Get Your Specimens in Order: Timely Use of Test Results

- Prepared and presented by Jennifer Bolen, JD
- **PainWeek and PainWeekEND – SPRING 2019**

Disclosures for Jennifer Bolen, JD (as of 03/01/2019)

Consultant: Paradigm Labs

Why are we still talking about drug testing?

FAILURE TO USE DRUG TEST RESULTS IN TREATMENT OF THE PATIENT:

- Physician prescribes morphine and hydrocodone to a patient who has had multiple UDTs positive for cocaine and negative for at least one of the Rx opioids.
- Opioid prescribing and UDT aberrancies span more than two years. In between, blocks and injections.
- No referrals. Patient ultimately discharged.

What are the problems here? What if this is a pattern for this physician?

Why are we still talking about drug testing?

- FAILURE TO TIMELY REVIEW DRUG TEST RESULTS:
- Physician prescribes opioids to a new patient.
- Physician sees the patient monthly and properly orders drug testing, but laboratory reports and timing of physician review of same is not managed properly. Physician sees the drug test results nearly 21 days after placed in patient file.
- Patient's test results show a consistent and developing pattern of concerning aberrancies: (a) positive codeine albeit during cold and flu season, (b) missing Rx opioid (oxycodone), (c) positive Gabapentin previously undisclosed, and (d) positive morphine prior to Rx morphine.
- Physician's last encounter with the patient involved a procedure. The physician's work flow did not include a review of recent UDT results, which showed the patient was positive for heroin.
- Patient died.
- What are the problems here? What if this is a pattern for this physician?

Course Objectives

Identify

- The Core Elements of Medical Necessity

Describe

- Individualized Testing in light of Medical Necessity Policies

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.

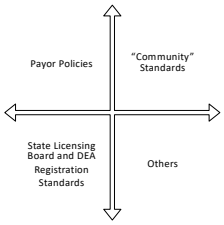
Explain

- How to create a due diligence checklist to ensure proper considerations for drug test menus and test methods/test partners.

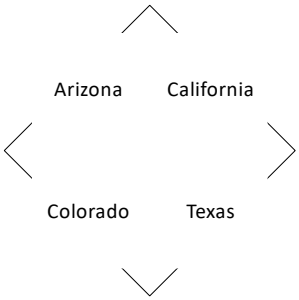
Basic Terminology and Common Test Methods

PRESUMPTIVE TESTING - Examples		**DEFINITIVE TESTING - Examples**	
"Screening"		"Confirmation"	
Immunoassay Detects "class" not specific analytes CANNOT TEST FOR SEVERAL DRUG CLASSES	LC-MS, LC-MS/MS Detects specific analytes	Usually Liquid Chromatography with Mass Spectrometry Detects specific analytes; results reported with quantitative values	Other

Drug Testing in Light of Stakeholder Perspectives

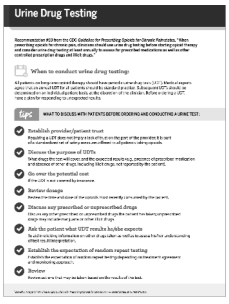


This Section Will Be Updated for Each PWE Lecture and Tailored to the Specific State Opioid Prescribing Policies and Drug Testing Guidelines/Requirements



CDC and Drug Testing

https://www.cdc.gov/drugoverdose/pdf/prescribing/CDC-DUIP-UrineDrugTesting_FactSheet-508.pdf


Urine Drug Testing

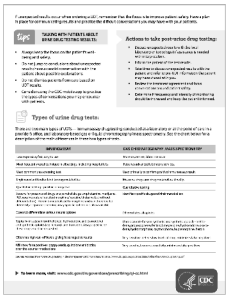
When to conduct urine drug testing:

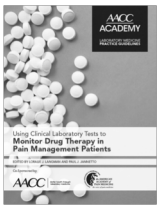
TIPS WHAT TO DISCUSS WITH PATIENTS BEFORE ORDERING AND CONDUCTING A URINE TEST.

- Establish provider/patient trust
- Discuss the purpose of UDTs
- Ask the patient what UDT results include experts
- Establish the expectation of random repeat testing
- Review

CDC and Drug Testing

https://www.cdc.gov/drugoverdose/pdf/prescribing/CDC-DUIP-UrineDrugTesting_FactSheet-508.pdf

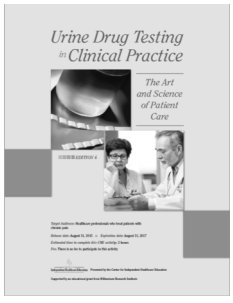




Two Other Resources (AAPM and AACC)

Reading File:
Urine Drug Testing in Clinical Practice

Doug L. Gourlay, MD, Howard A. Heit, MD, and Caplan, Yale H. Caplan, PhD



Sample Resources and Positions

(Test Frequency and Reference to Test Method)

Resource	Position on UDT	Year of Guidance/Policy
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

Common Work Flow Challenges Tied to Urine Drug Testing

The Drug Test Order is Connected to the Test Report. The Test Report is Connected to the Initial and Ongoing Treatment Plan . . . And your license and DEA registration

