results may not be timely for all or part of patient population
POCT Cup and EIA Analyzer by POL	LC-MS/MS by POL	Expensive	POL may repeat testing (1) to capture income regardless of patient drug use history, and (2) because of "lab in a box" science challenges.
POCT Cup	None	Inexpensive	Insufficient information
EIA Analyzer	None	Relatively Inexpensive	Insufficient information
LC-MS/MS or LDTD "Screen"	None or Tier 1	Cost-effective	Sufficient Information if Test Menus Properly Established
None	LC-MS/MS	Can be expensive depending on how priced, but may also be cost effective when bundled	Turn around time may be an issue, depending on lab Payors may not accept Definitive test code without Presumptive test and outcomes

Cost of Testing: Realities

UDT - Additional Medical Necessity Issues

Test Menu
Test Frequency
Test Utilization



Test Menu Issues –

What questions do you need to be asking to individualize testing?

Does your testing platform answer those questions? If not, where do you adjust to meet medical necessity?

Drug Class* (Only a few drug classes shown for illustration purposes)	POCT	EIA Analyzer	LC-MS or LC-MS/MS
Alcohol	Yes	Yes	See next class
Alcohol metabolites	No	EtG only	EtG and EtS
Amphetamines	Class	Class	Amphetamine, Methamphetamine, D & L Isomer, Phentermine
Barbiturates	Class	Class	Specific analytes (several)
Benzodiazepines	Class	Class	Specific analytes (many)
Buprenorphine	Yes	Yes	Yes, with lower cutoff level
Cocaine	Yes	Yes	Yes, with lower cutoff level
Fentanyl	No	Yes	Yes, with lower cutoff level and parent and metabolite for fentanyl, and other fentanyls, including Carfentanil
Gabapentin, Pregabalin	No	No	Yes
Heroin	No	Yes	Yes, with lower cutoff level and ability to measure codeine, morphine
Opiates	Class	Class (codeine, morphine)	Yes, with lower cutoff levels and ability to detect and measure codeine, morphine, their metabolites
	Class	Hydrocodone	Yes, with lower cutoff levels and ability to distinguish hydrocodone and its metabolites, from hydromorphone and its metabolites.
Oxycodone	Class	Class	Yes, with lower cutoff level and ability to distinguish oxycodone and its metabolites from oxymorphone and its metabolites.
Opioids and Opiate Analogs	No	Some	Dextromethorphan, Dextrorphan, Meperidine, Normeperidine, Naloxone, Naltrexone, Levorphanol
Tramadol	No	Yes	Yes, with lower cutoff level and ability to specifically identify metabolite

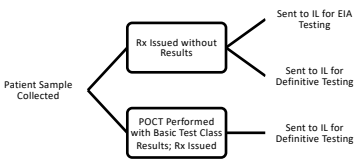
Payor Drug Testing Frequency Limitations

(hint: medical necessity does not mean it's ok to test to the policy frequency limit)

Payor -->	AETNA	ANTHEM BC of CA	CIGNA	HUMANA	UNITED
Effective Date	Summer 2018	6/28/18	2/15/18	7/1/19	7/11/18
Presumptive Test Frequency Limitation	NMT 8/year	NMT 24/year	NMT 32/year and NMT 1 per DOS	NMT 12/year	NMT 18/year and NMT 1 per DOS
Definitive Test Frequency Limitation	NMT 8/year	Specific to medical necessity	NMT 16 DOS/Year and NMT 8 classes per DOS	All definitive testing must be justified in writing and by presumptive test results.	NMT 18 annually and NMT 1 per DOS
Definitive CLASS/Tier Level Limitation	G0482 and G0483 require medical records submission with the claim	Must justify each component of a panel or profile.	NMT 8 units per DOS or 128 total class units/year G0482 and G0483 Considered NOT medically necessary.	NMT 7 classes (G0480); Non-Covered: G0481, G0482, G0483	May be in other new policies undergoing updates right now

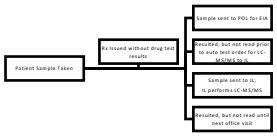
Utilization of Results and Timing Challenges - Example #1

Physician Sends Out to IL or Performs POCT then Sends Out for Definitive Testing

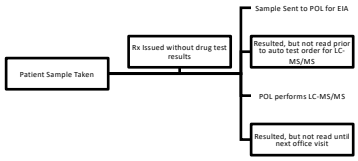


Utilization of Results and Timing Challenges - Example #2

Physician Office Lab Performs Presumptive EIA via Analyzer But Sends Out Definitive



Utilization of Results and Timing Challenges - Example #3
Physician Office Lab Performs Both Presumptive and Definitive Test



