The False Claims Act & Medical Necessity: Recent Cases Involving Clinical Labs and Drug Testing

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Disclosures

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Reasons for this Course

- **The federal government continues to pursue physician office and independent clinical laboratories**, and the individuals responsible for troublesome patterns of drug testing, using its authority under the False Claim Act (FCA) and related federal laws.

- The federal government has the option of bringing cases it originates or "stepping into" (intervening in) cases originating through "whistleblowers" (**Qui Tam cases**).

Reasons for this Course

- False claim allegations are often based on patterns of conduct showing actual knowledge of false claims OR deliberate ignorance OR reckless disregard of applicable payor coverage and reimbursement policies governing drug testing;
  - Expert testimony regarding drug testing standards is also used.
- **Profit motives are often a central focus** of these cases **and may include violations of the anti-kickback and stark laws**.
  - FCA cases may also involve allegations of inappropriate physician compensation schemes and other forms of inducement/kickbacks to gain test volume.
- **Documentation of testing protocols, decisions, and use of test results is central to proving these cases.**

Learning Objectives

Examine

Examine the basic legal framework of a False Claims Act Case, including Whistleblower (Qui Tam) Case.

Examine

Examine the difference between an FCA and an overpayment matter

Identify

Identify problematic conduct typically exposed in FCA cases and the theories used by the Government when it brings or intervenes in these cases.

Use

Use course information to facilitate the evaluation of physician and qualified healthcare practitioner business arrangements with clinical laboratories, including POLs, and drug testing patterns and processes; Evaluate the importance of proper test orders, documentation of testing rationale, and use of test reports.

Basic Legal Platform of False Claim Act (FCA) Cases

What is a False Claim?
What does the Government Need to Prove?
How doe FCA cases differ from overpayments?
What are the consequences/penalties?

Objectives 1 and 2

The False Claims Act

- Referred to as the “FCA”
- The FCA is one of the most powerful civil health care fraud enforcement tools.
- Found at 31 U.S.C. §§ 3729 *et seq* (and sections following).
- Originally designed to help the government fight unscrupulous contractors.
- Expanded and updated over time.

The FCA makes it illegal for any person to "knowingly" . . .

PRESENT (OR CAUSE TO BE PRESENTED)	MAKE OR USE (OR CAUSE TO BE MADE OR USED)	"KNOWINGLY" MEANS
• A false or fraudulent claim for payment or approval. • "Present" is broadly construed and does not mean the claim has to go "to the federal government." It's enough that the federal government provides any portion of the payment requested.	• A false record or statement material to a false or fraudulent claim.	• Actual Knowledge of the information, OR • Acts in deliberate ignorance of the truth or falsity of the information, OR • Acts in reckless disregard of the truth or falsity of the information. • PROOF OF SPECIFIC INTENT IS NOT REQUIRED.

Actions that *may* Constitute False and Fraudulent Claims

Billing for services not provided

Billing for services that were provided but not as billed

Billing for medically unnecessary services

Providing services but not billing for them in compliance with legal requirements or administrative guidelines

Non-billing offenses may also be considered in FCA cases – billing party provides the service and bills appropriately *but is not in compliance with underlying legal/regulatory/contractual obligations*.

Kickbacks as False Claims

- Claims for items or services resulting from an Anti-Kickback Statute (AKS) violation are false or fraudulent for purposes of the False Claims Act (FCA).

Overpayment versus False Claim

- Affordable Care Act (ACA) added a new form of false claim: Failure to disclose and repay government overpayments.
  - Legal OBLIGATION to do so within 60-days.

Overpayment versus False Claim

- If you discover an overpayment relating to drug testing, you have 60 days to refund the overpayment and provide a written explanation of the reason for the overpayment. There are additional timing rules here.
- If you do not refund the overpayment within 60-days, the overpayment becomes an "obligation" to pay the government. This is the concept of a "reverse false claim."
- The 60-day time clock starts running when:
  - The person has or should have, through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment;
  - The "lookback period" is 6 years, meaning if the overpayment is identified within 6 years of the date payment was received, the recipient of the payment must comply with the 60-day rule.
  - Repayments must take the form of "an applicable claims adjustment, credit balance, self-reported refund, or other appropriate process."

Overpayment versus False Claim

The 60-day time clock starts running when:

- The person has or should have, through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment;

- The “lookback period” is 6 years, meaning if the overpayment is identified within 6 years of the date payment was received, the recipient of the payment must comply with the 60-day rule.

Handling the Overpayment is Critical to Avoiding Potential FCA Liability

- **LESSON:** Do not ignore overpayment requests. Instead, exercise reasonable diligence to evaluate drug test orders and payments. Actual timing can be a little more complicated than this, and there are avenues for suspension of the 60-day clock, e.g., when the "obligated" entity is following the Provider Self-Disclosure Protocol under CMS's 2016 Final Rule.

- **LESSON:** Reasonable diligence is "demonstrated through the timely, good faith investigation of credible information, which is at most 6 months from the receipt of credible information [of a possible overpayment], except in extraordinary circumstances.

Summary: Reverse False Claim

- **Money is owed to the government**. The laboratory/physician office laboratory has an obligation to refund overpayments.
- IMPROPER AVOIDANCE OR CONCEALMENT: NOT A REQUIREMENT OF A FALSE STATEMENT; See Knowledge below.
- KNOWLEDGE: Defendant has actual knowledge of this OR “acts with deliberate ignorance” OR ”acts in reckless disregard” of the information showing money is owed to the government.
- **REMEMBER: COMPLIANCE WITH THE FEDERAL AKS and STARK LAW** is a condition of receiving payment under Medicare, Medicaid, and Tricare.

Implied Certification and the FCA

- **Failure to disclose non—compliance with a material, statutory, regulatory or contractual requirement can give rise to FCA liability if the omission makes the claim misleading.**
  - The omission (failure to disclose non-compliance with an obligation) does not have to expressly be a condition of payment; Instead, it is sufficient that the non-compliance concerns an obligation/requirement that is material to the government's decision to pay for the services. *Universal Health Services, Inc. v. Escobar*, 136 S.Ct. 1989 (2016).
- **Oversimplified Example:** A physician office/laboratory submits claims for high complexity testing services BUT only possesses a CLIA certificate of waiver. The failure to secure a proper CLIA registration or certificate is material to the government's decision to pay for laboratory services.