Experience Tells Us . . . UDT work flows are often general, driven by the EMR and timing of patient visits, and do not necessarily correlate with timely patient care

Test(s) Ordered/Specimen Collected	• Decision based on protocol or on the spot medical decision-making. • Specimen Collection Occurs
Test(s) Performed (Usually EIA to LCMS)	• Physician Office Lab usually tests AFTER patient has left the office • Independent Lab usually tests within 1 to 3 days of specimen collection
Test Results Received	• Physician Office Lab usually posts results to provider email or patient chart. • Independent lab usually posts results to provider fax, EMR interface, or allows provider to access via portal
Test Results Reviewed	• Physician/Practitioner often waits until the next visit to examine test results

Challenges with the Typical UDT Work Flow

- No universal test order process
- Outdated medication lists resulting in conflicting "labels" of patient results (lab often labels inconsistent or non-compliant with the medication plan based on the list provided)
- Medical necessity documentation burdensome if not understood; no universal process
- No universal medical necessity policy
- Time to get results (some labs take up to two weeks)
- Patient scheduling – medication management – timing challenges
- No formal triage system for handling notification of provider about abnormal results
- Provider doesn't see results until next visit
- Provider generally doesn't consult results if next visit is a "procedure" encounter, such as a block or injection
- No universal test resulting process; results difficult to read; mistakes in report labels - 'compliant', non-compliant, consistent, or inconsistent
- Other?

Medical Necessity and Drug Testing

OBJECTIVE 1 - 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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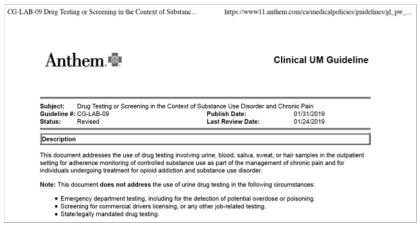
Sample UDT Policy – Anthem 2019



CG-LAB-09 Drug Testing or Screening in the Context of Substanc... https://www11.anthem.com/ca/medicalpolicies/guidelines/gl_pw_...

Anthem

Clinical UM Guideline

Subject: Drug Testing or Screening in the Context of Substance Use Disorder and Chronic Pain
Guideline #: CG-LAB-09 **Publish Date:** 01/31/2019
Status: Revised **Last Review Date:** 01/24/2019

Description

This document addresses the use of drug testing involving urine, blood, saliva, sweat, or hair samples in the outpatient setting for adherence monitoring of controlled substance use as part of the management of chronic pain and for individuals undergoing treatment for opioid addiction and substance use disorder.

Note: This document **does not address** the use of urine drug testing in the following circumstances:

- Emergency department testing, including for the detection of potential overdose or poisoning.
- Screening for commercial drivers licensing, or any other job-related testing.
- State/legally mandated drug testing.

Sample UDT Policy – Anthem 2019

Not Medically Necessary:

The use of *presumptive* urine drug testing is considered **not medically necessary** when the criteria above are not met.

The use of *definitive* urine drug testing is considered **not medically necessary** when the criteria above are not met.

The use of presumptive or definitive testing panels is considered **not medically necessary** unless all components of the panel have been determined to be medically necessary based on the criteria above. However, individual components of a panel may be considered medically necessary when criteria above are met.

The use of blood samples for drug testing is considered **not medically necessary** in all other circumstances, including when the criteria above have not been met.

The use of saliva, sweat, or hair samples for drug testing is considered **not medically necessary** in all circumstances.

The use of any of the following for *definitive* drug testing of urine or blood samples is considered **not medically necessary** in all circumstances:

A. Reflex testing; **or**
B. Standing orders; **or**
C. Blanket orders.

Sample UDT Policy – Anthem 2019

Medically Necessary:

Presumptive urine drug testing (UDT) to verify compliance with treatment, identify undisclosed drug use or abuse, or evaluate aberrant* behavior is considered **medically necessary** up to 24 times per year, beginning at the start of treatment, as part of a monitoring program tailored to the unique needs of individuals who are:

A. Receiving treatment for chronic pain with prescription opioid or other potentially abused medications; **or**
B. Undergoing treatment for, or monitoring for relapse of, opioid addiction or substance use disorder.

Presumptive urine drug testing is also considered **medically necessary** for the following:

A. To assess an individual when clinical evaluation suggests use of non-prescribed medications or illegal substances; **or**
B. On initial entrance into a pain management program or substance use disorder recovery program.

