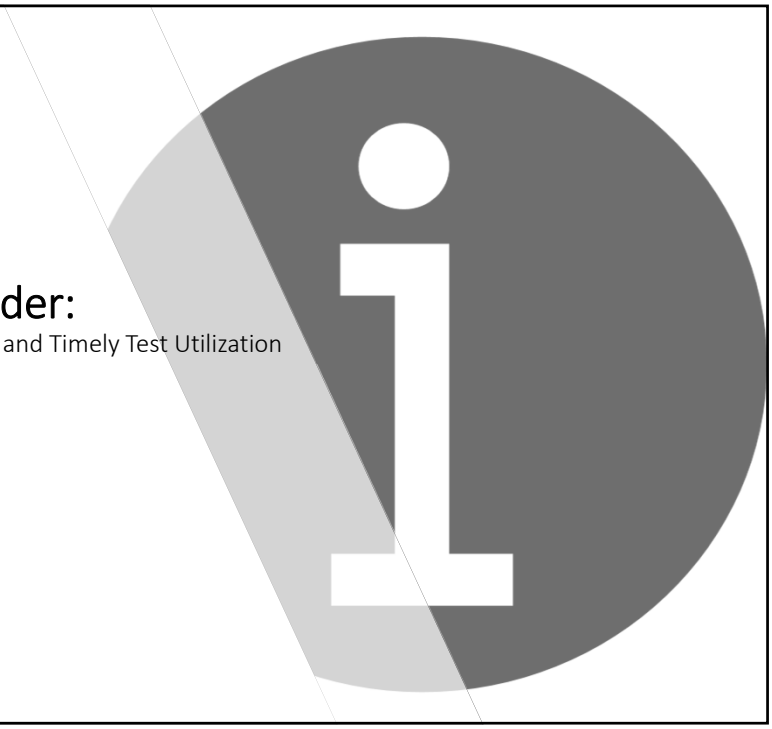
Get Your Specimens in Order:

The Importance of Individualized Test Orders and Timely Test Utilization



Jennifer Bolen, JD

Disclosures

Jennifer Bolen, JD

- Consultant to Generation Partners
- Consultant to Abbott
- Consultant to MTL Solutions, LLC
- Owner/Partner in Laboratory Revenue Partners, LLC
- Guest Speaker, Pernix Therapeutics

Course Objectives

01

Examine current fraud and inappropriate controlled substance prescribing investigations, and payer and regulatory focus on drug testing in pain management

02

Define medical necessity and identify common directives regarding individualization of patient testing and documentation of rationale for testing

03

Identify Action Steps to Improving Test Order and Utilization Process

2017-2018 signals demonstrating that investigations into drug testing tied to fraud and inappropriate prescribing will continue

- Medicare
- Commercial Payers
- State Licensing Boards
- Civil and Criminal Enforcement Cases

Medicare's Two-Pronged Approach

Part D – Controlled Substance Prescribing Investigations

Federal fraud (civil and criminal) Investigations

Medicare Part D Prescribing Investigations

Approach and Tie to Fraud Investigations Related to Drug Testing

Medicare's Position


January 5, 2017 Centers for Medicare & Medicaid Services (CMS) Opioid Misuse Strategy

CENTERS FOR
MEDICARE & MEDICAID SERVICES (CMS)
OPIOID MISUSE STRATEGY 2016

in less than two decades, yet pain reported by Americans has not changed during that time period. Now, after two decades of increasing prescriptions, nearly two million people suffer from prescription opioid use disorder. The Medicare population has among the highest and fastest-growing rates of diagnosed opioid use disorder, currently at more than 6 of every 1,000 beneficiaries.[3] For Medicaid beneficiaries, the prevalence of diagnosed opioid use disorder is even higher, at 8.7 per 1,000, a figure estimated to be over 10 times higher than in populations who receive coverage under private insurance companies.[4] Because there is no systematic policy of screening for opioid use disorder and patients are unlikely to volunteer that they are misusing their medication or are using opioids like heroin because of discrimination and stigma, these rates are likely underestimates.

CMS has made attacking this devastating epidemic a top priority and is providing help and resources to clinicians, beneficiaries, and families. This is an ongoing CMS strategy, as part of the HHS Opioid Initiative launched in March 2015,[5] to combat misuse and promote programs that support treatment and recovery support services. The CMS effort includes four priority areas:

1. *Implement more effective person-centered and population-based strategies to reduce the risk of opioid use disorders, overdoses, inappropriate prescribing, and drug diversion;*
2. *Expand naloxone use, distribution, and access, when clinically appropriate;*
3. *Expand screening, diagnosis, and treatment of opioid use disorders, with an emphasis on increasing access to medication-assisted treatment; and*
4. *Increase the use of evidence-based practices for acute and chronic pain management.*

