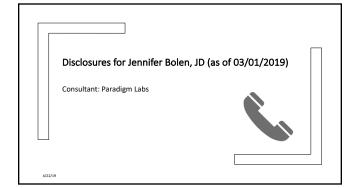
Get Your Specimens in Order: Timely Use of Test Results	
Prepared and presented by Jennifer Bolen, JD	
PainWeek and PainWeekEND – SPRING 2019	THE STATE OF THE S



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?

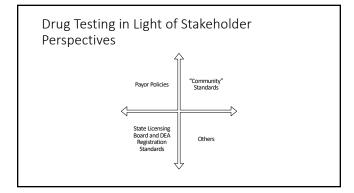
Why are we still talking about drug testing?

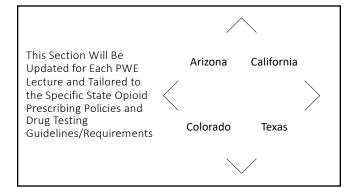
- FAILURE TO TIMELY REVIEW DRUG TEST RESULTS:
- Physician prescribes opioids to a new patient.
- Physician sees the patient monthly and properly orders drug testing, but laboratory reports and timing of
 physician review of same is not managed properly. Physician sees the drug test results nearly 21 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 Kx 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?

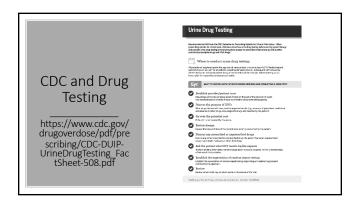
Identify • The Core Elements of Medical Necessity Describe • Individualized Testing in light of Medical Necessity Policies Review • The use of a protocol and template for capturing provider rationale for drug test orders and action steps to facilitate improved utilization of drug test reports in the medical practice.

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

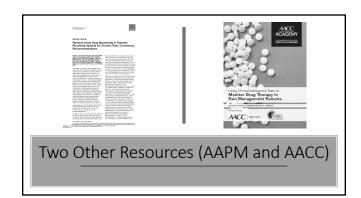
Basic Terminology and Common Test Methods PRESUMPTIVE TESTING - Examples "Screening" Immunoassay Detects 'class' not specific analytes CANNOT TEST FOR SEVERAL DRUG CLASSES DEFINITIVE TESTING - Examples "Confirmation" Usually Liquid Chromatography with Mass Other Spectrometry Detects specific analytes; results reported with quantitative values







CDC and Drug Testing Testing



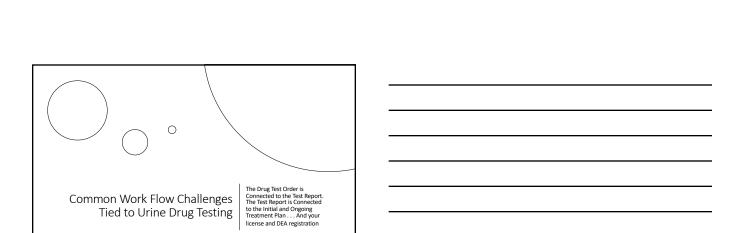
Reading File:

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-telease-practice-guidelines-for-using-jaboratory-tests-to-combat-onioid-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		



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

Test(s) Performed (Usually EIA to LCMS)

Test Results Received

Test Results Reviewed

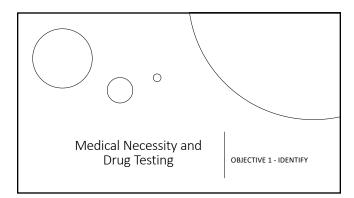
Challenges	with the	Typical	UDT	Work	Flow
CHallenges	WILLI LIIC	IVPICAL	001	VVOIN	1 10 00

- 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

- 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 - 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.



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	
<u> </u>	
CG-LAB-09 Drug Testing or Screening in the Context of Substane https://www11.authem.com/ca/medicalpolicies/guidelines/gl_pw	
Anthem.	
Subject: Drug Teeling or Screening in the Context of Substance Use Disorder and Chronic Pain Guideline 1: C0-LHS-00 "Built Date: 01/13/2019 Status: Revoked 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 addressor continuing of controlled substance use as part of the management of orbinor pain and for individuals underlying inferent for provid address and substance or decrease.	
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 policioning. Sciencing for commercial drivers licensing, or any other job-related leading. State-liquidy moderated drug tenting. 	
	1
Sample UDT Policy – Anthem 2019	
Sample ODT Folicy Alterior 2015	
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 uring or blood exprolace is considered not medically.	
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.	