Penalties for False Claims Act Cases

- Penalties for FCA cases are much more significant today.
- The amount of each claim.
- Penalties within a minimum and maximum range (increases frequently).
- Treble damages (calculated off the amount per claim).
- Potential for Civil Monetary Penalties (CMP) to be imposed by the OIG against providers when the conduct fits into a list of offenses justifying the same. SEE HANDOUT FOR AUTHORITIES AND SPECIFIC EXAMPLES.
- Many laboratory cases trigger the government's authority to seek CMP.

General Categories of CMP Offenses for which inappropriate laboratory conduct may apply

False and Fraudulent Claims

- The OIG may seek a CMP or exclusion against individuals or entities that present claims to Federal health care programs that the individual or entity knows or should know are for an item or service that was not provided as claimed or is false or fraudulent.
- For example, the OIG may seek a CMP or exclusion against an individual or entity who makes claims for a service that is not actually provided, is provided but is already covered under another claim, is not properly coded, or is not supported by the medical record.
- **Resource for both columns:** https://oig.hhs.gov/fraud/enforcement/cmp/cmpa.asp.

Grants, Contracts, and Other Agreements

- The OIG may impose CMPs, assessments, and exclusions against individuals and entities that engage in fraud and other improper conduct related to HHS grants, contracts, and other agreements.
- The OIG may impose sanctions for, among other things, knowingly presenting a specified claim under a grant, contract, or other agreement that is false or fraudulent, or knowingly making or using any false statement, omission, or misrepresentation of a material fact in any application, proposal, bid, progress report, or other document submitted to HHS in order to receive funds under an HHS grant, contract, or other agreement.

General Categories of CMP Offenses for which inappropriate laboratory conduct may apply

Kickbacks

- The Anti-Kickback Statute prohibits individuals or entities from asking for or receiving any remuneration in exchange for referrals of Federal health care program business.
- The OIG may seek a CMP or exclusion against individuals or entities who knowingly and willfully:
  - (1) offer or pay remuneration, directly or indirectly, to induce referrals of Federal health care program business; or
  - (2) solicit or receive remuneration, directly or indirectly, in return for referrals of Federal health care program business.

Physician Self-Referral (Stark Law)

- The Physician Self-Referral Statute, or Stark law as it is sometimes called, prohibits individuals or entities from referring Medicare or Medicaid patients for designated health services to entities with which individuals or entities have a direct or indirect financial relationship, unless an exception applies.
- The OIG may seek a CMP or exclusion against individuals or entities that present or cause to be presented a claim that the individual or entity knows or should know is for a service for which payment may not be made under the Stark law.
- **Resource for both columns:** https://oig.hhs.gov/fraud/enforcement/cmp/cmpa.asp.

Example: OIG-settled CMP Case Involving Lab and Physicians

- 03-12-2020

- Chad E. Boekes, M.D., Louis B. Kasunic, D.O., and Castle Rock Family Physicians, P.C. (collectively, "Castle Rock"), Castle Rock, Colorado, entered into a $54,982 settlement agreement with OIG.
- The settlement agreement resolved allegations that Castle Rock solicited and received remuneration from laboratory companies Health Diagnostic Laboratory, Inc. (HDL) and Singulex, Inc. (Singulex), in the form of "process and handling" payments related to the collection of blood.
- OIG alleged that Castle Rock solicited and received the remuneration from HDL and Singulex in exchange for Castle Rock and Castle Rock employees referring patients for laboratory testing services to HDL and Singulex, for which the Medicare program paid.
- **Resource:** OIG Exclusions and Enforcement Webpage, use index located at https://oig.hhs.gov/fraud/enforcement/cmp/index.asp and search for entry on 3/12/20 for “Castle Rock.”

False Claims Act and Qui Tam Provisions (Whistleblower Cases)

- The False Claims Act authorizes private whistleblowers (called “relators”) to file suits (called “qui tam” actions) on behalf of the United States, and to share in any recovery.
- A qui tam action is originally filed under seal and served only on the United States (and not on the defendant).
- The United States has at least 60 days (which may be extended) to investigate the relator’s allegations, and to elect whether to intervene and take over the lawsuit, or to let the relator pursue the action on his/her own.

Statute of Limitations for False Claims Act Cases (How long does the government have to bring the case?)

- A FCA action may be brought (1) 6 years from the date of the violation, or (2) 3 years from the date the U.S. official responsible for acting knew or should have known of the violation, but no later than 10 years from the date the violation occurred.

Common allegations and theories used by the government in FCA litigation involving drug testing

OBJECTIVE #3

Investigative Tools Used by the Government in FCA Cases

- The Government generally investigates qui tam and non-qui tam cases similarly.
  - In a qui tam case, the Government will likely begin its investigation by interviewing the relator.
  - In a non-qui tam case, the Government will begin by speaking with the source of the information – whether it is the referring agency, a confidential informant, or in some cases, a voluntary disclosure by the defendant.
- The Government will frequently use either Inspector General (IG) subpoenas or Civil Investigative Demands (CIDs) in connection with its investigation.
  - IG Subpoenas may be used to obtain documents and other tangible things.
  - CIDs may be used to obtain not only documents, but also answers to interrogatories and testimony.