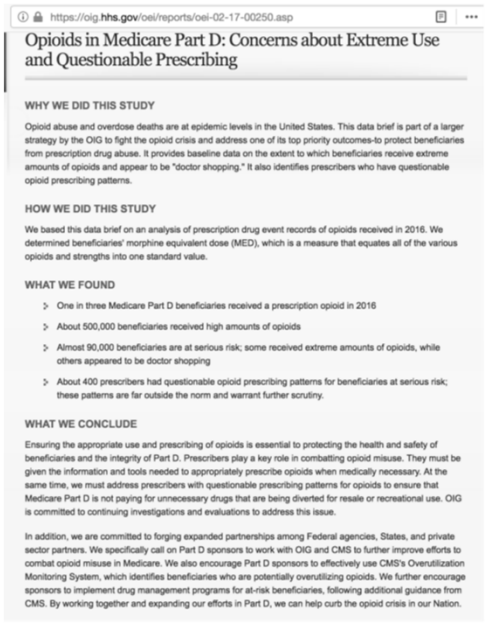
Medicare's Position

CMS PRIORITY AREAS AND VISION FOR THE FUTURE

HHS has articulated two key goals of its efforts to combat opioid misuse: (1) decreasing opioid overdoses and overall overdose mortality, and (2) decreasing the prevalence of opioid use disorder. To align with and achieve these goals, CMS convened a cross-agency working group to develop CMS's opioid strategy. CMS sought representatives from every component of the agency to ensure a broad range of expertise and perspectives. This diverse group assessed the benefits, limitations, and improvement opportunities within CMS's current policies and programs. The group then defined desired outcomes from the perspective of CMS's unique role as a leading payer of health care and identified key actions to achieve those outcomes.

HHS Priority Areas
Address opioid prescribing practices to reduce opioid use disorders and overdose
Expand use and distribution of naloxone
Expand use of medication-assisted treatment (MAT) to reduce opioid disorders and overdose

Medicare Part D – "Extreme Use and Questionable Prescribing"



https://oig.hhs.gov/oei/reports/oei-02-17-00250.asp

Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing

WHY WE DID THIS STUDY

Opioid abuse and overdose deaths are at epidemic levels in the United States. This data brief is part of a larger strategy by the OIG to fight the opioid crisis and address one of its top priority outcomes-to protect beneficiaries from prescription drug abuse. It provides baseline data on the extent to which beneficiaries receive extreme amounts of opioids and appear to be "doctor shopping." It also identifies prescribers who have questionable opioid prescribing patterns.

HOW WE DID THIS STUDY

We based this data brief on an analysis of prescription drug event records of opioids received in 2016. We determined beneficiaries' morphine equivalent dose (MED), which is a measure that equates all of the various opioids and strengths into one standard value.

WHAT WE FOUND

- One in three Medicare Part D beneficiaries received a prescription opioid in 2016
- About 500,000 beneficiaries received high amounts of opioids
- Almost 90,000 beneficiaries are at serious risk; some received extreme amounts of opioids, while others appeared to be doctor shopping
- About 400 prescribers had questionable opioid prescribing patterns for beneficiaries at serious risk; these patterns are far outside the norm and warrant further scrutiny.

WHAT WE CONCLUDE

Ensuring the appropriate use and prescribing of opioids is essential to protecting the health and safety of beneficiaries and the integrity of Part D. Prescribers play a key role in combatting opioid misuse. They must be given the information and tools needed to appropriately prescribe opioids when medically necessary. At the same time, we must address prescribers with questionable prescribing patterns for opioids to ensure that Medicare Part D is not paying for unnecessary drugs that are being diverted for resale or recreational use. OIG is committed to continuing investigations and evaluations to address this issue.

In addition, we are committed to forging expanded partnerships among Federal agencies, States, and private sector partners. We specifically call on Part D sponsors to work with OIG and CMS to further improve efforts to combat opioid misuse in Medicare. We also encourage Part D sponsors to effectively use CMS's Overutilization Monitoring System, which identifies beneficiaries who are potentially overutilizing opioids. We further encourage sponsors to implement drug management programs for at-risk beneficiaries, following additional guidance from CMS. By working together and expanding our efforts in Part D, we can help curb the opioid crisis in our Nation.

CMS and exercise of its expanded regulatory authority

Additionally, CMS is addressing the issue of drug diversion by identifying consistent thresholds across programs to flag providers as "high prescribers" and patients as "high utilizers" who may require additional scrutiny. The NBI MEDIC assists law enforcement and Part D plans in addressing drug diversion through data analysis and the Pill Mill Doctor Project results. For example, in response to requests for information from law enforcement, the NBI MEDIC conducts invoice reconciliations, impact calculations, and reviews of medical records.