Medical Necessity Checklist

- Review Carrier Policies
- CMS Documentation Guidelines
- If Physician-Office Laboratory, make sure your laboratory codes are included on your in-network contracts.
- If using an Independent Clinical Laboratory, make sure proper disclosures to the patient regarding the laboratory's status as in-network or out-of-network.
- Review Professional Licensing Board Guidelines and Rules Regarding Opioid Prescribing

Individualized Testing

Objective 2
DESCRIBE

The balancing act:
On Being the "Reasonably Prudent" Practitioner

- ONE PART SCIENCE

Heavy on the Documentation

The formula for Good Pain Medicine and Individualization of Test Orders

- ONE PART RELATIONSHIP
- DASH COMMON SENSE

Individualized Testing:
Questions Providers Need Answered

NEW PATIENT

Rx Opioids

- Are you using the opioids you reported to me as a new patient? Are you using other opioids that you did not disclose?

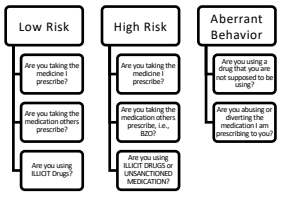
Rx Relevant Other

- Are you using any other relevant drug classes – disclosed or not?

Common Illicit and Commonly Abused (in community)

- Are you using any common illegal or unsanctioned prescribed drugs that are commonly abused?

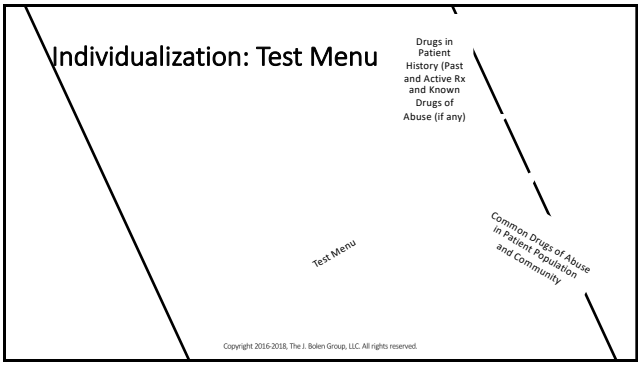
ESTABLISHED PATIENT



Capturing Provider Rationale

Objective 3
DESIGN

Individualization: Test Menu



I need to drug test Davy Jones because . . .

Initial Evaluation and Determining Risk Level	Ongoing Monitoring and Risk Level	Suspected Aberrant, Drug-Related Behavior
New patient – Is testing before Rx Opioids "Reasonably Prudent"?	Required licensing board monitoring of patient behavior and risk potentials via UDT	Anonymous call reporting patient might be diverting medication
New patient – Verify Report of Rx Drugs (PDMP) and Test when Treatment Plan Involves Opioids; Control Drug Supply	Periodic evaluation of patient's compliance with Rx treatment plan and elimination of risks associated with use of illicit drugs or unsanctioned prescribed medication	Patient spouse insisting that patient need more medication; wants increased dose despite 9/10 pain report and end of opioid trial period

Audience Input

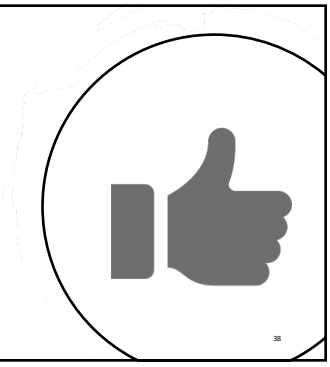
Individualization: What does it look like?

Example in Chronic Pain

Patient Risk Profile Level	Test Menus (Presumptive/Definitive)	Test Frequency	Test Utilization
New Patient	Full Presumptive, Definitive Testing of Positives and Unexpected Negatives (Rx Medication Match if applicable) Add Practice Profile Drug Classes	1x full then stratify into risk profiles by next visit	Use results (at least presumptive test results) BEFORE prescribing controlled medication or CONTROL Drug Supply
Low Risk	Low Risk Test Profile (Rx Medication Match) Definitive Testing of Positives and Unexpected Negatives Generally, Definitive Drug Class Tier 1	At least 1x every 6 months	Use results to determine when another patient encounter and treatment plan adjustment is necessary. Unless all testing performed by outside lab, presumptive results should be used prior to ordering definitive testing. Definitive results should be used within 24 to 48 hours of report receipt.
Moderate/ High Risk	Mod/High Risk Test Profile (Rx Medication Match) Definitive Testing of Positives and Unexpected Negatives Add Additional Definitive Drug Classes based on Patient and Practice Drugs of Abuse Profile)	At least 2x every 6 months (but varies significantly in applicable literature and state approaches)	Use results to determine when another patient encounter and treatment plan adjustment is necessary. Unless all testing performed by outside lab, presumptive results should be used prior to ordering definitive testing.

