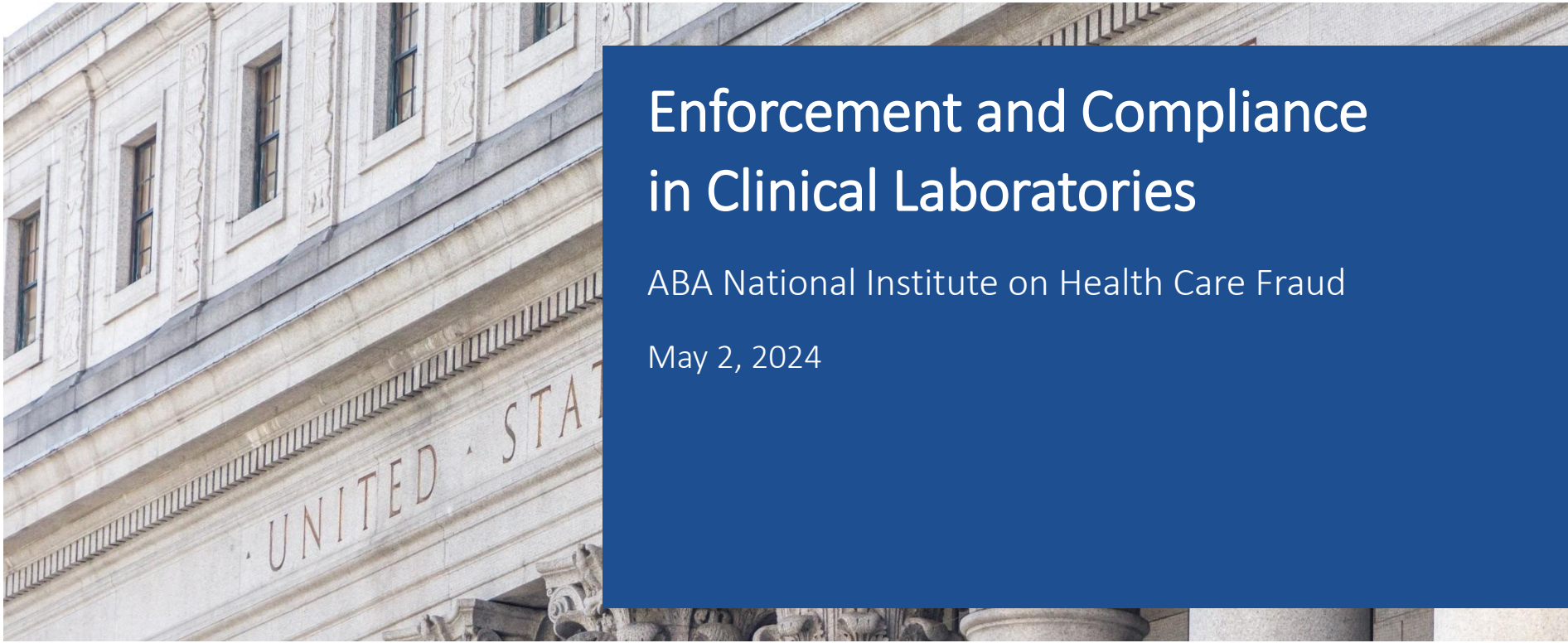

Enforcement and Compliance in Clinical Laboratories

ABA National Institute on Health Care Fraud

May 2, 2024

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DISCUSSION TOPICS

- Overview – The Laws
- Genetic Testing
- Labs in Telehealth
- COVID-19 Fraud
- Lab Kickback Issues
- Urine Drug Testing
- Looking Ahead

Overview – The Laws

- The Federal Anti-Kickback Statute ("AKS")
- The Federal False Claims Act ("FCA")
- The Federal Civil Monetary Penalties Law ("CMPL")
- The Federal Physician Self-Referral ("Stark") Law
- OIG Exclusion Authority
- The Federal Eliminating Kickbacks in Recovery Act ("EKRA")

EKRA – 18 U.S.C. § 220

- For any services covered by a health care benefit program
- Whoever knowingly and willfully
- Solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory; or
- Pays or offers any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
  - to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory; or
  - in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory
- Penalty: Fines of not more than $200,000, imprisonment of not more than 10 years, or both, for each occurrence

EKRA vs. AKS Summary

	EKRA	AKS
Applies to:	Health care benefit program business (includes private payors)	Federal health care program business (does not include exclusively private payors)
Prohibits:	Referrals of patients or patronage and in exchange for using	Referrals of individuals and arrange for/recommend purchasing etc.
Covered Referrals:	To recovery homes, clinical treatment facilities, and laboratories	For any item or services payable in whole or in part under a Federal health care program
Penalties:	Up to $200,000, 10 years imprisonment, or both	Up to $100,000, 10 years imprisonment, or both
Protection for Payments to *Bona Fide* Employees	Limited protection	Broad protection

EKRA EXCEPTIONS: EMPLOYEES AND CONTRACTORS

- EKRA exception is narrower than the AKS exception
- EKRA:
  - Payments made by an employer to *bona fide* employees and independent contractors if the payment is not determined by or does not vary by:
    - the number of individuals referred;
    - the number of tests or procedures performed; or
    - the amount billed to or received from, in part or in whole, from a health care benefit program from the individuals referred
  - Pre-2021 version of the AKS personal services and management contracts safe harbor
    - Means the aggregate compensation needs to be set in advance.
    - 2021 revision changed the requirement to the compensation methodology needs to be set in advance
- Federal AKS:
  - Payments made by an employer to *bona fide* employees for the provision of covered items and services
  - Independent contractors are covered by the personal services and management contracts SH

EKRA MARKETING CASES

S&G Labs v. Graves, 2021 WL 4847430 (D. Haw. Oct. 18, 2021)

- Employee compensation included 35% of monthly profits
- Lab terminated and employee sued for breach of contract
- Court held EKRA not apply because marketing to physicians not patients; client accounts were not individuals

US v. Schena, 2022 WL 1720083 (N.D. Cal. May 28, 2022)

- Criminal prosecution of lab president for paying kickbacks to individuals and marketing companies
- Court rejected S&G Labs, holding that "to induce a referral of an individual" includes a marketer causing an individual to obtain a referral from a physician
- Marketers received kickback to "influence" physician referrals

EKRA CASES

Southern District of Florida:

- **United States v. Bakhshi** (21-CR-60212): One Defendant charged by information with a 371 conspiracy to violate EKRA. The Defendant has pled guilty.

Central District of California:

- **United States v. Gonzalez** (21-CR-00120)**:** One defendant charged by information with one count of offering and paying kickbacks in violation of EKRA. The defendant has pled guilty.

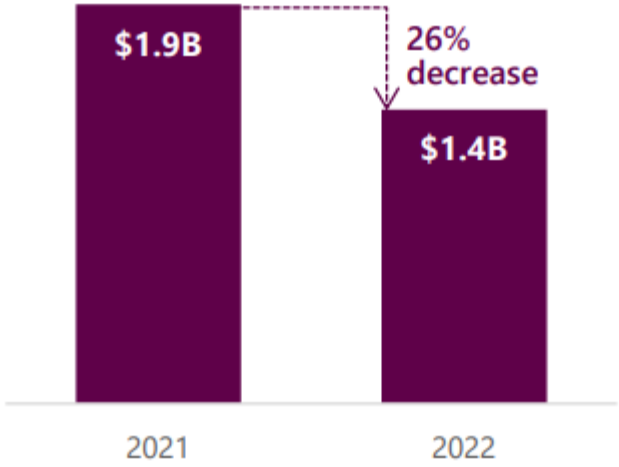
Eastern District of Kentucky:

- **United States v. Merced** (20-CR-00006): The defendant, a manager of a substance abuse treatment facility, solicited kickbacks from the CEO of a urine drug testing laboratory in exchange for the clinic's business (i.e, urine samples for tests). Defendant pled guilty in early 2020. We believe this is the first conviction for criminal EKRA charges in a case brought by the DOJ.

EKRA CASES

- From July 2020 – January 2021, with a takedown in September 2020, the Fraud Section (National Rapid Response Strike Force, Miami Strike Force, and Los Angeles Strike Force, and the United States Attorney's Office in the SDFL and CDCA), indicted four cases and charged 16 individuals.
- Three of these cases included EKRA charges:
  - **US v Markovich et al.**, 21-CR-60020 (SDFL). An approximately $112 million-dollar alleged addiction treatment fraud scheme. Charges include a 371 Conspiracy to violate EKRA, and substantive EKRA counts, against 5 Defendants for paying patients, recruiters, and laboratories kickbacks. (2 Defendants pled to a 371 Conspiracy to Violate EKRA).
  - **US v Port, et al.**, 19-CR-20583 (SDFL) Superseding indictment in an approximately $75 million alleged addiction treatment fraud scheme. Charges include a 371 Conspiracy to violate EKRA against 2 defendants, and substantive EKRA counts against 1 Defendant, involving paying patients, recruiter, and laboratories. (1 Defendant pled to a 371 Conspiracy to Violate EKRA).
  - **US v. Greiss**, 20-CR- 00131 (CDCA). Patient recruiter in Los Angeles area involving millions in billings, charged with a 371 Conspiracy to violate EKRA, and substantive counts.

GENETIC TESTING



Source: OIG analysis of 2021-2022 Medicare Part B claims data, 2023.

TOTAL SPENDING ON GENETIC TESTS DECREASED 26%. MOLECULAR PATHOLOGY TESTS DECREASED 69%

OEI-09-23-00350

OIG FRAUD ALERT: GENETIC TESTING SCAM

OIG.HHS.GOV/FRAUD/
CONSUMER-ALERTS/
ALERTS/GENETICSCAM.ASP

LABS IN TELEHEALTH

DOJ Press Release – September 27, 2019

PRESS RELEASE

Federal Law Enforcement Action Involving Fraudulent Genetic Testing Results in Charges Against 35 Individuals Responsible for Over $2.1 Billion in Losses in One of the Largest Health Care Fraud Schemes Ever Charged

Friday, September 27, 2019

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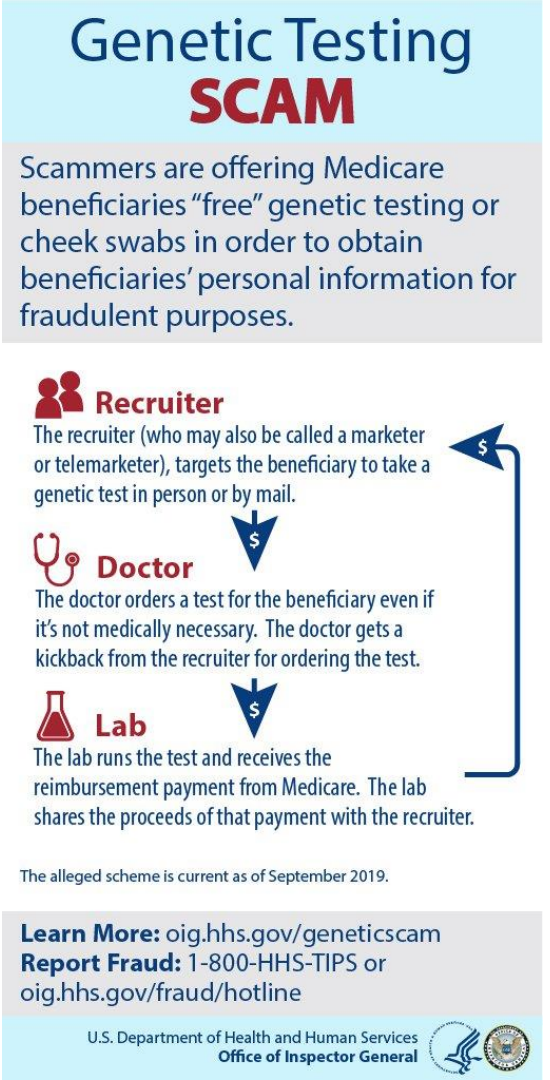
For Immediate Release