Common Themes/Theories in Government and Whistleblower FCA Cases

Kickback and Stark Related

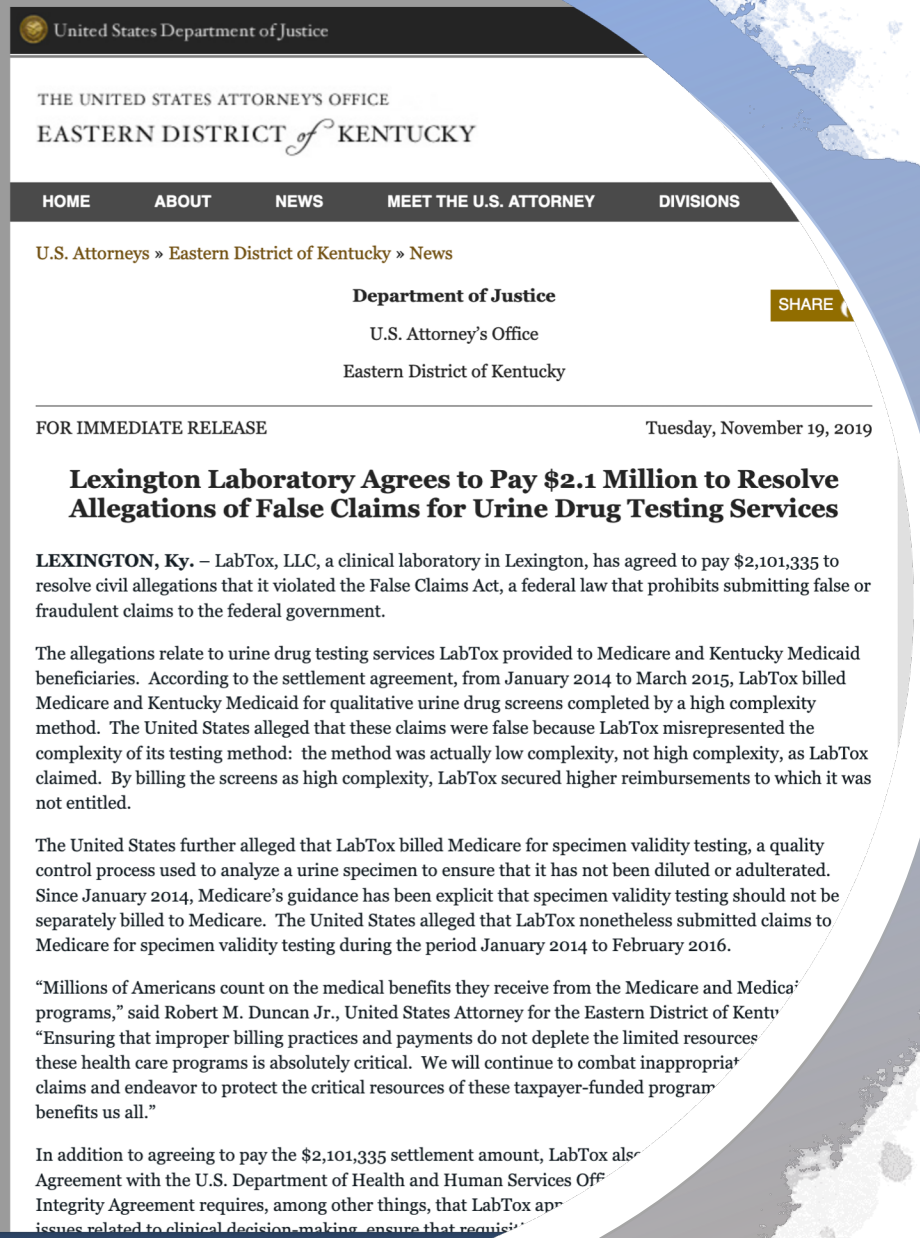
- Physician received kickbacks to order tests
- Physician compensated based on specimen volume
- Inappropriate use of specimen collectors
- Investment opportunities

Medical Necessity Related

- Limited test panel/profile selection (standing orders, custom profiles which are the same for all patients* (there are several issues with these)
- Different tests for insured and uninsured patients
- “Up-classing” the number of drugs to be tested – testing for unnecessary drugs of abuse as shown by laboratory positivity rates and unsupported by patient’s individual history (like upcoding)
- Over-testing (testing too frequently)
- Not using drug test results in a timely fashion to adjust or continue the treatment plan.
- Billing for medically unnecessary testing (global)

DOJ Settles FCA Case with LabTox (Kentucky)

November 2019 – LabTox to pay DOJ $2.1 million to resolve billing for services not provided (billing for high complexity testing when the laboratory performed low complexity testing



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FOR IMMEDIATE RELEASE Tuesday, November 19, 2019

Lexington Laboratory Agrees to Pay $2.1 Million to Resolve Allegations of False Claims for Urine Drug Testing Services

LEXINGTON, Ky. – LabTox, LLC, a clinical laboratory in Lexington, has agreed to pay $2,101,335 to resolve civil allegations that it violated the False Claims Act, a federal law that prohibits submitting false or fraudulent claims to the federal government.

The allegations relate to urine drug testing services LabTox provided to Medicare and Kentucky Medicaid beneficiaries. According to the settlement agreement, from January 2014 to March 2015, LabTox billed Medicare and Kentucky Medicaid for qualitative urine drug screens completed by a high complexity method. The United States alleged that these claims were false because LabTox misrepresented the complexity of its testing method: the method was actually low complexity, not high complexity, as LabTox claimed. By billing the screens as high complexity, LabTox secured higher reimbursements to which it was not entitled.

The United States further alleged that LabTox billed Medicare for specimen validity testing, a quality control process used to analyze a urine specimen to ensure that it has not been diluted or adulterated. Since January 2014, Medicare's guidance has been explicit that specimen validity testing should not be separately billed to Medicare. The United States alleged that LabTox nonetheless submitted claims to Medicare for specimen validity testing during the period January 2014 to February 2016.

"Millions of Americans count on the medical benefits they receive from the Medicare and Medica
programs," said Robert M. Duncan Jr., United States Attorney for the Eastern District of Kentu
"Ensuring that improper billing practices and payments do not deplete the limited resources
these health care programs is absolutely critical. We will continue to combat inappropriat
claims and endeavor to protect the critical resources of these taxpayer-funded program
benefits us all."

In addition to agreeing to pay the $2,101,335 settlement amount, LabTox als
Agreement with the U.S. Department of Health and Human Services Off
Integrity Agreement requires, among other things, that LabTox apr
issues related to clinical decision-making, ensure that requisi

LabTox FCA Settlement: $2.1 million (11/19)

Resource: https://www.justice.gov/usao-edky/pr/lexington-laboratory-agrees-pay-21-million-resolve-allegations-false-claims-urine-drug

FCA Settlement for Kickbacks leading to False Claims –Kumar (a PCLS Sales Manager)

December 2019 settlement of $649,407;

PCLS went out of business

Kumar (formerly with PCLS) FCA Settlement $649,407 (12/19)

- **Kickbacks to induce referrals**

- **RESOURCE:** https://www.justice.gov/usao-wdnc/pr/urine-drug-test-laboratory-sales-manager-agrees-pay-649407-settle-false-claims

-laboratory-sales-manager-agrees-pay-64940

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FOR IMMEDIATE RELEASE — Monday, December 16, 2019

Urine Drug Test Laboratory Sales Manager Agrees To Pay $649,407 To Settle False Claims Allegations With United States

CHARLOTTE, N.C. – The U.S. Attorney's Office for the Western District of North Carolina announced that it has settled claims with Manoj Kumar, a former sales representative and manager for Physician's Choice Laboratory Services (PCLS), a defunct urine drug testing laboratory that was based in Charlotte, N.C.

Kumar has paid $649,407 to resolve claims that he participated in schemes to illegally induce physicians to send medically unnecessary urine drug tests to PCLS. Kumar was a defendant in a civil complaint filed by the United States against Kumar, PCLS and other agents of the company.