Physician must use the drug test results to guide treatment and future testing

Use Drug Test Results to Guide Ongoing Treatment



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Physician Review of Test Results

- Adopt a plan for when the physician (or someone other medical provider) will review the presumptive and definitive test results.
  - Prompt review
  - Medical decision-making regarding patient's ongoing care

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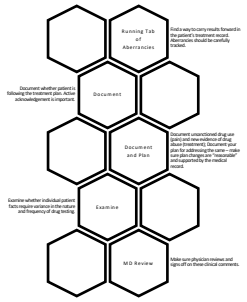
PROTOCOL FOR REVIEW OF DRUG TEST RESULTS AND PROVIDER RESPONSE

	Prior to Rx	After Office Visit	within 3 days of Test Results	within 5 days of Test Results	Prior to Next Rx	Day of Next Office Visit
Review of POCT (CLIA Waived Results)	○	○	○	○	○	○
Review of Presumptive POL Chemistry Analyzer Results	○	○	○	○	○	○
Review of LC-MS/MS Definitive Results from POL	○	○	○	○	○	○
Review of LC-MS/MS Definitive Results from Independent Laboratory	○	○	○	○	○	○

Basic Checklist for Documenting Provider Review of Drug Test Results



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Due Diligence Checklist

Objective 4

CREATE

Due Diligence Checklist – Basic Ideas

Task	Comments
Update POCT/POL test menus and add drugs that are most abused, i.e., fentanyl, hydrocodone, heroin	If you have a contract that limits your reagents to those selected by your lab management company, renegotiate it – you are missing critical drugs and possibly wasting money.
Update your test result review timing	If you do not look at analyzer results prior to ordering LC-MS/MS, this weakens your ability to respond to aberrant results and order medically necessary definitive testing. This comment does not apply if you send all specimens to an outside lab for drug testing – presumptive and definitive – because reflex allowed in that situation.
Positivity Rates	Ask your laboratory (POL or Independent) to supply you with a summary of your positivity rates for presumptive and definitive testing on all drugs/drug classes tested. Determine whether positivity rates support your test orders. Consider elimination of 0% positive drugs over large number of patients and time, i.e., propoxyphene and some of the synthetics (practice and regions may vary).
Test Frequency	Evaluate your drug test frequency in light of your state licensing board requirement for drug testing (if any) and Reading Material in this Slide Deck

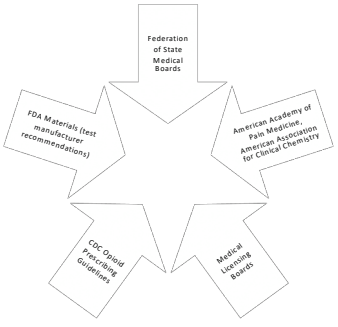
Documentation = "Cheese Trail"

1. Allows your team to understand what's going on with each patient.

2. Allows outside auditors to understand and report back that you know what you are doing.

3. Minimizes the potential for a bad outcome on an audit.

Resources for Test Orders: Selecting Test Menu, Test Frequency, and Utilization of Results

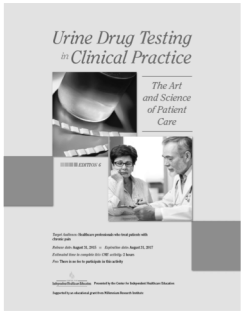


Sample Resources and Positions

(Test Frequency and Reference to Test Method)

Resource	Position on UDT	Year of Guidance/Policy
FSMB Guideline for Chronic Use of Opioid Analgesics	Periodic and Unannounced (including Chromatography). Clinical judgement trumps recommendations of frequency. Strong recommendation that if patient is in addiction treatment, test as frequently as necessary to ensure treatment adherence. http://www.fsmb.org/globalassets/advocacy/policies/opioid_guidelines_as_adopted_apr_il-2017_final.pdf.	2017
American Academy of Pain Medicine	Contains more specific guidance on test menu, test frequency, and test method. http://www.painmed.org/library/clinical-guidelines/.	2017
American Association for Clinical Chemistry	Contains more specific guidance on test menu, test frequency, and test method. https://www.aacc.org/media/press-release-archive/2018/01-jan/aacc-releases-practice-guidelines-for-using-laboratory-tests-to-combat-opioid-overdoses.	2018
American Society of Addiction Medicine	Recent paper on drug testing in the treatment of substance use disorders. https://www.asam.org/resources/guidelines-and-consensus-documents/drug-testing.	2017

Reading File: Urine Drug Testing in Clinical Practice (Doug L. Gourlay, MD, Howard A. Heit, MD, and Caplan, Yale H. Caplan, PhD)



Questions?

- Thank you!
- **Jennifer Bolen, JD**
- 865-755-2369
- jbolen@legalsideofpain.com

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