Sample UDT Policy – Anthem 2019

Definitive urine drug testing to verify compliance with treatment, identify undisclosed drug use or abuse, or evaluate aberrant* behavior is considered **medically necessary** up to 24 times per year, beginning at the start of treatment, as part of a monitoring program tailored to the unique needs of individuals whose requests meet criteria *both* A and B below:

A. Testing indications- *either* 1 or 2 below must be present:
   1. Receiving treatment for chronic pain with prescription opioid or other potentially abused medications; **or**
   2. Undergoing treatment for, or monitoring for relapse of, opioid addiction or substance use disorder; **and**
B. Testing scenarios- *either* 1 or 2 below have been met:
   1. Definitive testing following prior presumptive testing:
      a. The *presumptive* urine drug testing was done for a medically necessary reason; **and**
      b. The *presumptive* test was positive for an illegal drug (for example, but not limited to methamphetamine or cocaine), positive for a prescription drug with abuse potential which was not prescribed, or negative for prescribed medications; **and**
         i. The specific *definitive* test(s) ordered are supported by documented rationale for each test ordered; **and**
         ii. Clinical documentation reflects how the results of the test(s) will be used to guide clinical care; **or**

Sample UDT Policy – Anthem 2019

   2. Definitive testing without prior presumptive testing:
      a. *Presumptive* urine drug tests are not available for the drug in question (examples may include, opioids and their metabolites such as fentanyl, meperidine, tramadol, and tapentadol, muscle relaxants and their metabolites such as carisoprodol, synthetic cannabinoids and their metabolites, as well as cathinones ["Bath Salts"] and their metabolites); **and**
      b. The specific *definitive* test(s) ordered are supported by documented rationale for each test ordered; **and**
      c. Clinical documentation reflects how the results of the test(s) will be used to guide clinical care.

*Aberrant behavior includes, but is not limited to, lost prescriptions, repeated requests for early refills, prescriptions from multiple providers, unauthorized dose escalation, and apparent intoxication.

Note: Each definitive test request must be based on the tested individual's diagnosis, substance use patterns, results of presumptive testing and other clinical factors documented in the medical record. Community patterns of illicit drug use must not be imputed to an individual without a documented rationale. UDT monitoring of prescribed drugs is not a clinically appropriate way to estimate the therapeutic effectiveness of prescribed drugs. Definitive testing for more than 7 classes of drugs (including metabolites) would be unusual for most individuals.

Urine Drug Testing – Medically Necessary Orders and Proper Use of Test Results

ORDERS MUST BE . . .

- Individualized (tailored to the patient's individual medical and risk history) .
- Documented properly, communicating the rationale for the custom profile or other test order.

TEST RESULTS MUST BE . . .

- Used in a TIMELY fashion.
- Used according to the risk issues presented by the patient.
- Documented properly.

Payor Drug Testing Frequency Limitations

UPDATED CHART WILL BE PROVIDED PRIOR TO 3/21/19

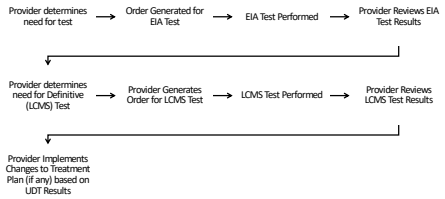
*Remember: medical necessity does not mean it's ok to test to the policy frequency limit

Payor -->	AETNA	ANTHEM BC of CA	CIGNA	HUMANA	UNITED
Effective Date	Summer 2018	6/28/18	2/15/18	7/1/18	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

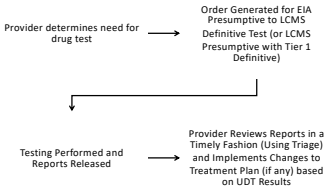
Moving from Presumptive Testing to Definitive Testing – Payor Policy Challenges

- **Not all payor policies are based on the science of drug testing**
  - Some plans will not allow a physician to seek LCMS testing of drugs that have not been tested using a presumptive "screen". However, this position overlooks important differences in test methods and the drugs for which they can test, among other things.

Merging Medical Necessity with Work Flow – Physician Office Laboratory



Merging Medical Necessity with Work Flow – Direct to Independent Laboratory



Review Carrier Policies and CMS Documentation Guidelines

Review Professional Licensing Board Guidelines and Opioid Prescribing Rules

If Physician-Office Laboratory, make sure your laboratory work flow comports with payor policies

Update your drug testing menus and testing frequency based on medical necessity policies and board rules

Update your documentation, including review of test results and modifications to treatment plan

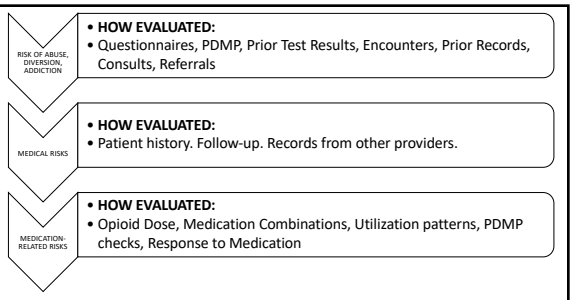
Medical Necessity Checklist

Individualized Testing

Objective 2
DESCRIBE

Typical Audit Findings Relative to Risk Mitigation and Use of Drug Testing

- No or minimal organization and thought toward UDT test order or test utilization protocols
- Inconsistent ordering of drug tests because risk is based solely on SOAPP-R or ORT scores (or similar)
  - Testing this way may overlook other risk domains and result in problematic medical necessity for testing and testing frequency.
- Untimely use of drug test results
  - Most providers do not review or use the drug test results until the next visit. However, this may be risky if aberrant, drug-related behavior at issue due to test results.