The United States alleged that Kumar, along with other agents of PCLS, provided benefits to physicians to induce them to send urine samples to PCLS for drug testing that was not medically necessary. The complaint alleges that Kumar's actions violated the Anti-Kickback Statute, which makes it illegal for any person to knowingly and willfully solicit or receive, or offer or pay any remuneration in exchange for the referral of items or services that are paid for by a federal health care program. The United States alleged that PCLS then submitted claims to Medicare for these tests in violation of the False Claims Act.

"Tests and other services should be ordered by physicians based on sound medical judgment, not on financial benefit," said Andrew Murray, United States Attorney for the Western District of North Carolina. "Paying inducements to obtain orders for tests and other services corrupts medical decision-making and causes unnecessary costs to federal healthcare programs."

The United States alleged that Kumar received payments from PCLS to channel urine drug tests to PCLS from physician practices that he managed. The United States further alleged that Kumar, along with a co-defendant in the case, provided equipment and related services to physicians in exchange for those physicians sending urine drug samples to PCLS.

"The Ant-Kickback Statute is meant to protect patients and federal health programs from medical
on-making corrupted by financial motive," said U.S. Attorney Murray. "My office will a
claims."

SPECIMEN VALIDITY TESTING AND OIG CIVIL MONETARY PENALTIES AND ENFORCEMENT

On February 3, 2020, Kentucky Pain Management Services, LLC (KPMS), Hazard, Kentucky, entered into a $230,685.82 settlement agreement with OIG. The settlement agreement resolves allegations that KPMS submitted claims to Medicare for specimen validity testing (SVT), a non-covered service.

- SVT is a quality control process that evaluates a urine drug screen sample to determine if it is consistent with normal human urine and to ensure that the sample has not been substituted, adulterated, or diluted.
- **RESOURCE:** OIG, https://oig.hhs.gov/fraud/enforcement/cmp/index.asp, scroll to the entry for 2/3/2020.

SPECIMEN VALIDITY TESTING AND OIG SETTLEMENT WITH CIVIL MONETARY PENALTIES AND ENFORCEMENT

On December 12, 2019, American Toxicology Lab, LLC (ATL), Johnson City, Tennessee, entered into a $175,889.72 settlement agreement with OIG. The settlement agreement resolves allegations that ATL submitted claims to Medicare for specimen validity testing (SVT), a non-covered service.

- SVT is a quality control process that evaluates a urine drug screen sample to determine if it is consistent with normal human urine and to ensure that the sample has not been substituted, adulterated, or diluted.
- **RESOURCE:** OIG, https://oig.hhs.gov/fraud/enforcement/cmp/index.asp, scroll to the entry for 12/12/2019.

Logan Labs, Tampa Pain Relief Centers, Michael T. Doyle, and Christopher Utz Toepke

April 2020 – Defendants to pay DOJ $41 million to resolve FCA case (kickbacks, medically unnecessary testing)

Logan Labs Case - Background

Allegations:

Practice management executives are alleged to have interfered with physician/practitioner discretion by pre-selecting patients for drug testing.

Alleged to have interfered with practitioner discretion to use simple immunoassay test cups (or similar), resulting in “gross over-utilization of expensive quantitative UDT.”

Alleged to have put extreme pressure on practitioners to order expensive UDT tests that were medically unnecessary and/or were not performed after a screening (presumptive) UDT.”

Involves FCA based on billing for medically unnecessary testing and kickbacks tied to compensation.

Logan Labs, Tampa Pain Relief Centers, Michael T. Doyle and Christopher Utz Toepke settle with DOJ for $41 MILLION to resolve FCA case

- RESOURCE: https://www.justice.gov/opa/pr/reference-laboratory-pain-clinic-and-two-individuals-agree-pay-41-million-resolve-allegations

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Office of Public Affairs

FOR IMMEDIATE RELEASE — Wednesday, April 15, 2020

Reference Laboratory, Pain Clinic, and Two Individuals Agree to Pay $41 Million to Resolve Allegations of Unnecessary Urine Drug Testing

Logan Laboratories Inc. (Logan Labs), a reference laboratory in Tampa, Florida; Tampa Pain Relief Centers Inc. (Tampa Pain), a pain clinic also based in Tampa Florida, and; two of their former executives, Michael T. Doyle and Christopher Utz Toepke (collectively, Defendants) have agreed to pay a total of $41 million to resolve alleged violations of the False Claims Act for billing Medicare, Medicaid, TRICARE, and other federal health care programs for medically unnecessary Urine Drug Testing (UDT), the Department of Justice announced today. Both Logan Labs and Tampa Pain are subsidiaries of Surgery Partners Inc. Doyle is the former CEO of Surgery Partners and Logan Labs. Toepke is the former Group President for Ancillary Services at Surgery Partners, with oversight of Logan Labs, and a former Vice President at Tampa Pain.

The government alleged that Defendants knowingly submitted or caused the submission of false claims to federal health care programs for presumptive and definitive UDT, in circumstances where such testing was not medically reasonable or necessary. Presumptive UDT are tests that screen for the presence of drugs, and definitive UDT are tests that identify the amounts of those drugs in a patient's system. The government alleged that Defendants developed and implemented a policy and practice of automatically ordering both presumptive and definitive UDT for all patients at every visit, without any physician making an individualized determination that either test was medically necessary for the particular patients for whom the tests were ordered. According to the government's allegations, the medically unreasonable and unnecessary definitive UDT was performed at Logan Labs, the medically unreasonable and unnecessary presumptive UDT was performed at Tampa Pain, and the respective resulting false claims were submitted by both Tampa Pain and Logan Labs to federal health care programs, from Jan. 1, 2010 through Dec. 31, 2017.

...e Department of Justice is committed to ensuring that federally-funded laboratory tests are ordered based on each ...t's medical needs and not for the purpose of increasing laboratory profits," said Assistant Attorney General Jody Hunt ...partment of Justice's Civil Division. "We do not tolerate practices that are not based on patient medial needs and ...nnecessary costs for federal health care programs."

...seeking profits at the expense of individualized patient care will be held accountable in our distri... ...a Lopez for the Middle District of Florida. "We will protect our district's residents fro... ...line overrides medical decision making."

Sterling Healthcare d/b/a Cordant Health Solutions

July 2020 – Cordant to pay DOJ $12 million to resolve FCA Case involving Kickbacks

July 20, 2020; U.S. Attorney's Office, Western District of Washington

- DOJ settles False Claims Act allegations against drug testing lab with operations in Tacoma and Denver: Cordant Health Solution pays nearly $12 million to settle allegations it paid kickbacks for urine testing referrals

  Seattle - The U.S. Department of Justice and Sterling Healthcare Opco, LLC d/b/a/Cordant Health Solutions (Cordant), today settled a civil suit alleging Cordant illegally paid kickbacks to generate urine testing business from government insured consumers.