Leveraging new authority in the Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act of 2015 (MACRA), CMS will continue its efforts to link fee-for-service payments to quality and value, and encourage improved prescribing practices. For example, CMS will promote methods to encourage prescribers to consult a PDMP prior to issuing a Schedule II prescription for a course lasting longer than three days, with states tailoring these methods to their existing policies. CMS also plans further development of a new measure in the Hospital Outpatient Prospective Payment System, which will report the rates and sources of concurrent prescriptions for opioids and benzodiazepines, a drug combination that places patients at high risk for respiratory depression.

CMS and Metrics for Opioid Prescribing (Part D)

Metrics

CMS is in the exploratory phase of identifying metrics to quantify and track progress in each priority area. For *priority area 1*, metrics are currently under consideration in the following areas:

For prescribers enrolled in Medicare who prescribe Part D drugs:

- Percentage of opioid prescriptions:
  - Exceeding CDC guideline of 90 morphine milligram equivalents (MME) per day
  - Exceeding 7 days of treatment
  - Written for extended release/long-acting opioids
- Percentage with beneficiaries receiving an opioid prescription without other supportive therapies/treatments

CMS and Metrics for Naloxone Use

Metrics

CMS is in the exploratory phase of identifying metrics to quantify and track progress in each priority area. For *priority area 2*, metrics are currently under consideration in the following areas:

- Percentage of naloxone prescriptions issued for beneficiaries receiving opioid prescriptions:
  - Over a certain period of time (e.g. over 90 days)
  - Over a certain dose (e.g., exceeding CDC recommended guideline), etc.
  - As a co-prescription with medication assisted treatment for opioid use disorder because these people may be vulnerable to overdose if they relapse.

For incidences in which naloxone is administered to beneficiaries, what percentage of those beneficiaries were receiving:

  - Opioid prescriptions exceeding the CDC guideline
  - Extended release/long-acting opioids
  - A concurrent benzodiazepine prescription
- Rate of naloxone administration to beneficiaries
- Institute reporting requirement for opioid-related adverse drug events (ADEs); compare data year-to-year

Commercial Payers

Changes to Medical Necessity Policies

Ongoing financial audits pertaining to drug testing utilization

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

Approach and Tie to Fraud Investigations Related to Drug Testing

Medicare Fraud in Drug Testing Investigations

Two General Test Method Categories

Presumptive Testing

Also referred to as "Screening"

- Typically immunoassay, but other test methods allowed
- Results in "positive" or "negative" values
- Has weaknesses; Testing frequency varies by payor

Definitive Testing

Also referred to as "Confirmation"

- Typically, LCMS or similar
- Quantitative Values Expressed
- Tests for more drugs; Payors more restrictive on test menu and frequency
- Subject to Drug Class Descriptors

Presumptive Drug Test Coding Framework

Waived Testing	Reader-Assisted Immunoassay	Qualified Test Methods (CLIA Registered High Complexity)
80305	80306	80307
1 unit only	1 unit only	1 unit only

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Medical Necessity: Definitive Drug Testing Tiers (G-Codes)

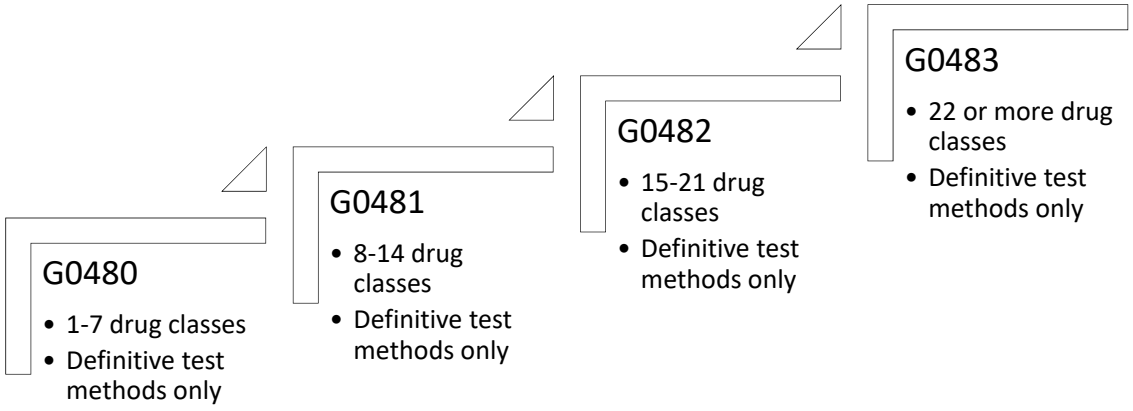

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Exhibit 5. Top 25 lab tests based on Medicare Part B payments in 2016