Examining Risk: Risk of or related to what? Examples

Individualization of Risk will Help You Individualize the Drug Test Menu

Drug Test Menus

The need to create Custom Profiles based on Individual Patient Information and Related Data

What does lab data show about your practice?

Lab data generally reveals:

- How you generally order tests.
- Whether you are involved in ordering and reviewing test results or delegate this work to others.
- Community drug testing trends (the drugs people in the community are using and abusing).
- Your practice lab positivity rates and the drugs your patients use.
- Whether you test everyone the same way or individualize testing.
- Whether you test everyone on a predictable schedule or routinely.
- Whether you keep your patient medication lists current.
- Whether you allow patients to repeatedly use illicit drugs.
- Whether you use test results in the treatment of your patients.

Why does lab data matter?

Payor Audit

- For POL, whether orders are medically necessary and whether test results used in treatment of patient. Can open the door to an inappropriate prescribing investigation.

Board/DEA Investigation

- Whether patient risk evaluation performed and ongoing risk monitoring tailored to individual patient's case;
- Whether opioid prescribing is for a legitimate medical purpose and performed by you in the usual course of professional practice.

Enzyme Immunoassay – Example Only* (more drug classes and variable test menus available in some cases)

EIA – CASSETTE or CUP	EIA – Chemistry Analyzer
	BIG
AMP	AMP
BAR	BAR
BZO	BZO
BUP	BUP
THC	THC
COC	COC
	FEN
	HYDROCODONE
MAMP	MAMP
MTD	MTD
OPI	OPI
OXY	OXY
PCP	PCP
TCA	TCA

Drug Test Menus Vary by Test Method

LCMS - Examples

- See Definitive Drug Class Descriptor List
- Specific analytes

Selecting a Drug Testing Menu for New Patients Using the 2019 CPT Descriptors for Drug Classes

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	Methylpheridate Opiates	33	Other unspecified

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Risk Evaluation Factors Translating to Drug Testing Menu – Case Examples

Audience Input

- How many of you perform your review UDT results just prior to the "next visit"?
  - UDT ordered on 1/3/19
  - UDT resulted on 1/7/19
  - UDT reviewed on ???

DO THIS, NOT THAT – Example 1

Selecting a Drug Testing Menu for New Patients Using the 2019 CPT Descriptors for Drug Classes

Class #	Class Descriptor	Class #	Class Descriptor	Class #	Class Descriptor
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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	Methylphenidate Opiates	33	Other unspecified

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DO NOT DO THIS . . .

- GRAPHIC OF A NON-BRANDED DRUG TEST ORDER FORM WITH A SINGLE PANEL CHECK BOX SELECTING ALL DRUGS FOR TESTING

THIS IS <u>NOT THE BEST WAY</u> TO CONSTRUCT A RISK-RELATED DRUG TEST MENU; Payor Push-Back and Potentially Faulty Ongoing Risk Monitoring Possible

PATIENT RISK SCORE ACCORDING TO SOAPP-14 or SOAPP-R or Similar	DRUG TEST MENU OR CUSTOM PROFILE	Test Menu and # Classes
Low Risk	Test 8-14 drug classes (all opioids, all major illicit drugs, Gabapentin)	AMPHETAMINES, BENZODIAZEPINES, BUPRENORPHINE, CANNABINOIDS, COCAINE, FENTANYL, HEROIN, METHADONE, OPIATES, OPIOIDS & OPIATE ANALOGS, OXYCODONE, PROPOXYPHENE, TAPENTADOL, TRAMADOL (Total 14 drug classes)
Moderate Risk	Test 15-21 drug classes (all opioids, all major illicit drugs, Gabapentin, Skeletal Muscle Relaxants, "Z" drugs (Zolpidem)	ALCOHOL METABOLITES, AMPHETAMINES, BARBITURATES, BENZODIAZEPINES, BUPRENORPHINE, CANNABINOIDS, COCAINE, FENTANYL, GABAPENTIN, HEROIN, KETAMINE, MDMA, METHADONE, OPIATES, OPIOIDS & OPIATE ANALOGS, OXYCODONE, PCP, PROPOXYPHENE, SKELETAL MUSCLE RELAXANTS, TAPENTADOL, TRAMADOL (Total 21 drug classes)
HIGH RISK	Test 22 + drug classes	All of the above, plus synthetic cannabinoids, synthetic stimulants, sleep medication, methylphenidate, and several others not referenced (Total 22+ drug classes)

THIS IS **AN EXAMPLE OF A MORE BALANCED AND MEDICALLY NECESSARY WAY** TO CONSTRUCT DRUG TEST MENUS (LOW & MODERATE RISK)