RESOURCE: https://www.justice.gov/usao-wdwa/pr/doj-settles-false-claims-act-allegations-against-drug-testing-lab-operations-tacoma-and#:~:text=DOJ%20settles%20False%20Claims%20Act%20allegations%20against%20drug,allegations%20it%20paid%20kickbacks%20for%20urine%20testing%20referrals

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FOR IMMEDIATE RELEASE — Monday, July 20, 2020

DOJ settles False Claims Act allegations against drug testing lab with operations in Tacoma and Denver

Cordant Health Solution pays nearly $12 million to settle allegations it paid kickbacks for urine testing referrals

Seattle – The U.S. Department of Justice and Sterling Healthcare Opco, LLC d/b/a/Cordant Health Solutions (Cordant), today settled a civil suit alleging Cordant illegally paid kickbacks to generate urine testing business from government insured consumers. Cordant has agreed to pay various government healthcare programs $11,942,913 to settle the allegations. Twenty percent of the settlement will go to the relator who first filed a *qui tam* case regarding the conduct in 2015, alerting the government to the misconduct.

According to the settlement, Cordant paid millions of dollars in remuneration to Northwest Physicians Laboratories, LLC ("NWPL"), and Genesis Marketing Group ("Genesis") in exchange for referrals of urine drug tests paid for by federal healthcare programs in violation of the Anti-Kickback Statute and the False Claims Act. The kickbacks were paid to NWPL for claims that were filed between January 1, 2013, and July 31, 2015, and to Genesis from August 7, 2013, through March 31, 2015.

"This is the largest civil settlement in the illegal kickback scheme involving Northwest Physicians

State False Claims Acts

- State False Claims Acts Many states and localities have their own False Claims Act statutes.
- They look very similar to the federal FCA.
- In qui tam cases, where State funds may be implicated (for example, where the alleged fraud involves Medicaid funds), relators are increasingly filing suit under both the federal and state statutes.

IMPROPER BILLING MEDICAID FOR UDT (July 2020)

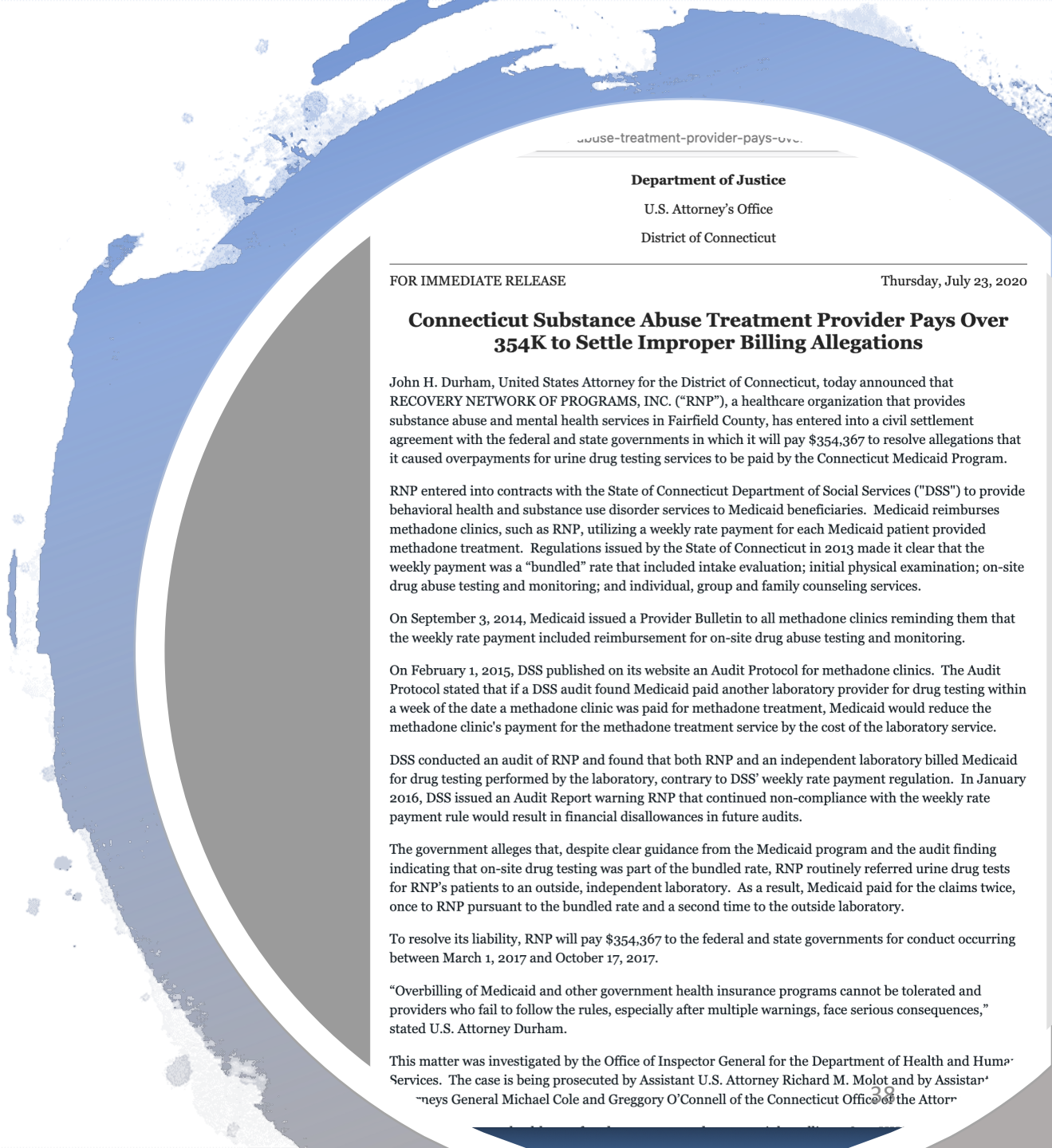
RNP and an independent laboratory billed Medicaid for drug testing performed by the laboratory, contrary to DSS' weekly rate payment regulation.

2016 Audit Report warned RNP that continued non-compliance with the weekly rate payment rule would result in financial disallowances in future audits.

Despite clear guidance from the Medicaid program and the audit finding indicating that on-site drug testing was part of the bundled rate, RNP routinely referred urine drug tests for RNP's patients to an outside, independent laboratory.

As a result, Medicaid paid for the claims twice, once to RNP pursuant to the bundled rate and a second time to the outside laboratory.