Office of Public Affairs

Case Overview

- 2019 – Indictments against 35 defendants including:
  a) Genetic testing laboratories
  b) 10 medical professionals (9 physicians)
  c) Telemedicine companies
- Kickback scheme that resulted in $2.1 billion in fraudulently billed cancer genetic tests
- Convictions or guilty pleas for 10 of 17 named in the 2019 press release



DOJ Press Release – July 20. 2022

PRESS RELEASE

Justice Department Charges Dozens for $1.2 Billion in Health Care Fraud

Wednesday, July 20, 2022

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For Immediate Release

Office of Public Affairs

Nationwide Coordinated Law Enforcement Action to Combat Telemedicine, Clinical Laboratory, and Durable Medical Equipment Fraud

The coordinated federal investigations announced today primarily targeted alleged schemes involving the payment of illegal kickbacks and bribes by laboratory owners and operators in exchange for the referral of patients by medical professionals working with fraudulent telemedicine and digital medical technology companies. Telemedicine schemes account for

DOJ Press Release – June 28, 2023

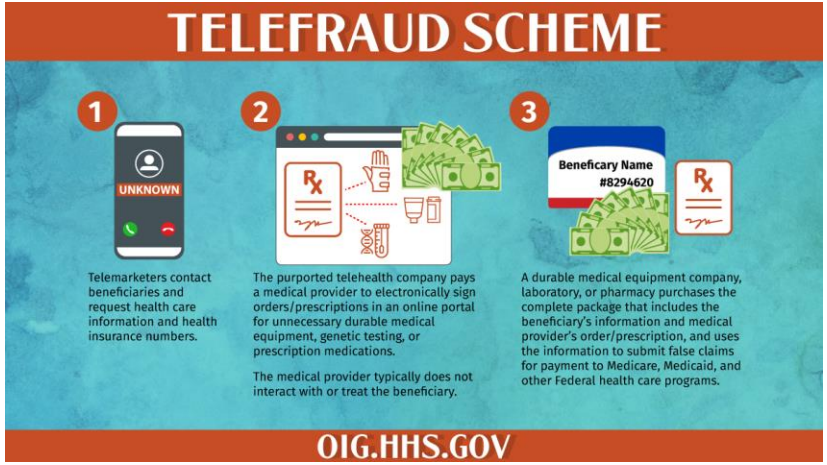
PRESS RELEASE

National Enforcement Action Results in 78 Individuals Charged for $2.5B in Health Care Fraud

Opioid Distribution and Other Types of Health Care Fraud

The charges also targeted over $150 million in false billings submitted in connection with other types of health care fraud, including the illegal distribution of opioids and clinical laboratory testing fraud. Today's enforcement action includes charges against 24 physicians and other

OIG.HHS.GOV/REPORTS-AND-PUBLICATIONS/FEATURED-TOPICS/TELEHEALTH/



OIG SPECIAL FRAUD ALERT ON TELEMEDICINE

OIG.HHS.GOV/DOCUMENTS/ROOT/1045/SFA-TELEFRAUD.PDF

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

Special Fraud Alert: OIG Alerts Practitioners To Exercise Caution When Entering Into Arrangements With Purported Telemedicine Companies

July 20, 2022

I. Introduction

The Office of Inspector General (OIG) has conducted dozens of investigations of fraud schemes involving companies that purported to provide telehealth, telemedicine, or telemarketing services (collectively, Telemedicine Companies) and exploited the growing acceptance and use of telehealth. For example, in some of these fraud schemes Telemedicine Companies intentionally paid physicians and nonphysician practitioners (collectively, Practitioners) kickbacks to generate orders or prescriptions for medically unnecessary durable medical equipment, genetic testing, wound care items, or prescription medications, resulting in submissions of fraudulent claims to Medicare, Medicaid, and other Federal health care programs. These fraud schemes vary in design and operation, and they have involved a wide range of different individuals and types of entities, including international and domestic telemarketing call centers, staffing companies, Practitioners, marketers, brokers, and others.

One common element of these schemes is the way Telemedicine Companies have used kickbacks to aggressively recruit and reward Practitioners to further the fraud schemes. Generally, the Telemedicine Companies arrange with Practitioners to order or prescribe medically unnecessary items and services for individuals (referred to here as "purported patients") who are solicited and recruited by Telemedicine Companies. In many of these arrangements, Telemedicine Companies pay Practitioners in exchange for ordering or prescribing items or services: (1) for purported patients with whom the Practitioners have limited, if any, interaction; and (2) without regard to medical necessity. Such payments are

Genetic Testing Marketing Schemes

	Date	Headline	Issue
1	9/21/2023	Nurse Practitioner Convicted of $200M Health Care Fraud Scheme	False Claims – Genetic Telemarketing
2	9/27/2023	Owner of Telemedicine Companies Pleads Guilty to $44 Million Medicare Fraud Scheme	Kickback – Genetic Telemarketing
3	10/3/2023	Convicted lab owner ordered to forfeit over $187 million in health care fraud proceeds	Kickback – Genetic Telemarketing
4	10/10/2023	Man Convicted in $67M "Doctor Chase" Genetic Testing Fraud Scheme	Kickback – Genetic Telemarketing
5	11/2/2023	Owner of Indian Marketing Company Admits Role in $11.5 Million Health Care Fraud and Kickback Scheme	Kickback – Genetic Marketing
6	12/20/2023	Mississippi Man Sentenced to 18 Months in Federal Prison on Medicare Fraud Conspiracy Charges	Kickback – Genetic Marketing
7	12/21/2023	Pharmaceutical Company Ultragenyx Agrees to Pay $6 Million for Allegedly Paying Kickbacks to Induce Claims for Its Drug Crysvita	Kickback – Genetic Marketing
8	1/24/2024	Columbia Physician Indicted for False Statements to Medicare	False Claims – Genetic Marketing
9	2/27/2024	California Man Charged in $10 Million Health Care Fraud, Wire Fraud, and Kickback Conspiracy	Kickback – Genetic Marketing
10	3/15/2024	Richland Physician, Health Care Staffing Company Agree to Pay $700,000 to Resolve False Claims Act Liability Arising from Telemedicine Scheme	Kickback – Genetic Telemarketing
11	3/26/2024	Laboratory Owner Pleads Guilty to $30M Medicare Fraud Scheme	Kickback – Genetic Marketing
12	3/28/2024	Florida Man Admits Role in $4.6 Million Kickback Scheme Related to Genetic Testing	Kickback – Genetic Marketing

Key Takeaways

- Laboratories should not make payments to (or otherwise provide a benefit to) patient recruiters or health care providers in exchange for arranging or referring genetic tests
- Genetic tests should be ordered only by a provider who is treating the patient
  - A lab that connects a patient with a telemedicine physician only so the physician can approve the test will face medical necessity scrutiny for the ordered tests
  - At minimum, ordering physicians should review the patient's medical history and consider how the test results would inform the patient's treatment

COVID-19 FRAUD

RESPIRATORY PATHOGEN PANEL TESTING

RPP TEST DETECTS CERTAIN RESPIRATORY VIRUSES AND BACTERIAL PATHOGENS

(NOT COVID-19)

SCHEME:

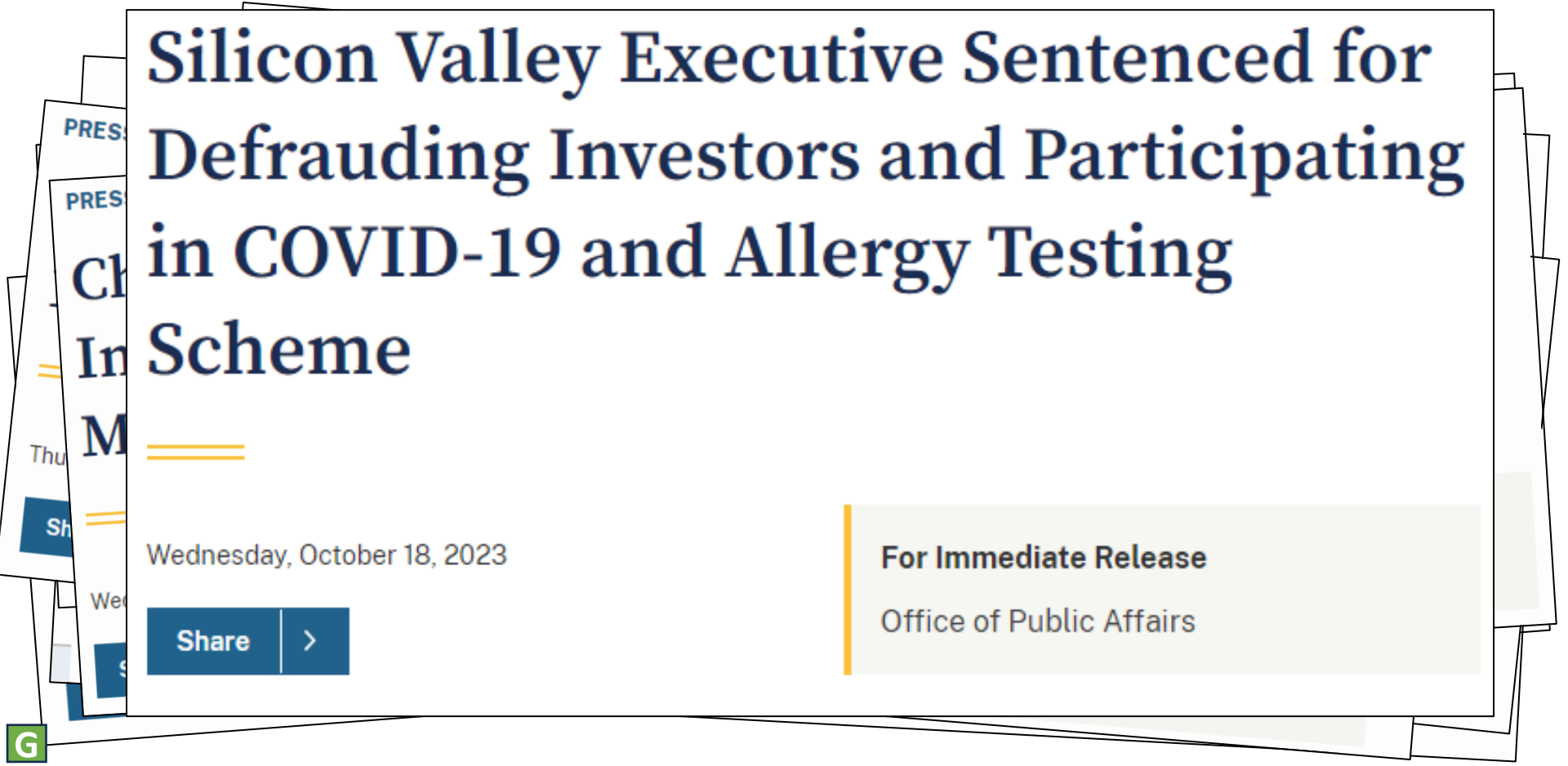
- MARKETER GETS PATIENT SWAB FOR COVID-19 TEST
- MARKETER PAYS KICKBACK TO DOCTOR
- DOCTOR ORDERS TESTS (COVID-19 AND RPP)
- LAB PAYS KICKBACKS TO MARKETER
- LAB BILLS MEDICARE FOR TESTS

Bundling COVID-19 Tests With Medically Unnecessary Genetic Tests

- 6 ½ year prison sentence for owner of laboratory who paid kickbacks and bribes to obtain doctors' orders for medically unnecessary tests
- COVID-19 tests were bundled with genetic tests for cardiovascular diseases, cancer, diabetes, obesity, Parkinson's, Alzheimer's and dementia, resulting in $6.9+ million in false claims to Medicare for medically unnecessary tests