	Test Description (Procedure Code)*	National Limitation Amount**	Number of Tests (Millions)	Medicare Payments (Millions)	Change From 2015 Payments (Millions)
1.	Blood test, thyroid-stimulating hormone (TSH) (84443)	$22.89	21.5	$482	⬆ $7.4
2.	Blood test, comprehensive group of blood chemicals (80053)	$14.39	41.6	$470	⬆ $11.7
3.	Complete blood cell count (red blood cells, white blood cells, platelets) and automated differential white blood cell count (85025)	$10.59	42.0	$433	⬆ $5.5
4.	Blood test, lipids (cholesterol and triglycerides) (80061)	-	29.0	$411	⬆ $31.7
5.	Vitamin D_3 level (82306)	$40.33	9.0	$350	⬆ $13.3
6.	Hemoglobin A1C level (83036)	$13.22	19.3	$250	⬆ $9.8
7.	Drug test(s), definitive, per day, 22 or more drug class(es), including metabolite(s) if performed (G0483)	$215.23	1.2	$241	*New code in 2016*
8.	Drug test(s), presumptive, any number of drug classes, per date of service (G0479)	$79.25	3.0	$221	*New code in 2016*
9.	Blood test, basic group of blood chemicals (80048)	$11.52	13.7	$133	⬇ $0.7
10.	Drug test(s), definitive, per day, 15–21 drug class(es), including metabolite(s) if performed (G0482)	$166.03	0.8	$127	*New code in 2016*
11.	Parathormone (parathyroid hormone) level (83970)	$56.23	2.2	$120	⬆ $6.2
12.	Cyanocobalamin (vitamin B_{12}) level (82607)	$20.54	5.6	$113	⬆ $2.7
13.	Blood test, clotting time (85610)	$5.36	19.6	$105	⬇ $11.5
14.	PSA (prostate specific antigen) measurement (84153)	$25.06	4.2	$103	⬇ $0.1
15.	Thyroxine (thyroid chemical) measurement (84439)	$12.28	7.1	$85	⬆ $3.7
16.	Bacterial colony count, urine (87086)	$11.00	7.6	$82	⬆ $2.3
17.	Drug test(s), definitive, per day, 8–14 drug class(es), including metabolite(s) if performed (G0481)	$122.99	0.6	$73	*New code in 2016*

Definitive Drug Testing; Drug Class Descriptors (Part 1)

DRUG CLASSES USED BY AMA CPT® and CMS		
Alcohol	Benzodiazepines	Opiates
Alcohol Biomarkers	Buprenorphine	Opioids and Opiate Analogs
Alkaloids	Cannabinoids, Natural	Oxycodone
Amphetamines	Cannabinoids, Synthetic	Phencyclidine
Anti-depressants (Serotonergic)	Cocaine	Pregabalin
Anti-depressants (Tricyclic)	Fentanyl	Propoxyphene
Anti-depressants (Other)	Gabapentin	Sedative Hypnotics (Non-BZO)
Anti-epileptics	Heroin	Skeletal Muscle Relaxants
Anti-psychotics	Ketamine	Stimulants, Synthetic
Barbiturates	Methadone	Tapentadol
		Tramadol

Weaknesses in Current CPT Class Descriptors

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)

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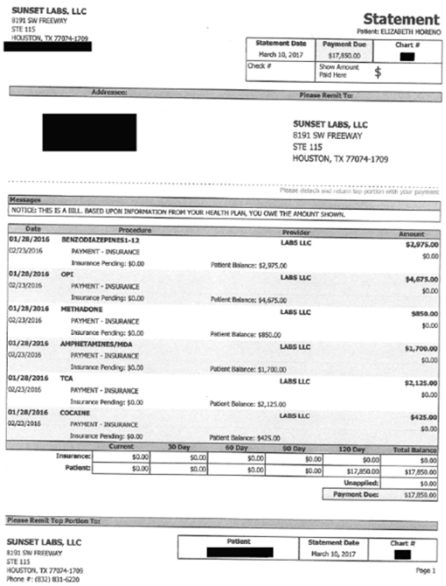
$17,850 lab bill



SUNSET LABS, LLC
8191 SW FREEWAY
STE 115
HOUSTON, TX 77074-1709

Statement
Patient: ELIZABETH MORENO

Statement Date	Payment Due	Chart #
March 10, 2017	$17,850.00	[redacted]
Check #	Show Amount Paid Here	$

Addressee: [redacted]

Please Remit To:
SUNSET LABS, LLC
8191 SW FREEWAY
STE 115
HOUSTON, TX 77074-1709

Please detach and return top portion with your payment.

Messages
NOTICE: THIS IS A BILL. BASED UPON INFORMATION FROM YOUR HEALTH PLAN, YOU OWE THE AMOUNT SHOWN.