Risk Category	Common Characteristics* (See Embrace Lecture)	DRUG TEST MENU OR CUSTOM PROFILE	Testing Frequency	Test Menu and # Classes
Low Risk	**No illicit drug use history, non-smoker, no or little ETOH use, No hx ADRB No BH co-morbidities beyond mild depression Non-methadone, non-Fentanyl user**	Most likely 1- 7 drug classes	**Testing is between 1 and 4 times per year, subject to applicable standards.* Periodic reliance on EIA result is acceptable according to standards.**	TEST UNEXPECTED POSITIVES FROM DRUG SCREEN TEST UNEXPECTED RX NEGATIVES FROM DRUG SCREEN TEST LARGE CLASSES: BENZODIAZEPINES, OPIOIDS & OPIATE ANALOGS TEST MAJOR DRUG OF ABUSE SYNTHETIC: FENTANYL IF RX, TEST TAPENTADOL IF RX, TEST TRAMADOL PERIODIC TESTING OF RX TO CONFIRM METABOLITES OR IF CONCERNS DEVELOP REGARDING METABOLISM OR COMPLIANCE
Moderate Risk	**No history of illicit drug use, except THC (medical or other), Social ETOH use.**	Most likely 8-14 drug classes, but periodic drop to 1-7 as patient establishes with provider	Testing frequency is between 3 to 5 times per year, subject to applicable standards.*	TEST UNEXPECTED POSITIVES FROM DRUG SCREEN TEST UNEXPECTED RX NEGATIVES FROM DRUG SCREEN TEST LARGE CLASSES: BENZODIAZEPINES, OPIOIDS & OPIATE ANALOGS TEST MAJOR DRUGS OF ABUSE: BUPRENORPHINE, FENTANYL, TRAMADOL TEST HEROIN IF OPIATES IS AN UNEXPECTED POSITIVE NOT EXPLAINED BY RX TEST MAJOR DRUGS OF ABUSE THAT ARE COMMON RX MEDICATIONS WHICH ARE UNAVAILABLE FOR EIA TESTING: GABAPENTIN, PREGABALIN, AND SKELETAL MUSCLE RELAXANTS IF RX, TEST TAPENTADOL PERIODIC TESTING OF RX TO CONFIRM METABOLITES OR IF CONCERNS DEVELOP REGARDING METABOLISM OR COMPLIANCE. ADD EtG, EtS if EIA positive EtG or suspicion. All documented.

***Frequency depends on which standard you examine and what your licensing board says, e.g., Georgia appears to require testing of all patients on COT 4x per year.**

THIS IS **AN EXAMPLE OF A MORE BALANCED AND MEDICALLY NECESSARY WAY** TO CONSTRUCT DRUG TEST MENUS (HIGH RISK)

Risk Category	Common Characteristics* (See Embrace Lecture)	DRUG TEST MENU OR CUSTOM PROFILE	Testing Frequency	Test Menu and # Classes
HIGH RISK	**Illicit drug use history, smoker, ETOH user, History of ADRB, BH co-morbidities, methadone Rx, fentanyl Rx**	Most likely 8-14 drug classes. In rare cases, the patient's drug use history and current drug treatment regimen with medical co-morbidities and dose considerations may require 15 to 21 drug classes, but this would be hard to justify routinely because the more drugs you have to test, the more likely that ongoing opioids becomes a significant issue from a clinical standard of care perspective.	Testing frequency is between 4 to 6 times per year, subject to applicable standards.*	TEST UNEXPECTED POSITIVES FROM DRUG SCREEN TEST UNEXPECTED RX NEGATIVES FROM DRUG SCREEN TEST LARGE CLASSES: BENZODIAZEPINES, OPIOIDS & OPIATE ANALOGS TEST MAJOR DRUGS OF ABUSE: BUPRENORPHINE, CANNABIS (Natural), FENTANYL, TRAMADOL TEST HEROIN IF OPIATES IS AN UNEXPECTED POSITIVE NOT EXPLAINED BY RX TEST MAJOR DRUGS OF ABUSE THAT ARE COMMON RX MEDICATIONS WHICH ARE UNAVAILABLE FOR EIA TESTING: GABAPENTIN, PREGABALIN, AND SKELETAL MUSCLE RELAXANTS IF RX, TEST TAPENTADOL PERIODIC TESTING OF RX TO CONFIRM METABOLITES OR IF CONCERNS DEVELOP REGARDING METABOLISM OR COMPLIANCE. ADD EtG, EtS if EIA positive EtG or suspicion. All documented. SAME AS ABOVE, BUT LIKELY ANTI-PSYCHOTICS, ANTI-DEPRESSANTS WILL NEED TO BE TESTED PERIODICALLY TO MONITOR COMPLIANCE WITH TREATMENT PLAN. THE SAME WILL APPLY WITH COCAINE AND OTHER ILLICIT DRUGS THAT PATIENT MAY HAVE A HISTORY OF USING, e.g., heroin.