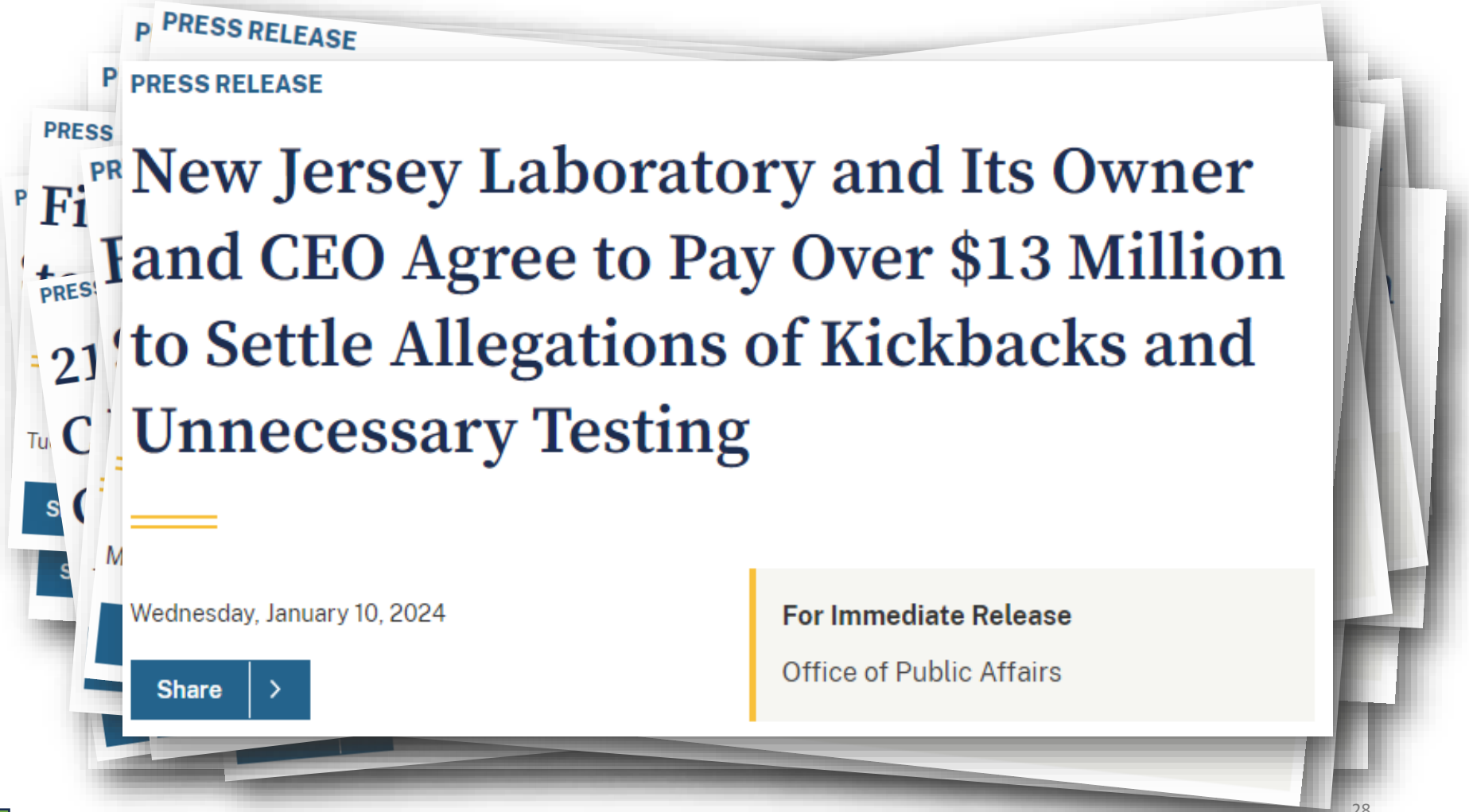
https://www.justice.gov/opa/pr/lab-owner-pleads-guilty-69-million-genetic-testing-covid-19-testing-fraud-scheme

2023 DOJ COVID Fraud Prosecutions



LAB KICKBACK ISSUES

The MSO Kickback Scheme


PRESS RELEASE
PRESS RELEASE
New Jersey Laboratory and Its Owner and CEO Agree to Pay Over $13 Million to Settle Allegations of Kickbacks and Unnecessary Testing
Wednesday, January 10, 2024
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For Immediate Release
Office of Public Affairs

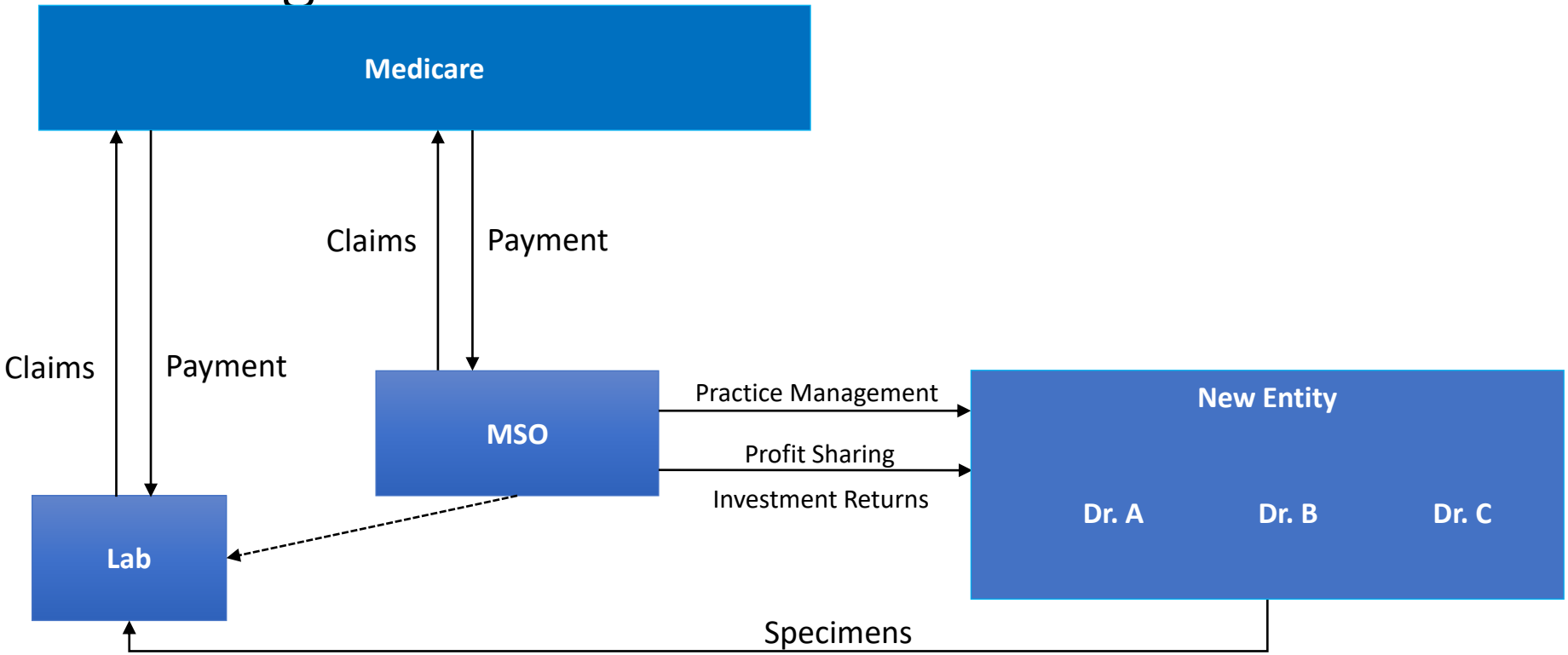
MSO Kickback Settlements

	Date	Headline	Issue
1	11/26/2019	Laboratory to Pay $26.67 Million to Settle False Claims Act Allegations of Illegal Inducements to Referring Physicians	Kickback – MSO
2	1/20/2022	Seven Texas Doctors and a Hospital CEO Agree to Pay over $1.1 Million to Settle Kickback Allegations	Kickback – MSO
3	3/22/2022	Ten Texas Doctors and a Healthcare Executive Agree to Pay over $1.68 Million to Settle Kickback Allegations	Kickback – MSO
4	4/4/2022	Justice Department Files False Claims Act Complaint Against Two Laboratory CEOs, One Hospital CEO and Others Across Texas, New York, and Pennsylvania	Kickback – MSO
5	5/26/2022	Justice Department Files False Claims Act Complaint Against Six Physicians in Texas Relating to Alleged Kickbacks and Improper Laboratory Testing Claims	Kickback – MSO
6	6/28/2022	Fifteen Texas Doctors Agree to Pay over $2.8 Million to Settle Kickback Allegations	Kickback – MSO
7	7/21/2022	21 Charged, Including Hospital and Lab CEOs, in Connection with Multistate Healthcare Kickback Conspiracy	Kickback – MSO
8	12/14/2022	Physician and Office Manager Agree to Pay Over $420,000 to Settle Kickback Allegations Involving New Jersey, Texas and South Carolina Laboratories	Kickback – MSO
9	7/20/2023	Missouri and Texas Physicians and Medical Practices Agree to Pay Over $525,000 to Settle Kickback Allegations Involving Laboratory Testing	Kickback – MSO
10	9/21/2023	Missouri Physicians and Pain Management Practices Agree to Pay Over $650,000 to Settle Kickback Allegations Involving Laboratory Testing	Kickback – MSO
11	11/2/2023	Florida Laboratory Agrees to Pay Over $1.1 Million to Settle Kickback Allegations	Kickback – MSO
12	12/4/2023	Hospital Executive and Three Texas Physicians to Pay Over $880,000 to Settle Kickback Allegations Involving Laboratory Testing	Kickback – MSO
13	1/10/2024	New Jersey Laboratory and Its Owner and CEO Agree to Pay Over $13 Million to Settle Allegations of Kickbacks and Unnecessary Testing	Kickback – MSO
14	4/1/2024	Marketers and Physicians in Five States Agree to Pay Over $1.5 Million to Settle Laboratory Kickback Allegations	Kickback – MSO

What is an MSO?

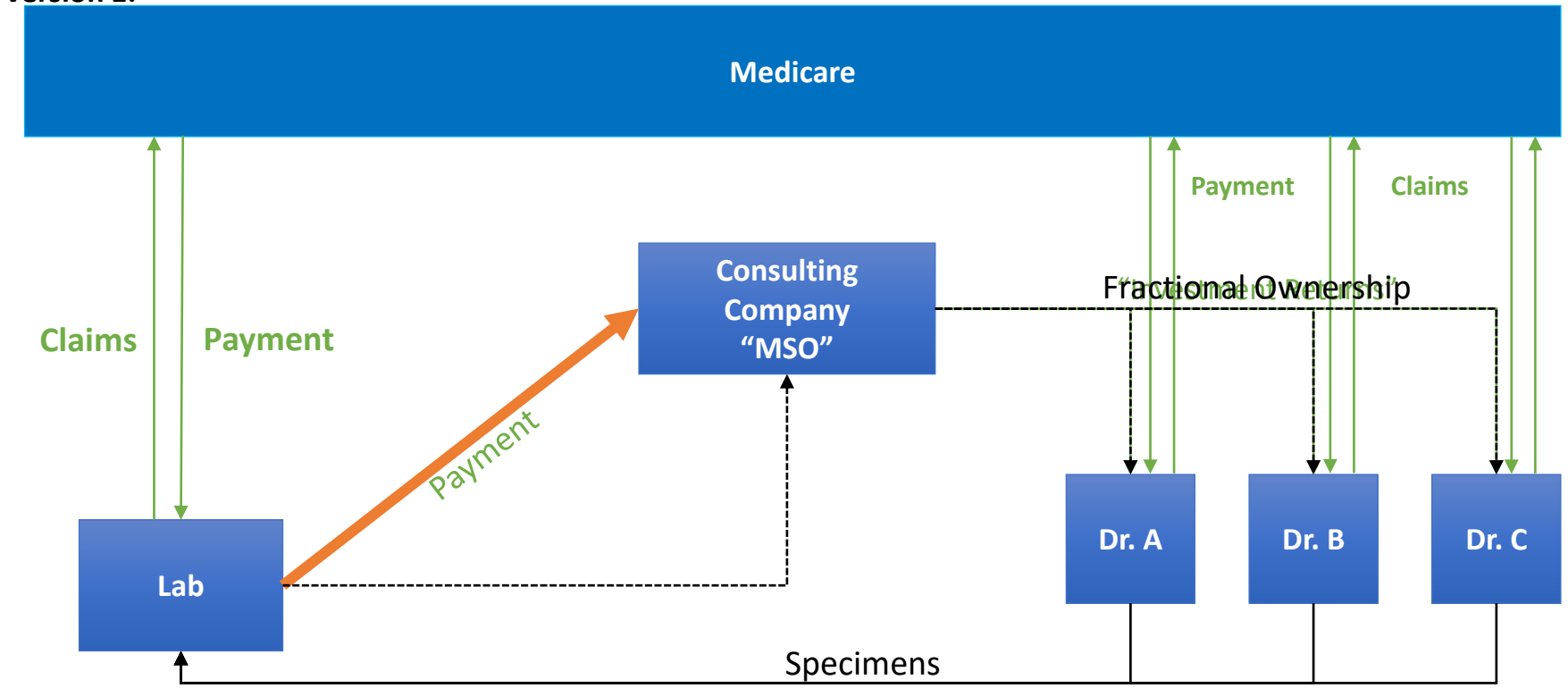
- MSO = Management Services Organization
- A legal entity that provides management services for a group of individual entities, e.g., Physician practices
- Advantage – Shared services and group purchasing
- Investment model – MSO runs the business and accounting, profit sharing