Date	Procedure	Provider	Amount
01/28/2016	BENZODIAZEPINES1-12	LABS LLC	$2,975.00
02/23/2016	PAYMENT - INSURANCE		$0.00
	Insurance Pending: $0.00	Patient Balance: $2,975.00	
01/28/2016	OPI	LABS LLC	$4,675.00
02/23/2016	PAYMENT - INSURANCE		$0.00
	Insurance Pending: $0.00	Patient Balance: $4,675.00	
01/28/2016	METHADONE	LABS LLC	$850.00
02/23/2016	PAYMENT - INSURANCE		$0.00
	Insurance Pending: $0.00	Patient Balance: $850.00	
01/28/2016	AMPHETAMINES/MDA	LABS LLC	$1,700.00
02/23/2016	PAYMENT - INSURANCE		$0.00
	Insurance Pending: $0.00	Patient Balance: $1,700.00	
01/28/2016	TCA	LABS LLC	$2,125.00
02/23/2016	PAYMENT - INSURANCE		$0.00
	Insurance Pending: $0.00	Patient Balance: $2,125.00	
01/28/2016	COCAINE	LABS LLC	$425.00
02/23/2016	PAYMENT - INSURANCE		$0.00
	Insurance Pending: $0.00	Patient Balance: $425.00	

	Current	30 Day	60 Day	90 Day	120 Day	Total Balance
Insurance:	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Patient:	$0.00	$0.00	$0.00	$0.00	$17,850.00	$17,850.00
					Unapplied:	$0.00
					Payment Due:	$17,850.00

Please Remit Top Portion To:
SUNSET LABS, LLC
8191 SW FREEWAY
STE 115
HOUSTON, TX 77074-1709
Phone #: (832) 831-6220

Patient: [redacted] | Statement Date: March 10, 2017 | Chart #: [redacted]

Page 1

$17,850 lab bill (magnified)

Please detach and return top portion with your payment.

Messages
NOTICE: THIS IS A BILL. BASED UPON INFORMATION FROM YOUR HEALTH PLAN, YOU OWE THE AMOUNT SHOWN.

Date	Procedure	Provider	Amount
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02/23/2016	PAYMENT - INSURANCE		$0.00
	Insurance Pending: $0.00	Patient Balance: $4,675.00	
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02/23/2016	PAYMENT - INSURANCE		$0.00
	Insurance Pending: $0.00	Patient Balance: $850.00	
01/28/2016	AMPHETAMINES/MDA	LABS LLC	$1,700.00
02/23/2016	PAYMENT - INSURANCE		$0.00
	Insurance Pending: $0.00	Patient Balance: $1,700.00	
01/28/2016	TCA	LABS LLC	$2,125.00
02/23/2016	PAYMENT - INSURANCE		$0.00
	Insurance Pending: $0.00	Patient Balance: $2,125.00	
01/28/2016	COCAINE	LABS LLC	$425.00
02/23/2016	PAYMENT - INSURANCE		$0.00
	Insurance Pending: $0.00	Patient Balance: $425.00	

	Current	30 Day	60 Day	90 Day	120 Day	Total Balance
Insurance:	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Patient:	$0.00	$0.00	$0.00	$0.00	$17,850.00	$17,850.00
					Unapplied:	$0.00
					Payment Due:	$17,850.00

Massachusetts lab agrees to forfeit $1 million for unnecessary urine drug screens

Attorney General Maura Healey says Massachusetts will get more than $400,000 in the settlement.

Healey said her office began an investigation into the lab after the use of the tests was flagged by MassHealth.

Healey said besides the use of more expensive urine drug tests, her investigation also found that Precision Testing Laboratories "aggressively marketed an expensive and unnecessarily complex drug testing package to sober houses, despite the fact that they knew that the tests were for residential sobriety monitoring, a violation of MassHealth regulations."

Jepsen, also a Democrat, said Precision Testing Laboratories had promoted itself as a laboratory committed to providing urine drug testing services to those in recovery from substance abuse.

He said the lab marketed the expensive drug testing to residential drug treatment facilities and sober homes, even though they knew the facilities and homes did not provide a physician-managed drug treatment program. He said the need for drug testing at those facilities and homes was limited to ensuring sobriety as a condition of residency and that a less expensive drug test result would have sufficed.

PGX testing and Fraud/Kickbacks

U.S. Attorneys » Northern District of Texas » News

Department of Justice

U.S. Attorney's Office

Northern District of Texas

SHARE

FOR IMMEDIATE RELEASE — Thursday, January 25, 2018

Laboratory and Owner of Lab Management Services Company to Pay $3.77 Million to Resolve Kickback and Medical Necessity Claims

DALLAS - Primex Clinical Laboratories, LLC has agreed to pay $3,500,000 to resolve allegations that it violated the False Claims Act by paying kickbacks in exchange for laboratory referrals for patient pharmacogenetic testing. In a related settlement, Mitch Edland, the Chief Executive Officer and owner of DNA Stat, LLC, has agreed to pay $270,000 to resolve similar allegations. Both settlements were announced today by U.S. Attorney Erin Nealy Cox of the Northern District of Texas.

Primex Clinical Laboratories, LLC (Primex), is a licensed clinical laboratory providing clinical diagnostic testing services, including pharmacogenetic testing. DNA Stat, LLC (DNA Stat) was a laboratory management company that employed sales representatives and licensed pharmacists. Primex and DNA Stat entered into a services agreement related to pharmacogenetic testing services.