***Frequency depends on which standard you examine and what your licensing board says, e.g., Georgia appears to require testing of all patients on COT 4x per year.**

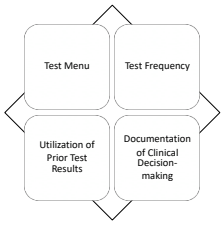
NEW PATIENT EXAMPLE (AUDIENCE INPUT)

Medical Risks	Medication Use & Risk	Risk of Misuse, Abuse, Diversion
Asthma, COPD, Diabetic, 69 y/o	Morphine at 90mg MME Tizanidine QHS Clonazepam QHS	SOAPP-R Score = Low Risk
Risk Level:	Risk Level:	Risk Level:
OVERALL RISK LEVEL & RATIONALE	**Test Menu should include:**	**Test Frequency should be:**

NEW PATIENT EXAMPLE (Discussion & More detail)

Medical Risks	Medication Use & Risk	Risk of Misuse, Abuse, Diversion
Asthma, COPD, Diabetic, 69 y/o	Morphine at 90mg MME Tizanidine QHS Clonazepam QHS	SOAPP-R Score = Low Risk; No Hx of abuse or diversion. Non-smoker; Non-drinker; Non-THC user.
Risk Level: HIGH RISK OVERDOSE	**Risk Level:** HIGH RISK BECAUSE OF MEDICATION DOSE & COMBINATION	**Risk Level:** LOW RISK FOR MISUSE AND ABUSE (algorithms show testing 1-2x/year, but this overlooks other risk factors and how test methods may impact nature of and testing frequency)
OVERALL RISK LEVEL & RATIONALE	**Test Menu should include (EXAMPLE):**	**General Test Frequency should be:**
High Risk Overall due to medication and medical risks. So the test menu may be smaller and the test frequency more varied than current algorithms show	**BASELINE LCMS UDT:** BZO, BUP, FEN, GAB, HEROIN, MTD/EDDP, OPI, OXY, Skeletal Muscle Relaxants, Z-Drugs (sleep medication), THC, Tapentadol, and Tramadol. **ONGOING DRUG TEST MENU:** LCMS testing of Rx Opioid, BZO, FEN (community drug of abuse), Gabapentin (community drug of abuse), Skeletal Muscle Relaxants and unexpected positives and negatives revealed in presumptive test.	2 to 4 times per year, depending on licensing board jurisdiction, which may require an additional test.
Test Menu includes more drug classes because patient using combination medication. Taper should be considered		Additional testing may be supported upon suspicion or test results; Must be documented.

Individualization: Ongoing Testing



Once you get the results for each patient . . .

IS IT REASONABLY PRUDENT
TO CONTINUE PRESCRIBING OPIOIDS
TO THE PATIENT
BASED ON THEIR DRUG TEST RESULTS
AND OTHER RISK/BENEFIT DATA?

DO THIS, NOT THAT – Example 2

Constructing Drug Test Menus

THIS IS NOT A GOOD OR BEST PRACTICE

UDT ORDERED

1/3/19	Point of Care Dip with LCMS Follow-Up

UDT RESULTED

1/7/19	LCMS Positive for Cocaine Metabolite and Fentanyl/Norfentanyl; Rx Hydrocodone is MISSING

UDT REVIEWED

2/5/19	Reviewed at patient's next visit and Rx Given to avoid patient withdrawal; Order another UDT

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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DO THIS INSTEAD

UDT ORDERED

1/3/19	Point of Care Dip with LCMS Follow-Up OR PRESUMPTIVE LCMS

UDT RESULTED

1/7/19	LCMS Positive for Cocaine Metabolite and Fentanyl/Norfentanyl; RX Hydrocodone is missing

UDT Reviewed

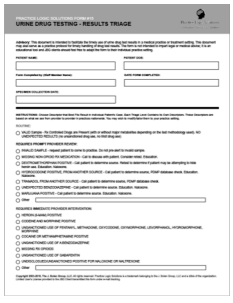
1/10/19	Reviewed by Triage Person and Results Flagged for Immediate Provider Review. Patient called in for a medication count. OTHER CLINICAL STEPS CONSIDERED, INCLUDING REFERRAL TO ADDICTION SPECIALIST. DISCUSSION ABOUT OPTIONS (GOOD ONES AND BAD ONES)

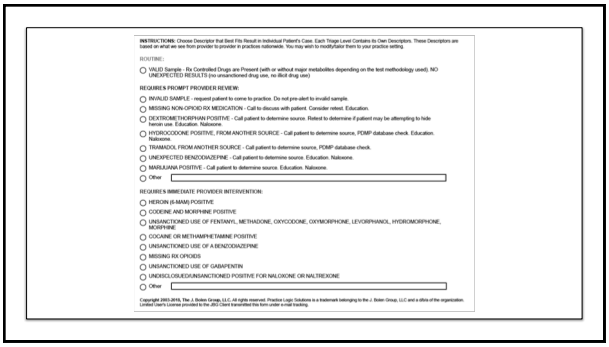
UDT Results TRIAGE – Create your own template

Routine	Prompt Action Needed	Critical/Urgent Action Needed

• What type of results would you consider as routine?
• What type of action do you expect if the results are routine?
• How would you train your staff to ensure routine is really routine?
	• What type of drug test results would you categorize as needing prompt action?
	  • Does unsanctioned or undisclosed THC fit into this category?
	  • Same questions but benzodiazepines instead of THC?
	  • Other drugs?
	  • How about questionable specimen validity?
	• What type of action do you consider to be "prompt"?
	• Who will carry out the interaction with the patient?
	• How will you make sure a "prompt action" item is called to your attention?
	• What type of staff training is needed here to ensure success?
		• What type of drug test results would you categorize as needing critical action or intervention with the patient?
		• Who will carry out the interaction/intervention with the patient?
		• How will you account for your patient's ongoing use of opioids in the face of a "critical" drug test result?
		• How will you make sure this "critical" item is called to your attention?
		• What type of staff training is needed here to ensure success?