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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 monotroing program silicred to the unique needs of individuals who are:	
A. Receiving treatment for chronic pain with prescription opicid or other potentially abused medications; or B. Undergoing treatment for, or monitoring for relapse of, opicid 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.	
	-
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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 (re example, but not limited to methamphetamine or coexime), 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	
Definitive testing without prior presumptive testing:	
opioids and their metabolites such as fentanyl, meperidine, tramadol, and tapentadol, muscle relaxants and their metabolites such as carisoproofs, syntheic cannabinoids and their metabolites, as well as cathinones [Eath 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 reflils, 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 whole rollinical factors documented in the medical record. Community patterns of illicit drug use	
must not be imputed to an individual without a documented rationale. UIT 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 . . .

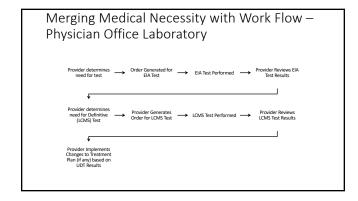
- Used in a TIMELY fashion.
- Used according to the risk issues presented by the patient.
- Documented properly.

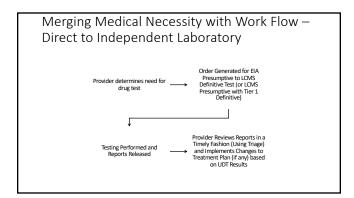
Payor Drug Testing Frequency Limitations
UPDATED CHART WILL BE PROVIDED PRIOR TO 3/21/19
*Remember: medical necessity <u>does no</u>t mean it's ok to test to the policy frequency limit

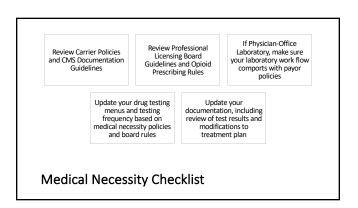
Payor>	AETNA	ANTHEM BC of CA	CIGNA	HUMANA	UNITED
Effective Date	Summer 2018	6/28/18	2/15/18	7/1/18	7/11/18
Presumptive Test Frequency Limitation	NMT 8/year	NMT 24/year	NMT 32/year and NMT 1 per DOS	NMT 12/year	NMT 18/year and NMT 1 per DOS
Definitive Test Frequency Limitation	NMT 8/year	Specific to medical 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 GO482 and GO483 Considered NOT	NMT 7 classes (G0480); Non-Covered: G0481, G0482, G0483	May be in other new policies undergoing updates right now

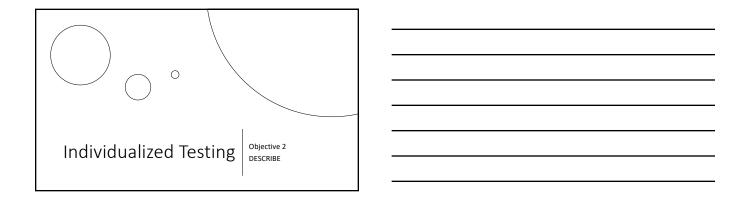
Moving from Presumptive Testing to Definitive Testing – Payor Policy Challenges

- 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.









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.

HOW EVALUATED: Questionnaires, PDMP, Prior Test Results, Encounters, Prior Records, Consults, Referrals	
• HOW EVALUATED:	
Patient history. Follow-up. Records from other providers.	
Opioid Dose, Medication Combinations, Utilization patterns, PDMP	
MEDICATION MEDICATION CHILD MASS checks, Response to Medication	
Examining Risk: Risk of or related to what? Examples	

	1
Drugs used by patient (now and historically) Patient Risk Level Based on Domains of Risk: Abuse, Misuse, Diversion Medical Medication-Related Other Behavloral	
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?
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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
COI	EtG
AMP	AMP
BAR	BAR
B2O	B20
BUP	BUP
THC	THC
coc	coc
	FEN
	HYDROCODONE
MAMP	MAMP
MTD	MTD
OPI	OPI
OXY	OKY
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	Cocaline	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	34 Methylphenidate Oplates	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

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1	Alcohol	12	Buprenorphine	23	Opioids and Opiate Analogs
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8	Anti-epileptics	19	Heroin	30	Stimulants, Synthetic
9	Anti-psychotics	20	Ketamine	31	Tapentadol
10	Barbiturates	21	Methadone	32	Tramadol
11	Benzodiazepines	22	34 Methylphenidate Opiates	33	Other unspecified