- RESOURCE: https://www.justice.gov/usao-ct/pr/connecticut-substance-abuse-treatment-provider-pays-over-354k-settle-improper-billing



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FOR IMMEDIATE RELEASE — Thursday, July 23, 2020

Connecticut Substance Abuse Treatment Provider Pays Over 354K to Settle Improper Billing Allegations

John H. Durham, United States Attorney for the District of Connecticut, today announced that RECOVERY NETWORK OF PROGRAMS, INC. ("RNP"), a healthcare organization that provides substance abuse and mental health services in Fairfield County, has entered into a civil settlement agreement with the federal and state governments in which it will pay $354,367 to resolve allegations that it caused overpayments for urine drug testing services to be paid by the Connecticut Medicaid Program.

RNP entered into contracts with the State of Connecticut Department of Social Services ("DSS") to provide behavioral health and substance use disorder services to Medicaid beneficiaries. Medicaid reimburses methadone clinics, such as RNP, utilizing a weekly rate payment for each Medicaid patient provided methadone treatment. Regulations issued by the State of Connecticut in 2013 made it clear that the weekly payment was a "bundled" rate that included intake evaluation; initial physical examination; on-site drug abuse testing and monitoring; and individual, group and family counseling services.

On September 3, 2014, Medicaid issued a Provider Bulletin to all methadone clinics reminding them that the weekly rate payment included reimbursement for on-site drug abuse testing and monitoring.

On February 1, 2015, DSS published on its website an Audit Protocol for methadone clinics. The Audit Protocol stated that if a DSS audit found Medicaid paid another laboratory provider for drug testing within a week of the date a methadone clinic was paid for methadone treatment, Medicaid would reduce the methadone clinic's payment for the methadone treatment service by the cost of the laboratory service.

DSS conducted an audit of RNP and found that both RNP and an independent laboratory billed Medicaid for drug testing performed by the laboratory, contrary to DSS' weekly rate payment regulation. In January 2016, DSS issued an Audit Report warning RNP that continued non-compliance with the weekly rate payment rule would result in financial disallowances in future audits.

The government alleges that, despite clear guidance from the Medicaid program and the audit finding indicating that on-site drug testing was part of the bundled rate, RNP routinely referred urine drug tests for RNP's patients to an outside, independent laboratory. As a result, Medicaid paid for the claims twice, once to RNP pursuant to the bundled rate and a second time to the outside laboratory.

To resolve its liability, RNP will pay $354,367 to the federal and state governments for conduct occurring between March 1, 2017 and October 17, 2017.

"Overbilling of Medicaid and other government health insurance programs cannot be tolerated and providers who fail to follow the rules, especially after multiple warnings, face serious consequences," stated U.S. Attorney Durham.

This matter was investigated by the Office of Inspector General for the Department of Health and Human Services. The case is being prosecuted by Assistant U.S. Attorney Richard M. Molot and by Assistant Attorneys General Michael Cole and Greggory O'Connell of the Connecticut Office of the Attorney

Example: State False Claim Act Case (June 2019)

- $1.5 million FCA Settlement
- Clinical Science Laboratory, Inc.
- Billing CT State Medicaid 19x what it charged to other customers PER URINE DRUG TEST
- Charged substance abuse clinics only $2/test
- Violated state Medicaid regulations (obligations)

OFFICE OF THE ATTORNEY GENERAL
CONNECTICUT

06/26/2019

ATTORNEY GENERAL TONG ANNOUNCES $1.5 MILLION FALSE CLAIMS SETTLEMENT WITH CLINICAL SCIENCE LABORATORY, INC.

(Hartford, CT) – Connecticut Attorney General William Tong today announced a $1.5 million settlement with Clinical Science Laboratory, Inc. (CSL) and its owners Stanley Elfbaum and Louis Amoruso resolving False Claims Act violations related to over billing for urine drug tests.

The Connecticut Department of Social Services requires that independent clinical laboratories enrolled in the state Medicaid program bill at "the lowest price charged or accepted for the same or substantially similar goods or services by the provider from any person or entity."

A joint investigation by the Office of the Attorney General, the United States Department of Health and Human Services, Office of the Inspector General, Office of Investigations, and the United States Attorney's Office, District of Connecticut led authorities to discover that CSL was billing the state for $38 per urine drug test, while charging substance abuse treatment clinics only $2, in violation of state Medicaid regulations.

"Clinical Science Laboratory was billing the state's Medicaid program 19 times what it charged to other customers—diverting taxpayer resources away from other critical needs. Connecticut has been disproportionately devastated by the opioid epidemic, and we must ensure we are getting the absolute most out of every treatment dollar spent," said Attorney General Tong. "I want to thank our federal law enforcement partners and the DSS Office of Quality Assurance for their joint efforts in this investigation

USING THIS INFORMATION TO EVALUATE YOUR BUSINESS RELATIONSHIPS AND UDT PLATFORM

Objective 4

Avoid Jumping into Business Arrangements with Individuals and Laboratories

Perform your due diligence; Make sure you are getting yourself into a compliant business arrangement

Avoid Doing Business with Businesses and People Who Do Not Understand Medical Necessity Requirements

Perform your due diligence; Make sure you understand your obligations when you “issue” a test order; Speak up if you are being pressured to order medically unnecessary tests (at least check things out with a peer or by reading the literature and licensing board and payor guidance)

From the Payor's Perspective:

Basic Cost Issues Tied to Drug Testing Patterns and Illustrating the Importance of Test Results to the Cost of Treating the Patient

Presumptive Test

- Nature of the Presumptive Test
  - Point of Care
  - Immunoassay (high complexity)
  - LCMS (same cost to payor as chemistry analyzer)
- Test Frequency