The Legitimate MSO



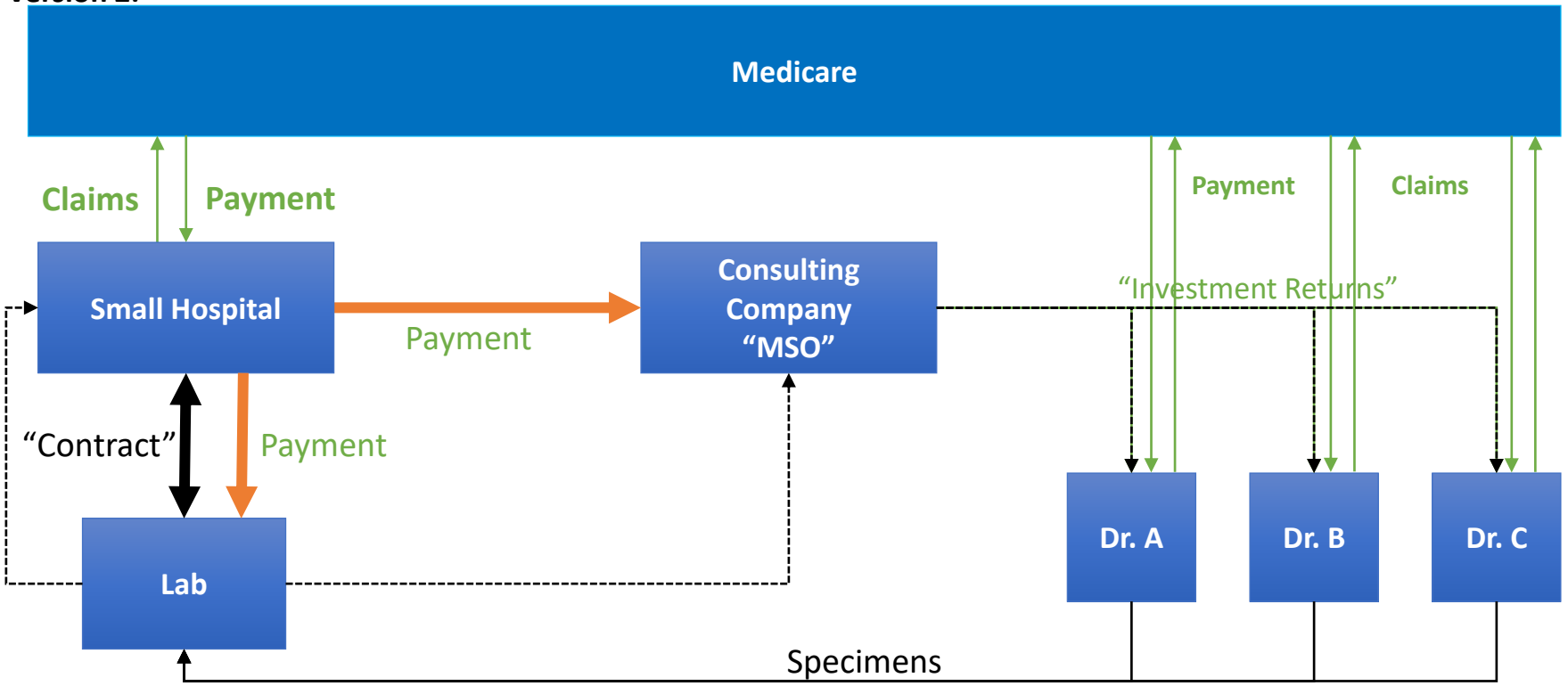
The MSO Kickback Scheme

Version 1:



The MSO Kickback Scheme

Version 2:



The Lab Rental Space Sham

PRESS RELEASE

South Carolina Physician and Nephrology Practice Agree to Pay Over $585,000 to Settle Laboratory Kickback Allegations

Friday, September 29, 2023

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For Immediate Release

Office of Public Affairs

- **Office Rent and Phlebotomy Kickbacks.** From June 2017 to December 2021, Dr. Moustafa and his practice allegedly received thousands of dollars in remuneration disguised as purported office space rental and phlebotomy payments, paid monthly or in a lump sum money order, from a clinical laboratory in Anderson, South Carolina, in return for Dr. Moustafa's laboratory referrals.

The Set-Up:

- Lab pays a practice or a *physician* to rent space in the office
- The rented space is usually labeled as:
  1. Storage space for lab testing supplies;
  2. Office space used by the lab's collectors; AND/OR
  3. A publicly available collection site that happens to be owned by the referral source
- Labs convince physicians/practices there is a contractual obligation
  - Not in the written agreement
  - Messaging from the sales representatives to secure the referrals

The Laws and Guidance:

The Anti-Kickback Statute prohibits offering, paying, soliciting, or receiving remuneration to induce referrals of items or services covered by Medicare, Medicaid, and other federally funded health care programs unless a specific exception, safe harbor, is met.

- **Space Rental Safe Harbor**
- **2000 Special Fraud Alert**
- **Physician Self-Referral Law (Stark Law)**

The Anti-Kickback Statute Safe Harbor

- No remuneration **IF** 6 requirements are met
- Requirement 4:

  The term of the lease is for not less than one year.
- Requirement 5:

  The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs.

The Space Rental Special Fraud Alert

- Full Title: Rental of Space in Physician Offices by Persons or Entities to Which Physicians Refer
- Published February 23, 2000
- Concern: The rental payments may be disguised kickbacks to physician-landlords to induce referrals
- “Threshold Inquiry” – “[W]hether payment for rent is appropriate at all.”
- “Payments of ‘rent’ for space that traditionally has been provided for free or for a nominal charge as an accommodation between the parties for the benefit of the physicians’ patients,…,may be disguised kickbacks.”

Stark Law Rental Exception

- The Stark Law prohibits a physician from referring Medicare business to a provider of designated health services (“DHS”) where the physician, or family member, has a financial relationship with the DHS provider, unless an exception is met.
- Rental of Office Space exception:
  - 7 Requirements
  - (6) “The lease arrangement would be commercially reasonable even if no referrals were made between the lessee and the lessor.”

Sham Agreement #1 – Storage of Testing Supplies

Scenario: Lab pays rent "to store the testing supplies used to send specimens to the lab" in a room or closet in the practice

- If testing is desired by the practice:
  - Supplies are needed
  - Supplies occupy space
  - Irrespective of who provides the supplies.
- Is this rental space necessary?
- Is it space that "traditionally has been provided for free"?
- If the practice stopped sending specimens, the rent would not continue
  - Solely dependent upon future referrals
  - Rental agreement is not less than a 1-year term
- **Physicians:** No payment absent the referral of the physician's specimens (Stark)
- **Conclusion:** Disguised Kickback and Stark violation

Sham Agreement #2 – Space Used By Lab Collectors

Scenario: Lab pays rent for the space used by its collectors to collect and ship specimens from the practice to the lab

- If the collectors were not there, the office staff would use the space for the drug testing collection and shipping
- The collector is relieving a burden from the practice—Paying to provide a benefit
- These labs are often not renting collector space from every practice
- Other labs do not pay rent for the space used by its collectors
- Is it space that "traditionally has been provided for free"?
- Language of SFA re: not traditionally paid for.
- If the practice stopped sending specimens, the rent would not continue
  - Solely dependent upon future referrals
  - Rental agreement is not less than a 1-year term
- **Physicians:** No payment absent the referral of the physician's specimens (Stark)
- **Conclusion:** Disguised Kickback and Stark violation

See, Appendix 6: Specimen Collection

Sham Agreement #3 – Patient Service Center

Scenario: Lab pays rent for office space that it labels a "Patient Service Center" claiming it is available to the public.

If it is available to the public, then:

- The hours and operations should be independent from the practice.
- The specimens collected should come from multiple, unpaid referral sources.
- The PSC should be publicly accessible by any patient.

Reality:

- The PSC is located inside and conjoined with the practice
- The hours of operation coincide with the practice's collection times
- All or substantially all specimens come from the physician or practice
- If the practice stopped sending specimens, the rent would not continue
  - Solely dependent upon future referrals
  - Rental agreement is not less than a 1-year term

Physicians: No payment absent the referral of the physician's specimens (Stark)

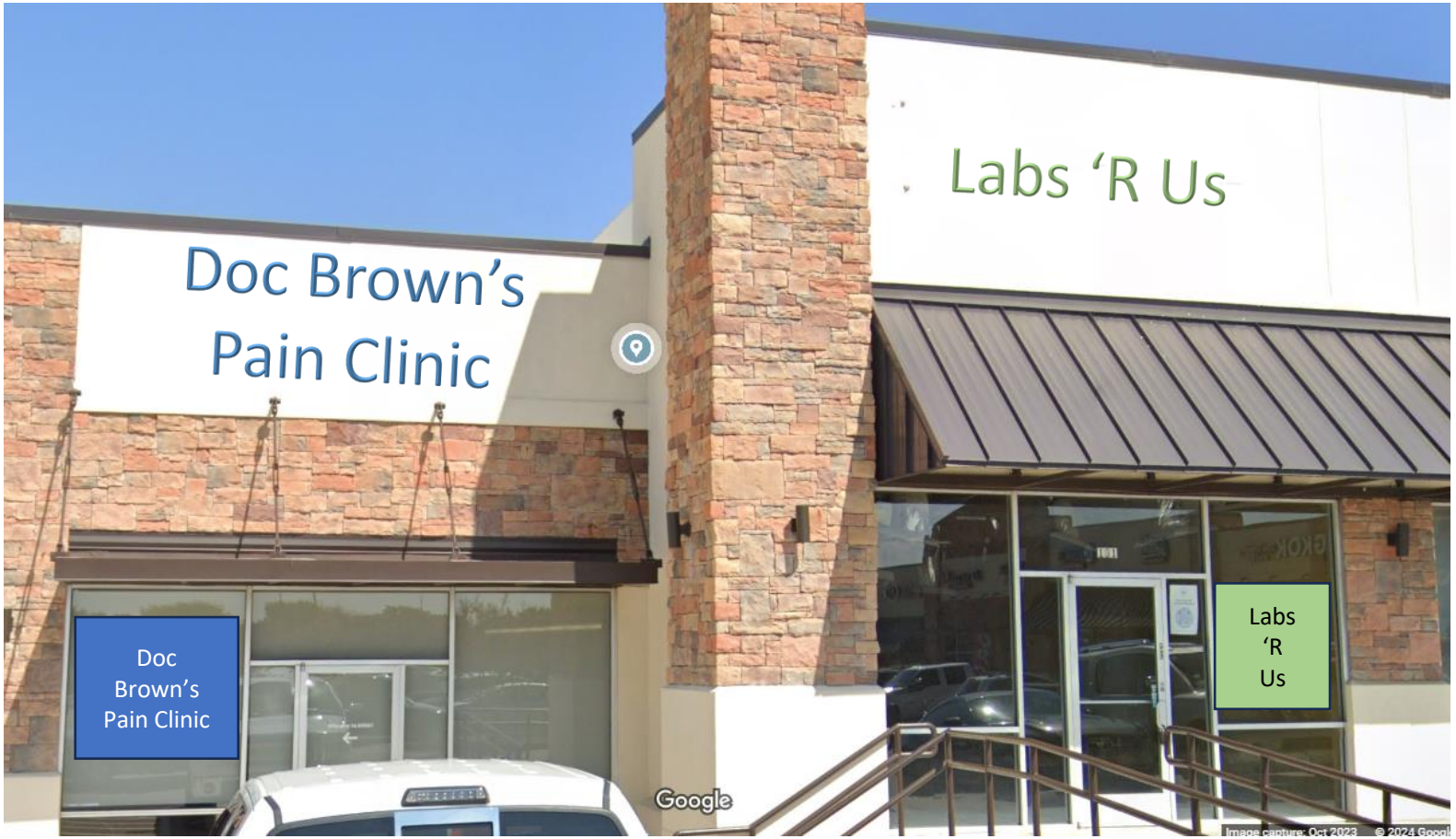
Conclusion: Disguised Kickback and Stark violation