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 ANALOSS, 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, BERZODIAZPINES, BUPRENOBRHINE, CAMANBAINODS, COCAINE, FENTANYL, GABAPENTIN, HEROIN, KETAMINE, MDMA, METHADONE, OPIATES, OPIDIOS & OPIATE ANALOSE, GOVOCHONE, PCP, PROPOZYPHENE, 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)

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INIENUS (LC	W & MODERATE RISE			
Risk Category	Common Characteristics' (See Embrace Lecture)	DRUG TEST MENU OR CUSTOM PROFILE	Testing Frequency	Test Menu and # Classes
	No illicit drug use history, non-smoker,		Testing is between 1 and 4 times per year, subject to applicable	TEST UNEXPECTED POSITIVES FROM DRUG SCREEN TEST UNEXPECTED RX NEGATIVES FROM DRUG SCREEN TEST LARGE CLASSES: BENZODIAZEPINES, OPIOIDS & OPIATE
Low Risk	no or little ETOH use, No hx ADRB No BH co-morbidities beyond	Most likely 1- 7 drug classes	standards.* Periodic reliance on EIA result is	ANALOGS TEST MAJOR DRUG OF ABUSE SYNTHETIC: FENTANYL
	mild depression Non-methadone, non-Fentan	Linner	acceptable according to standards.	IF RX, TEST TAPENTADOL IF RX, TEST TRAMADOL PERIODIC TESTING OF RX TO CONFIRM METABOLITES OR IF
	user			CONCERNS DEVELOP REGARDING METABOLISM OR COMPLIANCE
Moderate Risk	No history of illicit drug use, except THC (medical or other	Most likely 8-14 drug classes, but periodic drop to 1-7 as patient	Testing frequency is between 3 to 5 times per year, subject to	TEST UNEXPECTED POSITIVES FROM DRUG SCREEN TEST UNEXPECTED RX NEGATIVES FROM DRUG SCREEN TEST LARGE CLASSES: BENZODIAZEPINES, OPIOIDS & OPIATE
	Social ETOH use.	establishes with provider	applicable standards.*	ANALOGS TEST MAJOR DRUGS OF ABUSE: BUPRENORPHINE, FENTANYL, TRAMADOL
				TRAMADOL TEST HEROIN IF OPIATES IS AN UNEXPECTED POSITIVE NOT EXPLAINED BY RX
Frequency depe	nds on which standard you ex	amine and what your licer	sing board says, e.g., Georgia	TEST MAJOR DRUGS OF ABUSE THAT ARE COMMON RX MEDICATIONS WHICH ARE UNAVAILABLE FOR EIA TESTING: GABAPENTIN, PREGABAJIN, AND SKELETAL MUSCLE RELAXANTS IF RX, TEST TAPENTADOL
	appears to require testing	or an patients on COT 4x	es yedf.	IF RX, TEST TAPENTADOL PERIODIC TESTING OF RX TO CONFIRM METABOLITES OR IF CONCERNS DEVELOP REGARDING METABOLISM OR COMPLIANCE. ADD EtG, EtS if E1A positive EtG or suspicion. All
				COMPLIANCE. ADD EtG, EtS if EIA positive EtG or suspicion. All documented.
THIS IS AN I	EXAMPLE OF A MORE GH RISK)	BALANCED AND M	EDICALLY NECESSARY	WAY TO CONSTRUCT DRUG TEST
THIS IS AN I MENUS (HI	GH RISK)		EDICALLY NECESSARY	NAY TO CONSTRUCT DRUG TEST
THIS IS AN IMENUS (HI	Common Characteristics* (See	BALANCED AND M DRUG TEST MENU OR CUSTOM PROFILE	EDICALLY NECESSARY V	WAY TO CONSTRUCT DRUG TEST Test Menu and # Classes
MENUS (HI	GH RISK)	DRUG TEST MENU OR CUSTOM PROFILE	Testing Frequency	Test Menu and # Classes
MENUS (HI	Common Characteristics* (See	DRUG TEST MENU OR CUSTOM PROFILE Most likely 8-14 drug classe In rare cases, the patient's dr	Testing Frequency	Test Menu and # Classes TEST UNEXPICED POSITIVES FROM DRUG SCREEN TEST UNEXPICED FOR MEGATIVES FROM DRUG SCREEN TEST UNEXPICED FOR MEGATIVES FROM DRUG SCREEN TEST HASPEC LASSES ENDOMACETIVES OPPOISS & OPPATE
MENUS (HI	Common Characteristics* (See Embrace Lecture)	DRUG TEST MENU OR CUSTOM PROFILE Most likely 8-14 drug classe In rare cases, the patient's dr use history and current dru treatment orderines with ned	Testing Frequency	Test Menu and # Classes TEST UNEXPICED POSITIVES FROM DRUG SCREEN TEST UNEXPICED RX MIGGINES FROM DRUG SCREEN TEST LANGE CLASSES BRIZDOLEZ/FRIS, OPIDIOS & OPINIT TEST LANGE CLASSES BRIZDOLEZ/FRIS, OPIDIOS & OPINIT TEST MANOR DRUG SCAUSES BRIZDOLEZ/FRIS, CANADIS
MENUS (HI	Common Characteristics* (See Embrace Lecture)	DRUG TEST MENU OR CUSTOM PROFILE Most likely 8-14 drug classe In rare cases, the patient's du use history and current dru treatment regimen with med co-morbidities and dose considerations may require 12 drug classes, but this would	Testing Frequency Testing Frequency Testing frequency is between the 4 to 6 times per year, subject	Test Menu and # Classes TEST UNEXPICTED POSITIVES FROM DRUG SCREEN TEST UNEXPICTED BY MICHARDS FROM DRUG SCREEN THAT UNEXPICTED BY MICHARDS FROM DRUG SCREEN THAT THAT THAT THAT THAT THAT THAT THAT
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Risk Level:
Test Frequency should be:

Risk Level:
OVERALL RISK LEVEL & RATIONALE

Risk Level: Test Menu should include:

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; No 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 (JOS UDT) 820, BUP FEN, GAB, HEROIN, MITD/EDDP, OPI, ORY, Selectal Muscle Relationts, 2 Drugs (sleep medication), THC, Thermack, and Thermack, JOSCO Selectal for Googleid, SED, FEN, OSCOLAR, DUSC TEXT MORTH (JC), COS Selectar of Fo Opciols, SED, FEN, OSCOLAR, DUSC TEXT MORTH, SED, SED, SED, SED, SED, SED, SED, SED	2 to 4 times per year, depending on licensing board jurisdiction, which may require an additional test.
Test Menu includes more drug classes bed	ause patient using combination medication. Taper should be considered	Additional testing may be supported upon suspicion or test results; Must be documented.

Individualization: Ongoing Testing
Test Menu Test Frequency Utilization of Prior Test Results Documentation of Clinical Decision- making

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 Fentany//Norfentany/; 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

54

DO THIS INSTEAD	
UD	T ORDERED
1/3/19	Point of Care Dip with LCMS Follow-Up OB PRESUMPTIVE LCMS
	T RESULTED
1/7/19	LCMS Positive for Cocaine Metabolite and Fentanyl/Norfentanyl; RX Hydrocodone is missing
up	T Reviewed

UDT Results TRIAGE – Create your own template 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?
- Into this category?

 Same questions but benzodiazepines instead of THC?

 Other drugs?

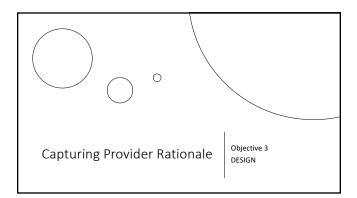
 How about questionable specimen validity?

- 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**

Advery: The document is intended to facilists the times use of units drug just revelor in a medical profession treatment under, This document may account a subject to profession for these profession for the profession of the pro Control of the Contro