The settlement resolves allegations brought by two whistleblowers that Primex submitted claims to Medicare that were rendered false as a result of Primex and DNA Stat providing kickbacks from June 2013 through March 2016. The relators alleged several kickback schemes, including a scheme where the defendants created the appearance of paying physicians to provide clinical study data for a Primex-sponsored study related to pharmacogenetic testing when, in fact, the physicians were being paid for referring patients for the testing. The relators also alleged a scheme where the defendants provided physicians with in-office medical technicians to do work related to the Primex-sponsored study in an effort to induce those physicians to order pharmacogenetic tests from Primex. Finally, the relators alleged that the pharmacogenetic tests were not medically necessary. The United States also contends that DNA Stat's agreement with Primex as well as its agreements with its sales representatives took into account the volume and value of referrals physicians made to Primex for pharmacogenetic tests when calculating compensation.

The settlement with Primex resolves the allegations centered on providing in-office medical technicians to physicians; entering into improper sales and services agreements; and submitting claims for pharmacogenetic tests that were not medically necessary. Mr. Edland's settlement resolves all allegations against him contained in the lawsuit. Neither party admitted any wrongdoing or liability.

The qui tam, or whistleblower, lawsuit was brought by relators Don Pyburn and David Choate, former sales representatives for DNA Stat. The qui tam or whistleblower provisions of the FCA authorize private parties to sue for fraud on behalf of the United States and share in the recovery. The relators will receive $754,000.

The investigation was conducted by Health and Human Services Office of Inspector General and the FBI. The case was handled by Assistant U.S. Attorneys Dawn Whalen Theiss and Lindsey Beran.

Objective 2 –

Medical Necessity and Individualized Drug Testing

Define medical necessity and identify common directives regarding individualization of patient testing and documentation of rationale for testing

Medical Necessity – What is it?

- The American Medical Association (AMA) defines medical necessity as:
  - those services that are "reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member."
- The AMA further defines medical necessity as:
  - health care services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is:
    - (1) in accordance with generally accepted standards of medical practice;
    - (2) clinically appropriate in terms of type, frequency, extent, site, and duration; and
    - (3) not primarily for the convenience of the patient, physician, or other health care provider."

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Medical Necessity – What is it?

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- Private insurance payors may use different definitions of medical necessity that include" prevailing standards of care" or "generally accepted standards of medical practice."
  - It is the responsibility of every ordering physician or medical professional to ensure that each test ordered from a laboratory is medically necessary for the treatment of the individual for whom the test is ordered.

Cigna HealthCare Definition of Medical Necessity for other Healthcare Providers

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

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

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

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

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

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

To Prevent Denials

The following conditions must be met:

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

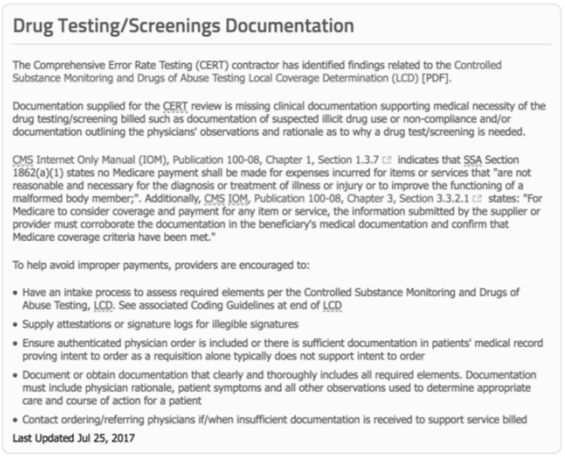
Medicare and Test Utilization

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

Resource:

MPBM, Ch. 15, § 80.1.

Example of Ongoing MAC Review of Drug Test Orders and Result Utilization (Noridian)



Drug Testing/Screenings Documentation

The Comprehensive Error Rate Testing (CERT) contractor has identified findings related to the Controlled Substance Monitoring and Drugs of Abuse Testing Local Coverage Determination (LCD) [PDF].

Documentation supplied for the CERT review is missing clinical documentation supporting medical necessity of the drug testing/screening billed such as documentation of suspected illicit drug use or non-compliance and/or documentation outlining the physicians' observations and rationale as to why a drug test/screening is needed.

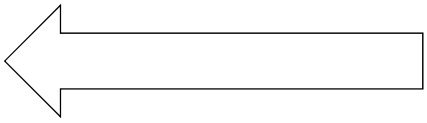
CMS Internet Only Manual (IOM), Publication 100-08, Chapter 1, Section 1.3.7 indicates that SSA Section 1862(a)(1) states no Medicare payment shall be made for expenses incurred for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member;". Additionally, CMS IOM, Publication 100-08, Chapter 3, Section 3.3.2.1 states: "For Medicare to consider coverage and payment for any item or service, the information submitted by the supplier or provider must corroborate the documentation in the beneficiary's medical documentation and confirm that Medicare coverage criteria have been met."