IDEA FOR ADDRESSING UDT RESULTS IN A TIMELY FASHION


URINE DRUG TESTING – RESULTS TRIAGE



INSTRUCTIONS: Choose Descriptor that Best Fits Result in Individual Patient's Case. Each Triage Level Contains its Own Descriptors. These Descriptors are based on what we see from provider to provider in practices nationwide. You may wish to modify/tailor them to your practice setting.

ROUTINE:

- ○ VALID Sample - Rx Controlled Drugs are Present (with or without major metabolites depending on the test methodology used). NO UNEXPECTED RESULTS (no unsanctioned drug use, no illicit drug use)

REQUIRES PROMPT PROVIDER REVIEW:

- ○ INVALID SAMPLE - request patient to come to practice. Do not pre-alert to invalid sample.
- ○ MISSING NON-OPIOID RX MEDICATION - Call to discuss with patient. Consider retest. Education.
- ○ DEXTROMETHORPHAN POSITIVE - Call patient to determine source. Retest to determine if patient may be attempting to hide heroin use. Education. Naloxone.
- ○ HYDROCODONE POSITIVE, FROM ANOTHER SOURCE - Call patient to determine source, PDMP database check. Education. Naloxone.
- ○ TRAMADOL FROM ANOTHER SOURCE - Call patient to determine source, PDMP database check.
- ○ UNEXPECTED BENZODIAZEPINE - Call patient to determine source. Education. Naloxone.
- ○ MARIJUANA POSITIVE - Call patient to determine source. Education. Naloxone.
- ○ Other

REQUIRES IMMEDIATE PROVIDER INTERVENTION:

- ○ HEROIN (6-MAM) POSITIVE
- ○ CODEINE AND MORPHINE POSITIVE
- ○ UNSANCTIONED USE OF FENTANYL, METHADONE, OXYCODONE, OXYMORPHONE, LEVORPHANOL, HYDROMORPHONE, MEPERIDINE
- ○ COCAINE OR METHAMPHETAMINE POSITIVE
- ○ UNSANCTIONED USE OF A BENZODIAZEPINE
- ○ MISSING RX OPIOIDS
- ○ UNSANCTIONED USE OF GABAPENTIN
- ○ UNDISCLOSED/UNSANCTIONED POSITIVE FOR NALOXONE OR NALTREXONE
- ○ Other

Capturing Provider Rationale

Objective 3
DESIGN

Provider Rationale for TEST ORDERS should answer the following questions:

1. **Why are you ordering the test? General Examples . . .**
   - **UDT needed for Compliance monitoring according to licensing board and applicable standards of care?**
   - **UDT needed because patient has not progressed as expected and desires more opioid medication; UDT with quantitative levels may help me determine whether patient is having trouble metabolizing the drug or may be using medication inappropriately.**
   - **UDT needed because patient conduct inconsistent with reports of pain to staff; test results may help me determine whether the patient is misusing or diverting medication.**

Provider Rationale for TEST ORDERS should answer the following questions:

1. **Why do you need to test for the drugs/drug classes contained in the order?**
   - **Which drugs/drug classes are traceable to the patient's individual drug use history, including what is revealed by the patient's recent drug test results and the patient's prescribed medication?** Examples:
     - Oxycodone
     - Hydrocodone
     - THC
     - Tramadol
   - **Are there specific community trends showing abuse of more esoteric drugs such that adding these to the test menu is also justified?** Examples:
     - Fentanyl
     - Heroin
     - Gabapentin
     - Buprenorphine

Provider Rationale for TEST ORDERS should answer the following questions:

1. **Is the testing frequency justified by the patient's documented risk level and previous drug test results? Example:**
   - While patient has been evaluated as "low risk" of abuse and diversion. However, the patient has also been evaluated to be "high risk" medically (asthma, COPD) and based on current medication regimen (long-acting morphine at a dose of 90mg MME) using criteria published by the CDC and other governmental and professional organizations. Thus, the patient's overall risk level is "high risk" suggesting testing is proper at 3x to 4x per year to minimize the potential of an adverse event and potential overdose or drug-drug interaction. This is consistent with current medical licensing board guidance and applicable standards of care.

Provider Rationale for TEST ORDERS should answer the following questions:

1. **Is there a specific reason to increase testing frequency in the patient's case? Example:**
   - Patient historically has been evaluated as "low risk" in all categories (misuse, abuse, diversion, medical, and medication-related). However, the UDT result from two months ago showed patient was using unsanctioned marijuana. Patient admitted to smoking recreationally with friends.
   - Retest is necessary to ensure patient has not continued to use recreational marijuana. Regardless of the state's position on recreational marijuana, marijuana remains a Schedule I controlled drug under DEA regulations. The test is necessary to further support prescribing opioids in the usual course of professional practice.