The Legal Patient Service Center Rental:

1. A substantial number of specimens from other sources beside those receiving rental payments
2. Open to the public with access to restrooms for other patients
3. Separate facility, phone, entrance, waiting area, and signage
   - Shared space/waiting area if used by others not receiving rental payment
   - Signage consistent with other tenants
4. Independent hours of operation
5. **Foundational question:** If the physician/practice receiving the rent stopped referring specimens, would it still make business sense to rent the space?

See generally, N.Y. Comp. Codes R. & Regs. Tit. 10 § 34-2.6

The Legal Patient Service Center Rental:



URINE DRUG TESTING

Custom Profiles
And
Medical Necessity

What is a Custom Profile?

1. Allows providers to order a pre-set testing menu
   - One-time test profile for all patients
   - Pre-set test order selected for patients
2. Attraction – Simplified ordering process
3. Risk – Non-medically necessary testing
4. Greater Risk – No provider involvement in testing decisions

Custom Profiles Connection

1. ***Custom Profile Setup***

- Ordering Provider reviews test menu
- Selects drugs to be tested

2. ***Custom Profile Utilization***

- "One-click" ordering of custom profile for the provider; OR
- Lab personnel do all ordering based on custom profile

3. ***Result–***

- Every patient receives the same tests
- Typically Tier 4
- Increase in the number of specimens tested

Genotox Laboratories (4/6/23)

- $5.9 million settlement
- Submission of claims to the Federal health care programs for laboratory tests that were not covered and/or not reasonable and necessary, including blanket orders and routine standing orders of drug testing for all patients in a provider's practice.
- Admissions about offering health care providers order forms known as "custom profiles" for each provider to pre-select the tests to order, primarily at the highest reimbursement categories, such as definitive drug testing for 22 or more drug classes.

THE UNITED STATES DEPARTMENT of JUSTICE

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JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE — Tuesday, April 4, 2023

Texas Laboratory Agrees to Pay $5.9 Million to Settle Allegations of Kickbacks to Third Party Marketers and Unnecessary Drug Tests

Genotox Laboratories Ltd., of Austin, Texas, has agreed to pay at least $5.9 million to resolve False Claims Act allegations that it paid volume-based commissions to third party marketers in violation of the Anti-Kickback Statute and submitted claims to federal health care programs for unnecessary drug tests. In parallel proceedings, the U.S. Attorney's Office for the Western District of Texas and Genotox entered into an eighteen-month Deferred Prosecution Agreement to resolve a criminal investigation regarding the same conduct.

"Laboratories are prohibited from paying kickbacks to third parties to arrange for laboratory orders," said Principal Deputy Assistant Attorney General Brian M. Boynton, head of the Justice Department's Civil Division. "We will hold accountable companies that violate the rules intended to protect the integrity and resources of federal health care programs."

Office of Public Affairs | Texas Laboratory Agrees to Pay $5.9 Million to Settle Allegations of Kickbacks to Third Party Marketers and Unnecessary Drug Tests | United States Department of Justice

Custom Profiles = Ordering Shortcuts

1. What are ordering shortcuts?

"We don't have to do anything"

"We only have to click one box to order drug testing"

"We completed one form and the lab just does it"

2. Why are they okay with this?
   A. Easy/Convenient
   B. No risk…

PRESS RELEASE

Kentucky Lab Agrees to $4.9 Million Civil Judgment and Drug Treatment Center Enters Settlement to Pay $2.2 Million to Resolve False Claims Act Allegations

Relatedly, the United States entered into a settlement agreement with Edgewater Recovery Center, LLC ("Edgewater"), the drug rehabilitation facility that caused the submission of those false laboratory claims, to resolve its own False Claims Act liability. Pursuant to that settlement agreement, Edgewater will pay the Government $2.2 million.

Share

U.S. Attorney's Office, Eastern District of Kentucky

“We don’t have to do anything”

“[T]he systems put in place by Defendants resulted in urine collectors who had no medical training…exercising decision-making authority about which clients would be tested, when, and to what extent.”

“Thoroughbred’s Regional Service Representative trained the Edgewater employees on how to collect the urine samples and specifically instructed them to place the same diagnosis code…on every Thoroughbred requisition form.”

“We only have to click one box to order drug testing”

“The Government alleged that Edgewater requested the same complex panel of urine drug tests for all its patients on a weekly basis, without considering whether individual patients needed them.”

“Medicare and Kentucky Medicaid only authorize payment for laboratory testing that is individualized to each patient, is used for medical diagnosis or treatment, and is supported by a proper medical order.”

“We completed one form and the lab just does it”

“No provider reviewed a specific patient chart, considered a disease state, consulted a treatment plan, exercised medical judgment, and made a client-specific decision to order a urine drug test as a means of diagnosing or treating an addiction or other disease.”

“The tests were also not tailored to the specific needs of any particular patient/client; rather, a one-size-fits-all method of testing was applied that tended to prioritize the monetization of … testing services, over the actual care, treatment, and recovery of patients.”

Medical Necessity Monitoring

Edgewater's CIA (2024):

K. Urine Drug Testing Monitoring

1. *Urine Drug Testing Monitoring*. Edgewater shall create and maintain a report of all orders for urine drug testing by Ordering Providers (Urine Drug Testing Report). The Urine Drug Testing Report shall include at least the following information: (a) specific type of testing ordered (including, for urine drug testing, whether the testing is screening, qualitative, or quantitative and the terms for when confirmation and quantitative testing will be conducted), (b) patient's name, (c) Ordering Provider name (d) date the testing was ordered, and (e) reason the testing was ordered (including relevant diagnosis code and explanation of the diagnostic relevance of the test results).

2. *Urine Drug Testing Review*.

On a monthly basis, the Compliance Officer and Medical Director of Edgewater shall both review the Urine Drug Testing Report (Urine Drug Testing Monthly Review) to monitor, by Ordering Provider: (a) that the entries contain the required information, (b) the medical reasonableness and necessity of the testing ordered, (c) that the test results were reviewed by the Ordering Provider, and (d) that the test results were utilized in patient treatment, as appropriate, by the Ordering Provider.

On a quarterly basis, the Compliance Committee shall review the Urine Drug Testing Report to identify trends or outlier Ordering Providers for further review (Urine Drug Testing Quarterly Review), including but not limited to: (a) providers whose testing frequency, patterns, or practices appear to be beyond what is medically reasonable and necessary; (b) providers whose number of drugs included per quantitative test appears to be beyond what is medically reasonable and necessary; and (c) providers who have not regularly and timely reviewed the results of testing ordered and acted, as appropriate, to modify patient care.

In each Annual Report, Edgewater shall include a summary of the results of the Urine Drug Testing Monthly Reviews and the Urine Drug Testing Quarterly Reviews for the applicable Reporting Period, along with a response/corrective action plan to address any identified issues.

Advising Clients on Custom Profiles

1. ***Are you using a custom profile?***
   - Orders must demonstrate medical necessity AND ordering provider intent
   - Monitor testing patterns for *de facto* custom profiles
2. ***What is your Tier utilization breakdown?***
   - Monitor the ratios – Tier 4 to Tiers 1, 2, & 3
   - Is Tier 4 less than 75%?
3. ***Are you monitoring provider Tier utilization and Frequency?***
   - Periodic audits of Tier 4 vs. total tests submitted
   - Frequency compared to clinical standards
   - Is it definitely wrong?
   - Set a follow-up plan:
     - Education
     - Documentation of education and reason
4. ***How are you documenting medical necessity?***
   - Evaluate your ordering process
   - Demonstrate the evidence of ordering provider intent

LOOKING AHEAD

The Health Care Fraud Statute

18 U.S.C. 1347

Requirements:

1. Arrangement, plan, or scheme
   - Attempted or actually carried out
2. Results in fraud on ANY health care program
3. Intent to engage in the ARRANGEMENT
   - NOT intent to engage in fraud or induce a referral

"The Health Care Fraud Statute is a powerful tool that can be used by the Department of Justice to prosecute cases because it allows for ***civil or criminal*** penalties because even if the underlying intent to induce a referral cannot be proven, the mere fact that it resulted in fraud on the health care system is sufficient to give rise to civil or criminal liability."

UDT and Opioid Treatment Program Bundled Payments

- Medicare pays opioid treatment programs (OTPs) a bundled payment for services provided that is intended to compensate for toxicology testing
- If OTP does not itself perform toxicology testing, expectation is that OTP will enter into a client-bill arrangement with outside laboratory, under which the laboratory is required to submit claims to the OTP and not to Medicare for testing performed for Medicare patients (as Medicare has already paid for the service).
- Some State Medicaid programs and private payers have adopted similar models of paying OTPs

Thank you

APPENDICES

Appendix 1:
Laboratory Spending

LABORATORY SPENDING

	Test Description (Procedure Code)	2022 payment rate	2022 volume (millions)		Volume change from 2021	2022 spending (millions)
1	**COVID-19 test:** Infectious agent detection by nucleic acid for COVID-19, high-throughput (U0003)	$75.00	9.0	↓	-28.4%	$663.5
2	Blood test, comprehensive group of blood chemicals (80053)	$10.56	38.7	↓	-2.2%	$410.3
3	Blood test, lipids (80061)	$13.39	25.6	↓	-3.4%	$338.6
4	Blood test, thyroid stimulating hormone (84443)	$16.80	19.3	↓	-3.0%	$320.3
5	Complete blood cell count, automated test (85025)	$7.77	36.8	↓	-2.9%	$287.9
6	**Genetic test:** Gene analysis (colorectal cancer) (81528)	$508.87	0.5	↑	8.0%	$269.2
7	Vitamin D-3 level (82306)	$29.60	8.8	↓	-2.5%	$257.5
8	**COVID-19 test:** Infectious agent detection by nucleic acid (DNA or RNA); severe acute (U0005)	$25.00	9.9	↓	-19.3%	$244.6
9	Detection test by nucleic acid for organism (87798)	$35.09	6.5	↑	6.6%	$224.4
10	**COVID-19 test:** Any technique, high-throughput technologies (U0004)	$75.00	2.5	↓	-14.7%	$186.3
11	Hemoglobin A1C level (83036)	$9.71	18.2	↓	-2.1%	$176.2
12	Drug test(s), definitive, 22 or more drug class(es) (G0483)	$246.92	0.7	↓	-16.0%	$168.4
13	Testing for presence of drug, by chemistry analyzers (80307)	$62.14	2.3	↓	-8.0%	$142.1
14	Drug test(s), definitive, 15-21 drug class(es) (G0482)	$198.74	0.6	↓	-4.5%	$122.9
15	Parathormone (parathyroid hormone) level (83970)	$41.28	2.6	↑	3.3%	$103.3
16	**COVID-19 test:** Amplified DNA or RNA probe detection of severe acute respiratory syndrome (87635)	$51.31	1.8	↓	-8.3%	$94.8
17	**COVID-19 test:** Detection test by immunoassay technique for severe acute respiratory syndrome (87426)	$-	2.7	↑	2.2%	$93.8
18	**Genetic test:** Test for detecting genes associated with breast cancer (81519)	$3,873.00	0.02	↑	2.0%	$93.3
19	**Genetic test:** Test for detecting genes associated with cancer (81455)	$2,919.60	0.03	**New to top 25**		$91.5
20	Cyanocobalamin (vitamin B-12) level (82607)	$15.08	5.9	↑	1.3%	$87.9
21	Blood test, basic group of blood chemicals (Calcium, total) (80048)	$8.46	9.7	↓	-5.8%	$84.2
22	Drug test(s), definitive, 1-7 drug class(es) (G0480)	$114.43	0.7	↓	-4.3%	$81.8
23	**COVID-19 test:** Respiratory infectious agent detection by RNA for severe acute respiratory (0241U)	$142.63	0.6	**New to top 25**		$81.2
24	**Genetic test:** Gene analysis of 55-74 genes associated with solid organ cancer in cell-free (0242U)	$5,000.00	0.02	↑	82.7%	$80.5
25	PSA (prostate specific antigen) measurement, total (84153)	$18.39	4.2	↑	0.2%	$76.6
	Total Medicare Part B spending on the top 25 lab tests in 2022: $4.8 billion					