To help avoid improper payments, providers are encouraged to:

- Have an intake process to assess required elements per the Controlled Substance Monitoring and Drugs of Abuse Testing, LCD. See associated Coding Guidelines at end of LCD
- Supply attestations or signature logs for illegible signatures
- Ensure authenticated physician order is included or there is sufficient documentation in patients' medical record proving intent to order as a requisition alone typically does not support intent to order
- Document or obtain documentation that clearly and thoroughly includes all required elements. Documentation must include physician rationale, patient symptoms and all other observations used to determine appropriate care and course of action for a patient
- Contact ordering/referring physicians if/when insufficient documentation is received to support service billed

Last Updated Jul 25, 2017

https://med.noridianmedicare.com/web/jeb/topics/drugs-biologicals-injections/drug-testing-screenings-documentation, accessed on 2/20/18



Example – Commercial Payer and Medical Necessity

- INSERT NEW POLICY DUE OUT ON OR ABOUT 2/21/18
  - CIGNA or UNITED

Medical Necessity Checklist

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

Objective 3 – Action Steps for Providers

Identify Action Steps to Improving Test Order and Utilization Process

Action Steps - Overview

Licensing Board	Review Board Position on Opioid Prescribing
	Identify Test Menu, Frequency, and Use Directives
Professional Society Standards	Review Society Position Statements on Drug Testing in Chronic Opioid Therapy
	Identify Test Menu, Frequency, and Use Directives
Payor Coverage and Medical Policies	Identify Test Menu, Frequency, and Use Directives
	Individualize to Patients and Practice Setting

Sample State (Will be inserted based on location of PWE)

- I will gather two or three examples from states likely represented by attendees.
- Example: Arizona (Board Position, Payor Position, and Lead-In to Individualization)

Individualization: Test Menu

Drugs in Patient History (Past and Active Rx and Known Drugs of Abuse (if any)

Common Drugs of Abuse in Patient Population and Community

Test Menu

Individualization: Test Frequency

New Patient History and Risk Evaluation and Stratification

Established Patient Risk and Treatment Monitoring and Impact on Monitoring Needs

Test Frequency

GUESS WHAT?

- Licensing board and professional society guidelines DO NOT align completely on:
  - Test Menu
  - Test Frequency
  - Test Method
- So . . .
  - Put together your protocols
  - Cite your resources
  - Follow your protocols or explain why you did not apply them to a certain patient's situation

Sample Resources and Positions
(Test Frequency and Reference to Test Method)

Resource	Position on UDT	Year of Guidance/Policy
FSMB Guideline for Chronic Use of Opioid Analgesics	Periodic and Unannounced (including Chromatography). Clinical judgement trumps recommendations of frequency. Strong recommendation that if patient is in addiction treatment, test as frequently as necessary to ensure treatment adherence.	2017
American Academy of Pain Medicine	Contains more specific guidance on test menu, test frequency, and test method	2017
American Association for Clinical Chemistry	Contains more specific guidance on test menu, test frequency, and test method	2018

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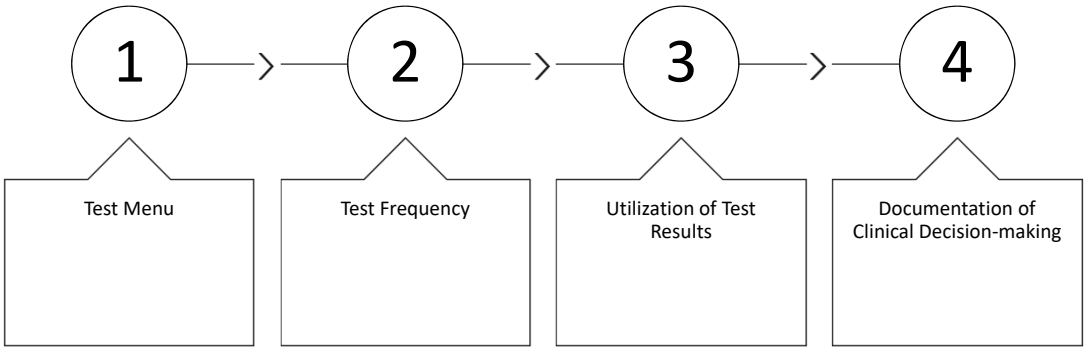
NOTE: This may vary somewhat by payer and state.