Provider's Timely Use of Drug Test Results – The Medical Record Should Show:

1. The provider reviewed the drug test results in a timely fashion accompanied by reasonably-prudent medical decision-making in light of the patient's specific situation.
   - Do the results support continued opioid prescribing or modification of the treatment plan including consideration as to whether a referral is needed?

Due Diligence Checklist

Objective 4
CREATE

Due Diligence Checklist – Basic Ideas

Steps you can take
1. Update test menus
2. Update your test result review timing
3. Review Presumptive and Definitive Positivity Rates
4. Review Test Frequency Patterns and Documentation of Rationale
5. Seek a basic chart review and obtain recommendations for improvements

NEW ANTI-KICKBACK LAW IMPACTING
ADDICTION TREATMENT FACILITITES
AND LABORATORIES

OCTOBER 24, 2018

NEW LAW – OCTOBER 24, 2018

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- On October 24, 2018, President Trump signed the
- "Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act" or the "SUPPORT for Patients and Communities Act" (the "SUPPORT Act") into law.

The SUPPORT ACT COVERS LOTS OF GROUND

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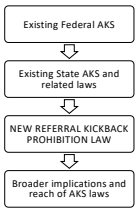
- Pain Management
- Opioids
- Federal Funding for Addiction Treatment
- NEW ANTIKICKBACK PROHIBITIONS
- More

- The entire act (law) is 660 PAGES



Life in Pictures –
Expansion of Anti-Kickback and Related Laws

FOR LABORATORIES:

THIS NEW LAW APPEARS TO IMPACT ALL SERVICES

Applies to the solicitation or receipt of remuneration for any referrals to clinical laboratories.

And may likely to apply regardless of whether referrals relate to testing of patients for substance use disorders.

The Recovery Kickback Prohibition
APPLIES TO ALL PAYORS (NOT JUST THE FEDS)

01

The Federal AKS applies only to referral of patients who are covered by a "Federal Health Care Program."

02

The Eliminating Kickbacks in Recovery Act extends its prohibitions to any and all health care benefit programs.

NEW REFERRAL KICKBACK PROHIBITION

- The Eliminating Kickbacks in Recovery Act, one of the SUPPORT Act's constituent bills, makes it a federal crime to receive or offer "[i]llegal remunerations for referrals to recovery homes, clinical treatment facilities, and laboratories" (the "Recovery Kickback Prohibition").
- CRIMINAL PENALTIES: Violation of the Referral Kickback Prohibition is punishable by a fine of no more than $200,000 and imprisonment of not more than 10 years for each occurrence.

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UNLIKE THE FEDERAL ANTIKICKBACK STATUTE, EKRA appears to apply only to certain entities (i.e., recovery homes, clinical treatment facilities, and laboratories) due to patient brokering problems.

However, some states have laws that make it more probable that EKRA's reference to "laboratories" may be interpreted more broadly.

Whether EKRA applies to laboratories outside of those servicing recovery homes and clinical treatment facilities remains to be seen. "

"(2) pays or offers any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

"(A) to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory; or

"(B) in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory,

- To a recovery home
- To a clinical treatment facility
- To a laboratory

PROHIBITS INDUCEMENTS/ EXCHANGES TO GAIN REFERRALS

PHYSICIAN-LAB INVESTORS BEWARE

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- The Recovery Kickback Provision materially changes the landscape by expanding the government's reach to private market payors.

PHYSICIAN LAB INVESTORS BEWARE:

- Laboratories that have structured their business operations around the Federal AKS because they did not receive money from federal health care programs MUST NOW reevaluate and likely restructure their business arrangements to ensure they address the increased risk presented by these ventures under this new law.
- The Department of Justice is likely to aggressively pursue those individuals and entities that violate the Eliminating Kickbacks Act.

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POSSIBLE EXCEPTIONS

Certain disclosed discounts under a health care benefit program

Certain payments to bona fide employees and independent contractors

Discounts on drugs furnished under the Medicare coverage gap discount program

Payments for services that meet the Federal AKS safe harbor for personal services and management contracts

Certain coinsurance and copayment waivers and discounts

Certain federally qualified health center arrangements that meet the Federal AKS exception

Remuneration made pursuant to certain arrangements that the secretary of US Department of Health and Human Services deems necessary.

PROHIBITS WAIVERS OF CO-PAYS AND DEDUCTIBLES UNLESS . . .

"(5) a waiver or discount (as defined in section 1001.952(h)(5) of title 42, Code of Federal Regulations, or any successor regulation) of any coinsurance or copayment by a health care benefit program if—

"(A) the waiver or discount is not routinely provided; and

"(B) the waiver or discount is provided in good faith;

WARNING REGARDING EKRA

- No one really knows how this will be applied or interpreted.

Thank you!

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Questions?

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