Sources: OIG analysis of 2021–2022 spending on lab tests in Medicare Part B, 2023. Payment rates are from the 2022 CLFS. Local Medicare Administrative Contractors are responsible for developing the payment amount for claims they receive for some newly created procedure codes until Medicare establishes national payment rates (e.g., procedure code 87426, line 17).

MEDICARE PART B SPENT $4.8 BILLION ON THE TOP 25 LAB TESTS IN 2022

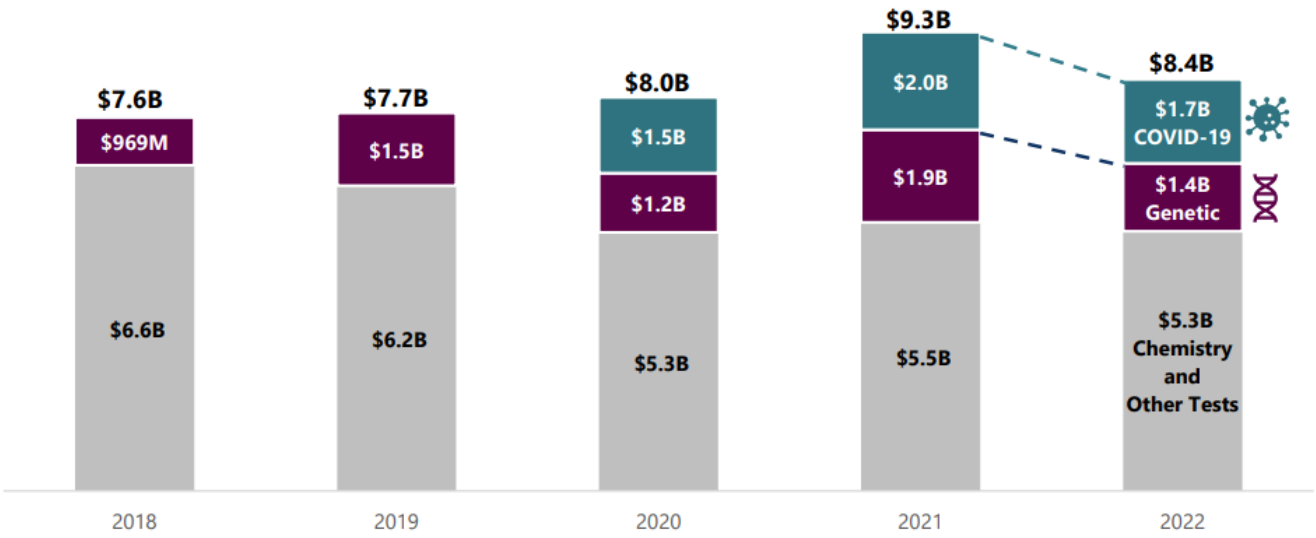
OEI-09-23-00350

**By comparison, Medicare Part B spent $5.48 billion on the top 25 lab tests in 2020.*

See OEI-09-21-00240

LABORATORY SPENDING

Medicare Part B spent less on COVID-19 and genetic tests in 2022 compared to 2021. The largest share of Medicare's Part B total spending on lab tests continued to be for chemistry and other tests.



Source: OIG analysis of 2018-2022 Medicare Part B claims data, 2023.
Because of rounding, spending in the lab test categories may not sum to the total spending for the year.

OVERALL MEDICARE PART B SPENDING *DECREASED BY 10 PERCENT* IN 2022, DRIVEN BY DECREASED TESTING VOLUMES ACROSS ALL CATEGORIES ----------

OEI-09-23-00350

Appendix 2: Telemedicine and Genetic Testing Settlement Details

Telemarketing, Telemedicine and Cancer Genetic Tests – Enforcement Action

- LabSolutions LLC and Minal Patel
  - 27-year prison sentence
  - Forfeiture of over $187 million in health care fraud proceeds
  - Includes including over $30 million seized from personal and corporate bank accounts, a 2018 Red Ferrari Spider, a 2019 Land Rover Range Rover, and real property.
- Conduct involved marketing of cancer genetic tests to Medicare beneficiaries through telemarketing campaign and health fairs activities.
- Southern District of Florida | Convicted lab owner ordered to forfeit over $187 million in health care fraud proceeds | United States Department of Justice

"The sentence also demonstrates the Criminal Division's ongoing commitment to fighting telemedicine and genetic testing fraud that exploits patients and drains health care benefit programs."

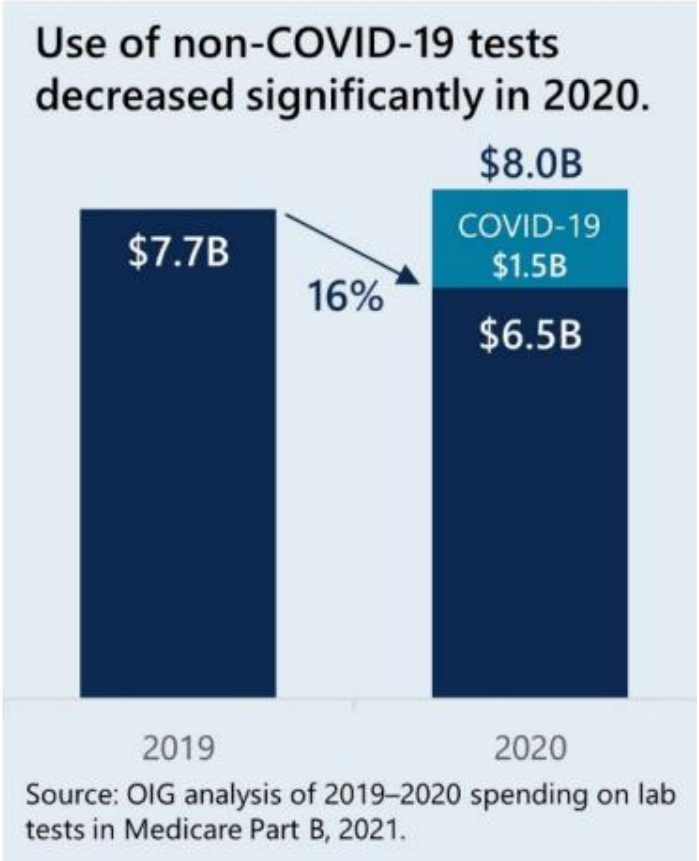
- Acting Assistant Attorney General Nicole M. Argentieri
  Criminal Division, Department of Justice

Telemedicine and Genetic Tests – Enforcement Action

- Daniel M. Carver and Louis “Gino” Carver, owner and manager of call centers engaged in deceptive telemarketing campaigns targeting Medicare beneficiaries.
- Convicted of Medicare fraud for submitting claims for medically unnecessary genetic testing and DME procured through kickbacks.
  - Pled guilty to a $67 million fraud scheme
- Kickbacks and bribes were paid to telemedicine companies for forged doctors’ and patients’ signatures.

Office of Public Affairs | Two Men Plead Guilty to $67M Medicare Fraud Scheme | United States Department of Justice

Appendix 3:
OIG COVID-19 Materials



COVID-19 TESTS DROVE AN INCREASE IN TOTAL MEDICARE PART B SPENDING ON LAB TESTS IN 2020, WHILE USE OF NON-COVID-19 TESTS DECREASED SIGNIFICANTLY

OIG.HHS.GOV/OEI/REPORTS/OEI-09-21-00240.PDF

Overview | Strategic Plan | Reports | Enforcement Actions | Policies & Guidance | Outreach

Notice
OIG COVID-19 flexibilities ended upon the expiration of the COVID-19 Declaration on May 11, 2023. For more information, see this announcement.

The emergence of COVID-19 has created unprecedented challenges for the Department of Health and Human Services (HHS) and for the delivery of health care and human services to beneficiaries. HHS leads the Federal public health and medical response during public health emergencies. **As the oversight agency for HHS, OIG promotes the effectiveness of HHS's COVID-19 response and recovery efforts.** These pages describe our COVID-19 work agency wide.

What's New

04-01-2024

- New Jersey Significantly Improved Its Oversight of Medicaid Adult Partial Care Services Except for Those Provided Using Telehealth During the COVID-19 Public Health Emergency A-02-22-01007
- IHS Did Not Coordinate Supply Service Center Operations Before and During the COVID-19 Pandemic and Should Consider Upgrading Supply Centers' Inventory Management Systems and Implementing Policies and Procedures To Enhance Coordination and Alignment A-07-22-04131

03-27-2024

- Laboratory Owner Pleads Guilty to $30M Medicare Fraud Scheme

03-14-2024

- Tulare County Man Pleads Guilty to Falsely Marketing Products as Effective in Treating Medical Conditions Including COVID-19

03-07-2024

- HRSA Made Some Potential Overpayments to Providers Under the Phase 2 General Distribution of the Provider Relief Fund Program

Resources

- Coronavirus.gov
- CDC.gov/coronavirus
- USA.gov/coronavirus
- Pandemic Response Accountability Committee

OIG
COVID 19
PORTAL

OIG.HHS.GOV/
CORONAVIRUS/
INDEX.ASP

COVID-19 Exploitation Scheme

Marketers offer beneficiaries COVID-19 tests at senior living facilities, medical offices, and other locations. While collecting samples for COVID-19 tests, **marketers suggest additional, unrelated testing** supposedly free to patients and covered by Medicare (e.g., allergy, genetic, respiratory testing).

⚠ These additional tests are medically unnecessary and far more expensive.

Fraudulent labs pay marketers to receive beneficiaries' samples and Medicare information for processing.

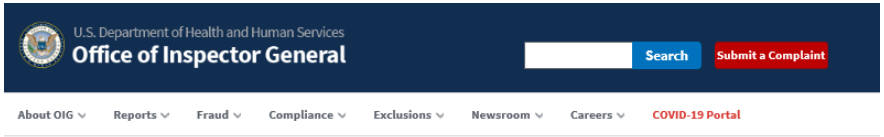
⚠ These COVID-19 test results are typically not timely or reliable. Results for the unnecessary tests are useless to the patients and their actual treating physicians.

Conspiring telemedicine providers are paid by marketers or labs to authorize referrals for the unnecessary tests. Referrals are required for Medicare payment of these tests.

⚠ If beneficiaries have consultations with these providers, appointments are brief and do not adequately validate need for testing.