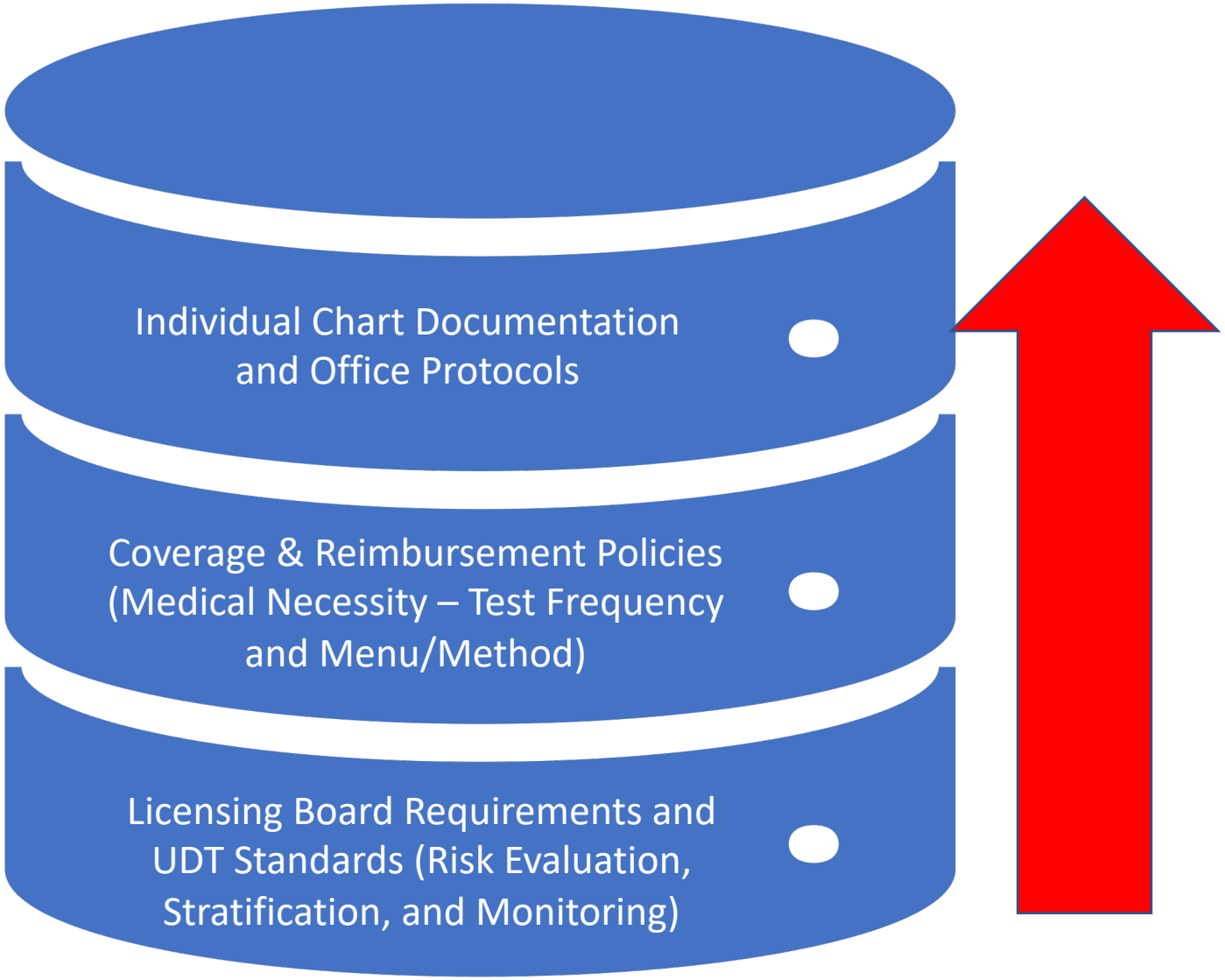
Definitive Test

- Number of Drug Classes tested
  - Problems with Orders
  - Broad Panels
- Test Frequency

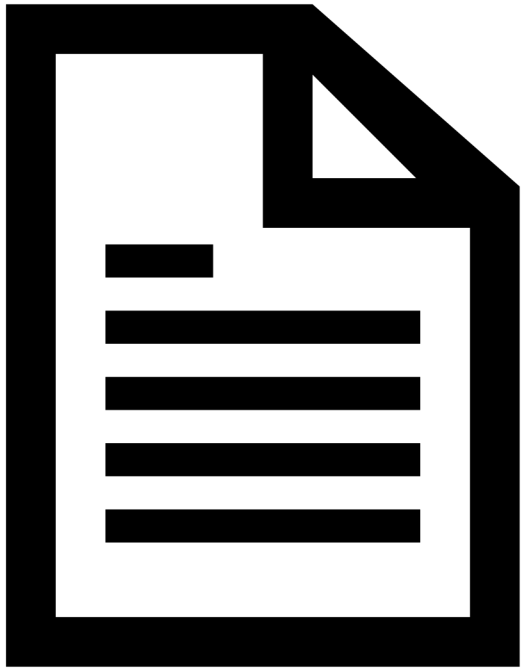
The Prescribed Drugs and Other Medical Costs

- The Rx (Controlled and Non-Controlled)
- The office visits
- The procedures
- The diagnostic tests
- The ED visits
- The naloxone

Document Due Diligence Efforts



Continued Focus on Due Diligence



Business Arrangement

Specimen collectors

Investments

Compensation

Testing

Orders (individualized)

Frequency and Test Menu tied to defensible platform and documentation

Use of Test Results

Documentation

Protocols

Individual Patient Charts

Updated evaluation of state licensing board requirements

Updated evaluation of medical necessity policies

Due Diligence for Patient Risk Evaluation and Monitoring

- Please attend PAINWEEK - MDL-02
- Things to remember:
  - The government often focuses on the Risk of Abuse/Diversion when examining drug testing patterns.
  - Clinical Risk Mitigation in Pain Management is NOT that narrow! Risk mitigation includes:
    - Medical Risks
    - Behavioral Risks
    - Medication Risks
    - Facts as they develop
  - Simply using a risk tool, like ORT, may not be sufficient to support drug testing patterns in the eyes of the payor/government.

    - Drug testing of new patients is easy to understand – get a baseline

    - Drug testing of established patients requires more documentation to support drug testing decisions: (1) focus on risk level and tie to drug test menu, drug test frequency; (2) timing of use of drug test results; and (3) clear documentation of your reasons for testing and response to test results as individualized to the patient.

Drug Class Breakdown and Relation to Test Orders

Opiates*, Opioids, and Descriptor-Related Classes

(Buprenorphine, Codeine, Fentanyl, Heroin*, Hydrocodone, Hydromorphone, Methadone, Morphine*, Oxycodone, Oxymorphone, Propoxyphene**, Tapentadol, Tramadol)*

(9 classes; 9 codes)

Federal 5

(THC, OPIATES, COC, PCP, AMP)*

(5 classes; 5 codes)

Alcohol and its Metabolites, and Alkaloids

(3 classes; 3 codes)

Behavioral and Mental Health-Related Medication

(5 classes; 5 codes)

Adjuvant Medications

(Skeletal Muscle Relaxants, Gabapentin, Pregabalin, and Non-Benzodiazepine Sedative Hypnotics)

(4 classes; 4 codes)

Designer and Synthetic non-opioids

(2 classes; 2 codes)

General Insights for Test Menu & Frequency

- Not every patient requires testing of every drug available for testing
- Baseline test menu is broader than most established patient test menus
- **Low Risk**
  - Less frequent testing and generally a more limited test menu, tailored to the individual needs of the patient; intermittent broader compliance checks
- **Moderate Risk**
  - In between low- and high-risk patients; frequency and test menu depend on individual needs of patient
- **High Medical Risk**
  - More frequent testing, but the test menu is generally more limited and tailored to the individual needs of the patient
- **High Behavioral Risk (and should they still be on opioids)?**
  - More frequent testing and generally a greater test menu that is tailored to the individual facts of the patient.