INSTRUCTIONS: Choose Descriptor that Best Fils Result in Individual Patent's Case. Each Titige Level Contains its Own Descriptor or what we see from provider to provider in practice rationwide. You may wish to modificialist them to your practice setting	gites. These Descriptors are 0.	
ROUTINE:		
 VALID Sample - Rx Controlled Drugs are Present (with or without major metabolites depending on the test method: UNEXPECTED RESULTS (no unsanctioned drug use, no illicit drug use) 	Jology used), NO	
REQUIRES PROMPT PROVIDER REVIEW:		
NVALID 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. Refeet to determine if patient may be attent heroin use. Education. Nationone. 	spling to hide	
 HYDROCODONE POSITIVE, FROM ANOTHER SOURCE - Call patient to determine source, POMP database che Naloscene. 	sck Education.	
O TRAMADOL FROM ANOTHER SOURCE - Call patient to determine source, POMP database check.		
 UNEXPECTED BENZODIAZEPINE - Call patient to determine source. Education. Nalowone. 		
MARUUANA POSITIVE - Call patient to determine source. Education. Nationone.		
Other		
REQUIRES IMMEDIATE PROVIDER INTERVENTION:		
○ HEROIN (6-MAM) POSITIVE		
CODEINE AND MORPHINE POSITIVE		
O LINSANCTIONED USE OF FENTANYS, METHADONE, DXYCODONE, DXYMORPHONE, LEVORPHANOS, HYD. MORPHINE.	JROMORPHONE,	
○ COCAINE OR METHAMPHETAMINE POSITIVE		
○ UNSANCTIONED USE OF A BENZODIAZEPINE		
MISSING RX OPIOIDS		
O UNISANCTIONED USE OF GABAPENTIN		
UNDISCLOBUEDIUMSANCTIONED POSITIVE FOR NALOXONE OR NALTREXONE		
0.00%		
· -		
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Provider Rationale for TEST ORDERS should answer the following questions:

- 1. Why are you ordering the test? General Examples \dots
 - 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	e for TEST ORDERS should
answer the follow	ing questions:

- 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
 Hydroc

 - THC

 - 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:

- 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 drugdrug 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.

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

- 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 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 Pain Management Opioids Federal Funding for Addiction Treatment NEW ANTIKICKBACK PROHIBITIONS More The entire act (law) is 660 PAGES	

E	xisting Federal AKS	
	Union Charles AVE and	
Б	isting State AKS and related laws	
NEV	V REFERRAL KICKBACK PROHIBITION LAW	
	ader implications and	
	reach of AKS laws	
Life in Pictures –		-
Expansion of Anti-Kickback	and Related Laws	
	Applies to the solicitation or receipt of remuneration for	
i	any referrals to clinical	
FOR LABORATORIES:	laboratories.	
THIS NEW LAW APPEARS TO IMPACT	And may likely to apply	
ALL SERVICES	regardless of whether referrals relate to testing of	
	patients for substance use	
(disorders.	
The Recovery Kickb	ack Prohibition	
APPLIES TO ALL PAY	ORS (NOT JUST THE FEDS)	
01	02	
The Federal AKS applies only to referral of patients who are	The Eliminating Kickbacks in Recovery Act extends its prohibitions to any and all	
covered by a "Federal Health Care Program."	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.

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."

10	(2) pays or offers any remaineration (including	
19	any kiekback, bribe, or rebate) directly or indirectly,	
20	overtly or covertly, in cash or in kind—	
21	"(A) to induce a referral of an individual	
22	to a recovery home, clinical treatment facility,	
23	or laboratory; or	To a recovery home
24	"(B) in exchange for an individual using	To a clinical treatment facility
25	the services of that recovery home, clinical	To a laboratory
26	treatment facility, or laboratory,	

PROHIBITS INDUCEMENTS/ EXCHANGES TO GAIN REFERRALS

	<u>-</u>
PHYSICIAN-LAB INVESTORS BEWARE	-
The picture can't be displayed.	
The Recovery Kickback Provision materially	
changes the landscape by expanding the	
government's reach to private market payors.	
	J
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PHYSICIAN LAB INVESTORS BEWARE:	
Laboratories that have structured their business The picture can't be displayed.	
operations around the Federal AKS because they did not receive money from federal health care programs MUST	
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 	-
pursue those individuals and entities that violate the Eliminating Kickbacks Act.	
	1
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.	
POSSIBLE EXCEPTIONS	

PROHIBITS WAIVERS OF CO-PAYS AND DEDUCTIBLES UNLESS 12 "(5) a waiver or discount (as defined in section 13 1001.952(b)(5) of title 42, Code of Federal Regula- tions, or any successor regulation) of any consum- ance or copagnent by a health care benefit program (C) PAYS AND DEDUCTIBLES UNLESS 18 "(4) the waiver or discount is not reutinely provided, and 19 "(15) the waiver or discount is provided in 20 good faith;	
	1
WARNING REGARDING EKRA	
No one really knows how this will be applied or interpreted.	
	1
Thank you!	
Jennifer Bolen, JD	
865-755-2369	
jbolen@legalsideofpain.com	
Questions?	