Labs submit claims to Medicare and receive reimbursement for COVID-19 and additional, unrelated tests.

⚠ Medicare pays for illegitimate and inappropriate tests. Beneficiaries may be responsible for any costs of tests denied by Medicare.



Copies can also be obtained by contacting the Office of Public Affairs.

The Number of Beneficiaries Who Received Medicare Part B Clinical Laboratory Tests Decreased During the First 10 Months of the COVID–19 Pandemic

11-09-2022 | A-09-21-03004 | Complete Report | Report in Brief

Why OIG Did This Audit

Clinical laboratory (lab) tests, when used appropriately, are important because they provide health care providers with information to prevent, detect, diagnose, treat, and manage disease (including managing chronic medical conditions). These conditions have health impacts and economic costs, and prevention can reduce costs. To help contain the spread of COVID-19, Federal, State, Tribal, and local government agencies implemented community mitigation activities, including some issuing orders or advisories to residents to stay at home. These and other factors may have contributed to Medicare beneficiaries receiving fewer clinical services, including lab tests. Our preliminary analysis of lab tests billed to and paid by Medicare Part B found decreases in the number of beneficiaries who received lab tests when compared with a similar period before the pandemic.

Our objective was to identify changes in the number of beneficiaries who received Medicare Part B lab tests during the first 10 months of the COVID-19 pandemic-specifically, the number of beneficiaries who received: (1) all lab tests and (2) lab tests associated with certain chronic medical conditions (i.e., diabetes, kidney disease, and heart disease) common among Medicare beneficiaries.

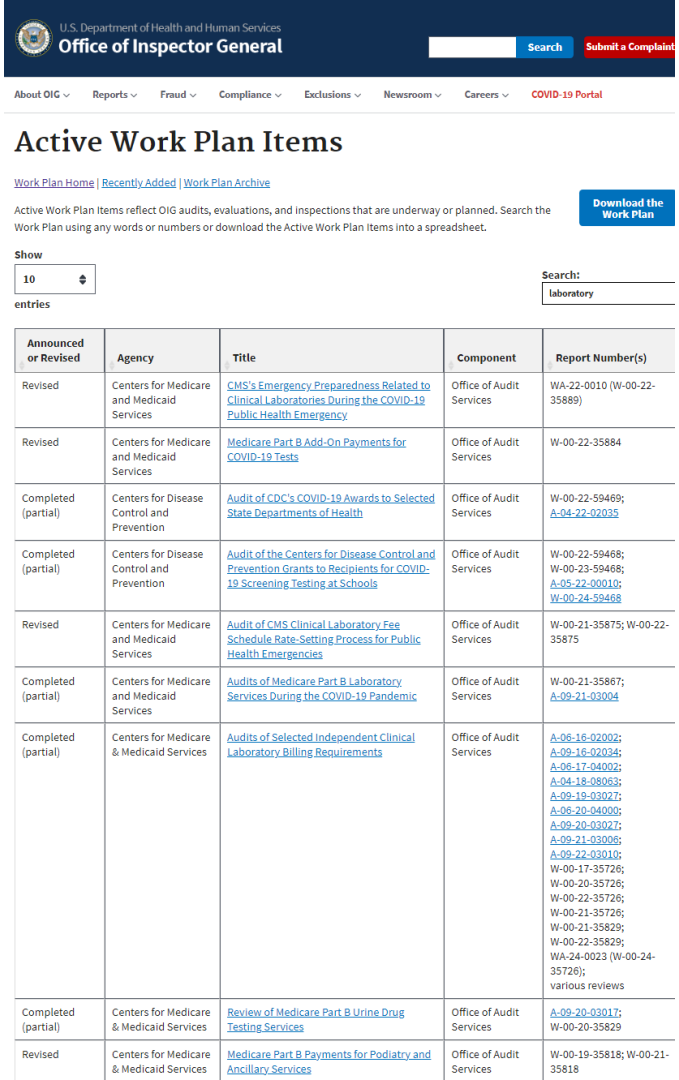
How OIG Did This Audit

Our audit covered Part B claims for lab tests provided from March through December 2019 ("pre-pandemic period") and from March through December 2020 ("pandemic period").

What OIG Found

During the pandemic period, the number of beneficiaries who received Medicare Part B lab tests decreased for: (1) all lab tests and (2) lab tests associated with certain chronic medical conditions (i.e., diabetes, kidney disease, and heart disease) common among Medicare beneficiaries. From March through December in 2016, 2017, and 2018 and for the pre-pandemic period (in 2019), the number of beneficiaries who received lab tests paid for by Medicare

OIG.HHS.GOV/OAS/REPORTS/REGION9/92103004.ASP



U.S. Department of Health and Human Services
Office of Inspector General

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Active Work Plan Items

Work Plan Home | Recently Added | Work Plan Archive

Active Work Plan Items reflect OIG audits, evaluations, and inspections that are underway or planned. Search the Work Plan using any words or numbers or download the Active Work Plan Items into a spreadsheet.

Download the Work Plan

Show 10 entries

Search: laboratory

Announced or Revised	Agency	Title	Component	Report Number(s)
Revised	Centers for Medicare and Medicaid Services	CMS's Emergency Preparedness Related to Clinical Laboratories During the COVID-19 Public Health Emergency	Office of Audit Services	WA-22-0010 (W-00-22-35889)
Revised	Centers for Medicare and Medicaid Services	Medicare Part B Add-On Payments for COVID-19 Tests	Office of Audit Services	W-00-22-35884
Completed (partial)	Centers for Disease Control and Prevention	Audit of CDC's COVID-19 Awards to Selected State Departments of Health	Office of Audit Services	W-00-22-59469; A-04-22-02035
Completed (partial)	Centers for Disease Control and Prevention	Audit of the Centers for Disease Control and Prevention Grants to Recipients for COVID-19 Screening Testing at Schools	Office of Audit Services	W-00-22-59468; W-00-23-59468; A-05-22-00010; W-00-24-59468
Revised	Centers for Medicare and Medicaid Services	Audit of CMS Clinical Laboratory Fee Schedule Rate-Setting Process for Public Health Emergencies	Office of Audit Services	W-00-21-35875; W-00-22-35875
Completed (partial)	Centers for Medicare and Medicaid Services	Audits of Medicare Part B Laboratory Services During the COVID-19 Pandemic	Office of Audit Services	W-00-21-35867; A-09-21-03004
Completed (partial)	Centers for Medicare & Medicaid Services	Audits of Selected Independent Clinical Laboratory Billing Requirements	Office of Audit Services	A-06-16-02002; A-09-16-02034; A-06-17-04002; A-04-18-08063; A-09-19-03027; A-06-20-04000; A-09-20-03027; A-09-21-03006; A-09-22-03010; W-00-17-35726; W-00-20-35726; W-00-22-35726; W-00-21-35726; W-00-21-35829; W-00-22-35829; WA-24-0023 (W-00-24-35726); various reviews
Completed (partial)	Centers for Medicare & Medicaid Services	Review of Medicare Part B Urine Drug Testing Services	Office of Audit Services	A-09-20-03017; W-00-20-35829
Revised	Centers for Medicare & Medicaid Services	Medicare Part B Payments for Podiatry and Ancillary Services	Office of Audit Services	W-00-19-35818; W-00-21-35818

WORK PLAN ITEMS INVOLVING LABORATORY SERVICES

COVID-19

OIG.HHS.GOV/REPORTS-AND-PUBLICATIONS/WORKPLAN/ACTIVE-ITEM-TABLE.ASP#EXAMPLE=FLABORATORY

Appendix 4: Commissions for Contract Sales Personnel

OIG ADVISORY OPINION 23-06

https://oig.hhs.gov/documents/advisory-opinions/1031/AO-22-09.pdf

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information, unless otherwise approved by the requestor(s).*]

Issued: September 25, 2023

Posted: September 28, 2023

[Address block redacted]

Re: OIG Advisory Opinion No. 23-06 (Unfavorable)

Dear [redacted]:

The Office of Inspector General ("OIG") is writing in response to your request for an advisory opinion on behalf of [redacted] ("Requestor") regarding the proposed purchase of the technical component of anatomic pathology services from certain laboratories (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement, if undertaken, would constitute grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (the "Act") or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act (the "Federal anti-kickback statute").

Requestor has certified that all of the information provided in the request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties in connection with the Proposed Arrangement, and we have relied solely on the facts and information Requestor provided. We have not undertaken an independent investigation of the certified facts and information presented to us by Requestor. This opinion is limited to the relevant facts presented to us by Requestor in connection with the Proposed Arrangement.

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement, if undertaken, would generate prohibited remuneration under the Federal anti-kickback statute, if the requisite intent were present, which would constitute grounds for the imposition of sanctions under sections 1128A(a)(7) and 1128(b)(7) of the Act.

Commission Payments to Contract Sales/Marketing Personnel

- United States ex rel. Lutz v. Mallory, 988 F.3d 730 (4th Cir. 2021)
- US ex rel. Nicholson v. Medcom Carolinas, Inc. (4th Cir. 2022)
- Genotox Laboratories Ltd. (2023)
  - $5.9 Million FCA settlement
  - "Genotox admitted and accepted responsibility for paying independent contractor marketers, whom Genotox referred to as "1099" representatives, a percentage of the revenue Genotox received from billing Medicare [and other FHCPs] for laboratory testing orders facilitated or arranged for by the 1099 representatives." DOJ Press Release

Appendix 5:
Specimen Collection

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

Special Fraud Alert: Laboratory Payments to Referring Physicians

June 25, 2014

Summary

This Special Fraud Alert addresses compensation paid by laboratories to referring physicians and physician group practices (collectively, physicians) for blood specimen collection, processing, and packaging, and for submitting patient data to a registry or database. OIG has issued a number of guidance documents and advisory opinions addressing the general subject of remuneration offered and paid by laboratories to referring physicians, including the 1994 Special Fraud Alert on Arrangements for the Provision of Clinical Laboratory Services, the OIG Compliance Program Guidance for Clinical Laboratories, and Advisory Opinion 05-08. In these and other documents, we have repeatedly emphasized that providing free or below-market goods or services to a physician who is a source of referrals, or paying such a physician more than fair market value for his or her services, could constitute illegal remuneration under the anti-kickback statute. This Special Fraud Alert supplements these prior guidance documents and advisory opinions and describes two specific trends OIG has identified involving transfers of value from laboratories to physicians that we believe present a substantial risk of fraud and abuse under the anti-kickback statute.

I. The Anti-Kickback Statute

One purpose of the anti-kickback statute is to protect patients from inappropriate medical referrals or recommendations by health care professionals who may be unduly influenced by financial incentives. Section 1128B(b) of the Social Security Act (the Act) makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, referrals of items or services reimbursable by a Federal health care program. When remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to 5 years, or both. Conviction will also lead to exclusion from Federal health care programs, including Medicare and Medicaid. OIG may also initiate administrative

2014 OIG SPECIAL FRAUD ALERT ON LABORATORY PAYMENTS TO REFERRING PHYSICIANS

OIG.HHS.GOV/DOCUMENTS/SPECIAL-FRAUD-ALERTS/866/OIG_SFA_LABORATORY_PAYMENTS_06252014.PDF

"When permitted by State law, a laboratory may make available to a physician's office a phlebotomist who collects specimens from patients for testing by the outside laboratory. While the mere placement of a laboratory employee in the physician's office would not necessarily serve as an inducement prohibited by the anti-kickback statute, the statute is implicated when the phlebotomist performs additional tasks that are normally the responsibility of the physician's office staff. These tasks can include taking vital signs or other nursing functions, testing for the physician's office laboratory, or performing clerical services.