SAMPLE TEST FREQUENCY & DRUGS TESTED** - Must be tailored to your state licensing board materials, applicable coverage and reimbursement policies, and the individual patient; This is not a "one size fits all" table.

Patient OVERALL Risk Level (NOT JUST ABUSE-DIVERSION CRITERIA)	Presumptive Test	Definitive Test	Definitive TIER* (Varies)	FREQUENCY* (Varies; Check State Board Rule)
Low Risk	Yes	Rx meds and metabolites, unexpected positives, unexpected negatives, and add-on because cup cannot test or to complete/distinguish drugs in the class: REMAINING BZO, FEN, GAB, PREGAB, OPIATES, OXY	G0480 (1-7 classes)	1 to 3x year
Moderate Risk	Yes	Rx meds and metabolites, unexpected positives, unexpected negatives, and add-on of classes cup cannot test or larger classes: ANTI-PSYCHOTICS, REMAINING BZO, FENTANYL, GABAPENTIN, HYDROCODONE, OPIATE CLASS TO DISTINGUISH, OXYCODONE TO DISTINGUISH, ILLICIT CLASSES RELEVANT TO HX OR REGION, SMR, SEDHYP	Split between G0480 (1-7 classes) AND G0481 (8-14 classes), depending on all facts	3 to 4x year
High Medical Risk	Yes	Rx meds and metabolites, unexpected positives, unexpected negatives, and add-on because cup cannot test or to complete/distinguish drugs in the class: REMAINING BZO, FEN, GAB, PREGAB, OPIATES, OXY	G0480 (1-7) classes	4 to 6x year with varied nature of testing
High Behavioral Risk	Yes	Rx meds and metabolites, unexpected positives, unexpected negatives, and add-on of classes cup cannot test or larger classes: ANTI-PSYCHOTICS, REMAINING BZO, FENTANYL, GABAPENTIN, HYDROCODONE, OPIATE CLASS TO DISTINGUISH, OXYCODONE TO DISTINGUISH, ILLICIT CLASSES RELEVANT TO HX OR REGION, SMR, SEDHYP	Split between G0480 (1-7 classes) AND G0481 (8-14 classes), depending on all facts	4 to 6x per year with varied nature of testing

Documentation

- **The Test Orders must be clear and must be placed by an individual who is “authorized” to order tests.**
- The Test Orders must be for drug testing that is individualized to the patient. Standing orders (no thought in UDT) and generalized test panels used for all patients are generally problematic.
- Test Results must be used in a timely fashion.
  - If you are testing in-house, you should review the presumptive test results BEFORE you send the specimen on for definitive testing.
  - In all cases, “use of test results” means the treating provider evaluated and tied back to the ongoing treatment of the patient; requires documentation of decision-making.
  - Documentation should show the timely use and explain how the results are used in the ongoing treatment of the patient.
- Make sure patient records show careful patient risk evaluation and a drug testing plan that is randomized and tailored to the patient in terms of frequency and test menu/type.

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Indiana Pain Management Prescribing Final Rule

Adopted by the Indiana Medical Licensing Board September 25, 2014
Summary created by the Indiana State Medical Association - Updated October 25, 2016

Background

The Medical Licensing Board of Indiana (MLB) adopted an Emergency Rule on Oct. 24, 2013 that regulates physicians engaged in the practice of pain management prescribing, enforced Dec. 15, 2013, pursuant to Senate Enrolled Act 246. The Final Rule was adopted on Sept. 25, 2014. The Final Rule went into effect Nov. 6, 2014, except drug testing, which goes into effect Jan. 1, 2015. Differences between the Emergency Rule and Final Rule are designated with *. The MLB made changes to the Rule effective Sept. 21, 2016.

The Prescribing Rule

Applies only to the prescribing of opioid-containing controlled substances for pain management. (See definitions section.)

Drug Monitoring Tests (Effective Jan. 1, 2015)

*At any time the physician determines that it is medically necessary, whether at the outset of the treatment plan, or any time thereafter, a prescribing physician shall perform or order a drug monitoring test that must include a confirmatory test using a method selective enough to differentiate individual drugs within a drug class.

*In determining the medical necessity of a drug monitoring test, the physician shall consider these factors where applicable and reasonably feasible:

1. Whether there is reason to believe a patient is not taking or is diverting the opioids prescribed
2. Whether there has been no appreciable impact on the chronic pain despite being prescribed for a period of time that would generally have an impact
3. Whether there is reason to believe the patient is taking or using controlled substances other than opioids or other drugs or medications including illicit street drugs that might produce significant polypharmacological effects or have other detrimental interaction effects
4. Whether there is reason to believe patient is taking or using additional opioids not prescribed by any treating physician
5. Attempts by patient to obtain early refills of opioid-containing prescriptions
6. Number of instances when patients allege their prescriptions were lost or stolen
7. INSPECT report provides irregular or inconsistent information

Don’t forget to review your Medical Licensing Board Rule on Pain Management Prescribing (or similar); Example: INDIANA

RESOURCE AVAILABLE: https://iupui.libguides.com/Opioid/prescribing; accessed 08-18-20

INDIANA LICENSING BOARD RULE AND DRUG TESTING

8. Previous drug monitoring tests raised concerns about opioid usage
9. Necessity of verifying the patient no long has substances in their system that are not appropriate under the treatment plan
10. Patient engages in apparent aberrant behavior or shows apparent intoxication
11. Patient's opioid usage shows an unauthorized dose escalation
12. Patient is reluctant to change medications or is demanding certain medications
13. Patient refuses to participate in or cooperate with a full diagnostic work-up or examination
14. Whether a patient has a history of substance abuse
15. Patient has a health status change (e.g., pregnancy)
16. Co-morbid psychiatric diagnoses
17. Other evidence of chronic opioid use, controlled substance abuse or misuse, illegal drug use or addiction, or medication non-compliance
18. Any other factor the physician believes is relevant to making an informed professional judgment about the medical necessity of a prescription

*Physicians are required to consider all of the factors in determining whether to order/perform a drug test. However, once a physician determines that a drug test is medically necessary, any remaining factors (of the 18) that have not yet been considered do not have to be considered.

SUMMARY

Thank you!

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