A few "how to" Recommendations on Individualizing Patient Testing

Individualization Data Points



Resources for Test Orders (Selecting Drug Classes for Testing and Testing Frequency):

Federation of State Medical Boards

American Academy of Pain Medicine, American Association for Clinical Chemistry

Medical Licensing Boards

CDC Opioid Prescribing Guidelines

FDA Materials (test manufacturer recommendations)

Individualization: Test Orders and Other Issues

Test Orders

Lab Custom Panels v. Physician Custom Profiles

Standing Orders

Patient Consent and Authorized Provider Approval

Reminder:
Standard laboratory test order forms

- Can be difficult to read
- May not help capture "individualized" testing
- May not help capture "medical necessity" beyond ICD-10 codes
- May not cultivate complete entries of other relevant data (medication match, etc.)
- Often turn physician decision-making into a "check-box" mentality, which is dangerous when it comes to controlled substance prescribing and substance use disorder treatment

Individualization: What does it look like?

Example in Chronic Pain

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

Use Drug Test Results to Guide Ongoing Treatment

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

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Physician and Patient Involvement and Responsibility

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- 1. Orders are authenticated by the ordering provider for specified timeframe
- 2. Lab results are reviewed by the ordering provider and individualized treatment plan revised as needed, based on results
- 3. Required signatures on orders and requisitions

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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Basic Checklist for Documenting Provider Review of Drug Test Results

1	2	3	4	5
Carry results forward in the patient's treatment record.	Comment as to whether patient is following the treatment plan.	Comment as to unsanctioned drug use (pain) and new evidence of drug abuse (treatment).	Discuss whether individual patient facts require variance in the nature and frequency of drug testing.	Make sure physician reviews and signs off on these clinical comments.

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Pain Management and Drug Testing

Two Quick Documentation Examples

Documentation Ideas – Pain Setting

Please answer each question	Yes	No
Is this test part of a baseline evaluation of a new patient or an established patient who is being considered for chronic opioid therapy or other long-term therapy involving controlled substances?		
Have you evaluated the patient's risk potential and documented his/her risk level?		
Is the patient prescribed (A) one or more opioids of any type (natural, semi-synthetic, synthetic), (B) combination opioid and drugs in any of these classes: Anti-depressants, Anti-epileptics, Anti-Psychotics, Non-Benzodiazepine Sedative Hypnotics (sleep medicine), Skeletal Muscle Relaxants, or (C) a drug containing buprenorphine, naloxone, or naltrexone?		
Does the patient have documented medical co-morbidities or insufficiencies relating to the hepatic, renal, or respiratory systems?		

Case Example – Jane Smith, 45 y/o female

NEW PATIENT

No history of SA

No currently using chronic opioid therapy, but has had Hydrocodone in the past for dental procedures

Scores Low Risk on Risk Assessment Questionnaire

Documentation Examples: Then and Now

Then

- UDT Today

Now

- Baseline UDT to rule out use of Rx opioids, Illicit Drugs, and Other Drugs that May Interfere with Safety of Chronic Opioid Therapy.
- Presumptive testing necessary to determine whether a short-term opioid prescription is appropriate.
- Definitive testing necessary pursuant to State Licensing Board Rule and New Patient Evaluation.
- Apply Custom Profile for New Patients

Case Example – John Road, 57 y/o male

ESTABLISHED PATIENT

No history of SA	Currently on Chronic Opioid Therapy (Morphine, 30mg TID)	Scored Low Risk on Risk Assessment Questionnaire, but has a history of using marijuana periodically	Baseline test was 6 months ago and appropriate; Last POCT Presumptive test was 2 months ago and showed THC, which was confirmed positive.

Documentation Examples: Then and Now

Then

- POCT UDT appropriate. Confirm all drugs.

Now

- Patient tested twice previously in 12 months. While patient scored low risk on questionnaire, last UDT showed confirmed positive for THC use (2 months ago). Patient is prescribed a high dose of morphine (90mg MME).
- Presumptive testing necessary to determine whether a short-term opioid prescription remains appropriate.
- Definitive testing necessary pursuant to State Licensing Board Rule and Established Patient Evaluation for Ongoing Use of Opioids. Testing frequency is appropriate given patient's prior use of THC along with Rx Opioid.
- Apply Custom Profile for Established Patients (all opioid classes, except Tapentadol and Propoxyphene); Add THC Definitive test, even if POCT negative. Definitive Test all presumptive positives and heroin, due to morphine as Rx. Add ETG to determine if patient is drinking alcohol, as this patient previously admitted to social drinking.

Documentation = "Cheese Trail"

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

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

3. Minimizes the potential for a bad outcome on an audit – whether behavioral health or lab.

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Reminder: Co-Pays and Deductibles

- Clinical laboratories are required to make good faith efforts to collect co-pays and deductibles.
  - Asking a lab not to bill your patients may put you in the "cross-hairs" of a fraud investigation.
  - Several labs are known for sending only three "statements" and offering a "wink and a nod" toward collection of co-pays and deductibles.
- Waiving co-payments and deductibles may be viewed as an inducement under the Anti-Kickback Statute (federal) and related state laws.

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Summary

Where do we go from here?

Questions?

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- Thank you!

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