Where the phlebotomist performs clerical or medical functions not directly related to the collection or processing of laboratory specimens, a strong inference arises that he or she is providing a benefit in return for the physician's referrals to the laboratory. In such a case, the physician, the phlebotomist, and the laboratory may have exposure under the anti-kickback statute. This analysis applies equally to the placement of phlebotomists in other health care settings, including nursing homes, clinics and hospitals. Furthermore, the mere existence of a contract between the laboratory and the health care provider that prohibits the phlebotomist from performing services unrelated to specimen collection does not eliminate the OIG's concern, where the phlebotomist is not closely monitored by his [of her] employer or where the contractual prohibition is not rigorously enforced."

1994 OIG SPECIAL FRAUD ALERT ON THE PROVISION OF PHLEBOTOMY SERVICES TO PHYSICIAN

OIG.HHS.GOV/DOCUMENTS/PHYSICIANS-RESOURCES/980/121994.PDF

OIG
ADVISORY
OPINION
22-09

OIG.HHS.GOV/DOCUMENTS/
ADVISORY-OPINIONS/1031/
AO-22-09.PDF

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information, unless otherwise approved by the requestor(s).*]

Issued: April 25, 2022

Posted: April 28, 2022

[Address block redacted]

Re: OIG Advisory Opinion No. 22-09

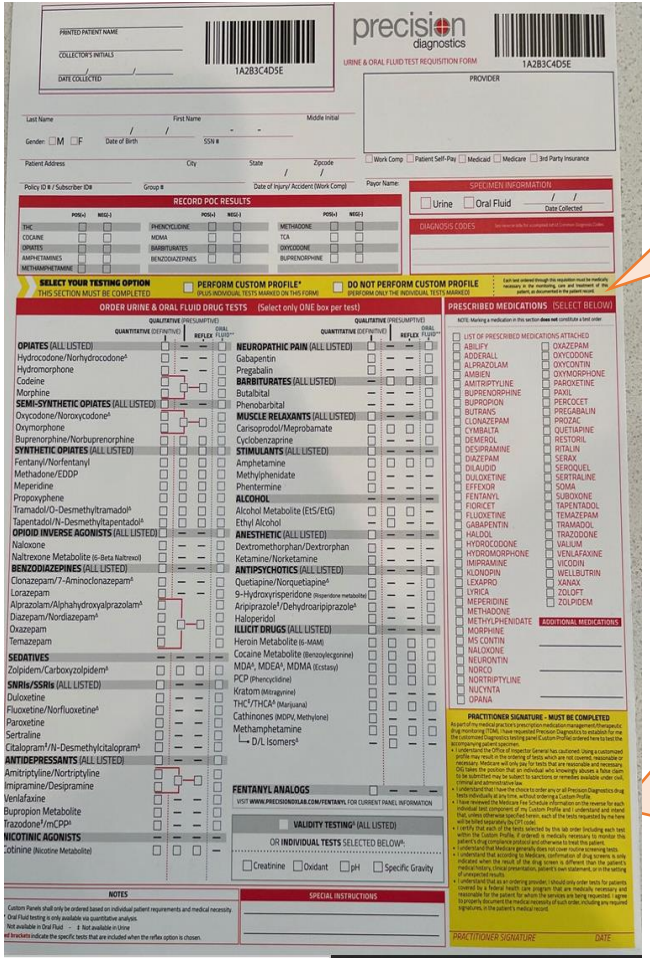
Dear [redacted]:

The Office of Inspector General ("OIG") is writing in response to your request for an advisory opinion on behalf of [redacted] ("Requestor") regarding a proposed arrangement pursuant to which Requestor would compensate hospitals for certain specimen collection services for laboratory tests furnished by Requestor (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement, if undertaken, would constitute grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (the "Act") or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act (the "Federal anti-kickback statute").

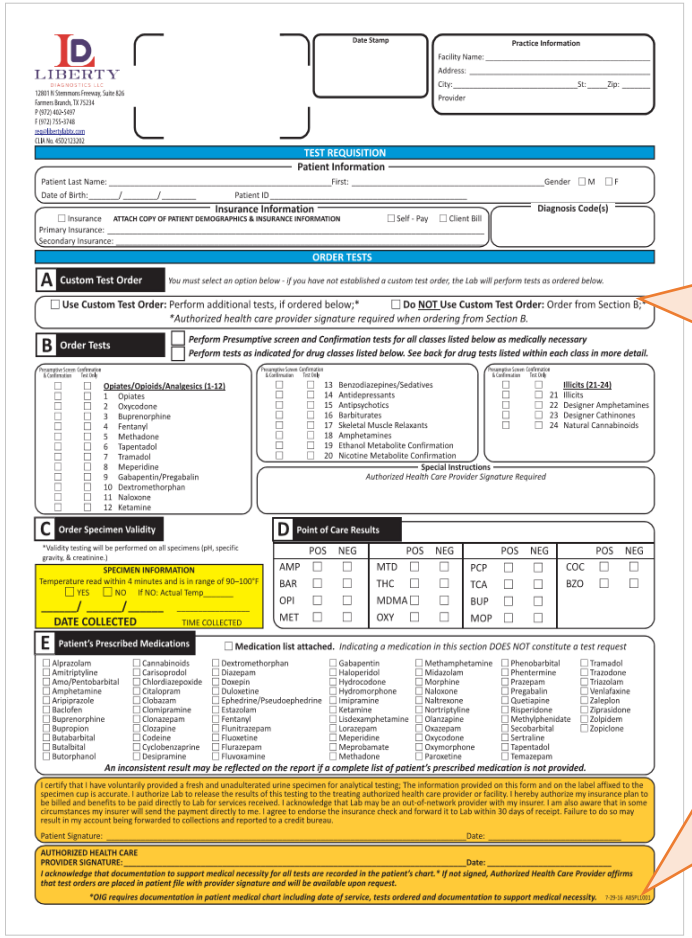
Requestor has certified that all of the information provided in the request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties in connection with the Proposed Arrangement, and we have relied solely on the facts and information Requestor provided. We have not undertaken an independent investigation of the certified facts and information presented to us by Requestor. This opinion is limited to the relevant facts presented to us by Requestor in

Appendix 6: Custom Profiles and OIG Report on Lab Testing

Custom Profile Example 1:



Custom Profile Example 2:



LIBERTY DIAGNOSTICS, LLC
12801 N Stemmons Freeway, Suite 826
Farmers Branch, TX 75234
P (972) 460-5497
F (972) 755-5748
ord@libertylabs.com
CLIA No. 45D2123282

Date Stamp

Practice Information
Facility Name:
Address:
City: St: Zip:
Provider

TEST REQUISITION

Patient Information
Patient Last Name: First: Gender ☐ M ☐ F
Date of Birth: / / Patient ID

Insurance Information
☐ Insurance ATTACH COPY OF PATIENT DEMOGRAPHICS & INSURANCE INFORMATION ☐ Self - Pay ☐ Client Bill
Primary Insurance:
Secondary Insurance:

Diagnosis Code(s)

ORDER TESTS

A Custom Test Order *You must select an option below - if you have not established a custom test order, the Lab will perform tests as ordered below.*

☐ **Use Custom Test Order:** Perform additional tests, if ordered below;* ☐ **Do NOT Use Custom Test Order:** Order from Section B;*
**Authorized health care provider signature required when ordering from Section B.*

B Order Tests
☐ *Perform Presumptive screen and Confirmation tests for all classes listed below as medically necessary*
☐ *Perform tests as indicated for drug classes listed below. See back for drug tests listed within each class in more detail.*

Presumptive Screen	Confirmation & Confirmation Test Only		
		Opiates/Opioids/Analgesics (1-12)	
☐	☐	1 Opiates	
☐	☐	2 Oxycodone	
☐	☐	3 Buprenorphine	
☐	☐	4 Fentanyl	
☐	☐	5 Methadone	
☐	☐	6 Tapentadol	
☐	☐	7 Tramadol	
☐	☐	8 Meperidine	
☐	☐	9 Gabapentin/Pregabalin	
☐	☐	10 Dextromethorphan	
☐	☐	11 Naloxone	
☐	☐	12 Ketamine	

Presumptive Screen	Confirmation & Confirmation Test Only		
☐	☐	13 Benzodiazepines/Sedatives	
☐	☐	14 Antidepressants	
☐	☐	15 Antipsychotics	
☐	☐	16 Barbiturates	
☐	☐	17 Skeletal Muscle Relaxants	
☐	☐	18 Amphetamines	
☐	☐	19 Ethanol Metabolite Confirmation	
☐	☐	20 Nicotine Metabolite Confirmation	

Presumptive Screen	Confirmation & Confirmation Test Only		
☐	☐	**Illicits (21-24)**	
☐	☐	21 Illicits	
☐	☐	22 Designer Amphetamines	
☐	☐	23 Designer Cathinones	
☐	☐	24 Natural Cannabinoids	

Special Instructions
Authorized Health Care Provider Signature Required

C Order Specimen Validity
**Validity testing will be performed on all specimens (pH, specific gravity, & creatinine.)*

SPECIMEN INFORMATION
Temperature read within 4 minutes and is in range of 90–100°F
☐ YES ☐ NO If NO: Actual Temp_____
_____/_____/_____ _____
DATE COLLECTED TIME COLLECTED

D Point of Care Results

	POS	NEG		POS	NEG		POS	NEG		POS	NEG
AMP	☐	☐	MTD	☐	☐	PCP	☐	☐	COC	☐	☐
BAR	☐	☐	THC	☐	☐	TCA	☐	☐	BZO	☐	☐
OPI	☐	☐	MDMA	☐	☐	BUP	☐	☐			
MET	☐	☐	OXY	☐	☐	MOP	☐	☐			

E Patient's Prescribed Medications ☐ **Medication list attached.** *Indicating a medication in this section DOES NOT constitute a test request*

☐ Alprazolam	☐ Cannabinoids	☐ Dextromethorphan	☐ Gabapentin	☐ Methamphetamine	☐ Phenobarbital	☐ Tramadol
☐ Amitriptyline	☐ Carisoprodol	☐ Diazepam	☐ Haloperidol	☐ Midazolam	☐ Phentermine	☐ Trazodone
☐ Amo/Pentobarbital	☐ Chlordiazepoxide	☐ Doxepin	☐ Hydrocodone	☐ Morphine	☐ Prazepam	☐ Triazolam
☐ Amphetamine	☐ Citalopram	☐ Duloxetine	☐ Hydromorphone	☐ Naloxone	☐ Pregabalin	☐ Venlafaxine
☐ Aripiprazole	☐ Clobazam	☐ Ephedrine/Pseudoephedrine	☐ Imipramine	☐ Naltrexone	☐ Quetiapine	☐ Zaleplon
☐ Baclofen	☐ Clomipramine	☐ Estazolam	☐ Ketamine	☐ Nortriptyline	☐ Risperidone	☐ Ziprasidone
☐ Buprenorphine	☐ Clonazepam	☐ Fentanyl	☐ Lisdexamphetamine	☐ Olanzapine	☐ Methylphenidate	☐ Zolpidem
☐ Bupropion	☐ Clozapine	☐ Flunitrazepam	☐ Lorazepam	☐ Oxazepam	☐ Secobarbital	☐ Zopiclone
☐ Butabarbital	☐ Codeine	☐ Fluoxetine	☐ Meperidine	☐ Oxycodone	☐ Sertraline	
☐ Butalbital	☐ Cyclobenzaprine	☐ Flurazepam	☐ Meprobamate	☐ Oxymorphone	☐ Tapentadol	
☐ Butorphanol	☐ Desipramine	☐ Fluvoxamine	☐ Methadone	☐ Paroxetine	☐ Temazepam	

An inconsistent result may be reflected on the report if a complete list of patient's prescribed medication is not provided.

I certify that I have voluntarily provided a fresh and unadulterated urine specimen for analytical testing; The information provided on this form and on the label affixed to the specimen cup is accurate. I authorize Lab to release the results of this testing to the treating authorized health care provider or facility. I hereby authorize my insurance plan to be billed and benefits to be paid directly to Lab for services received. I acknowledge that Lab may be an out-of-network provider with my insurer. I am also aware that in some circumstances my insurer will send the payment directly to me. I agree to endorse the insurance check and forward it to Lab within 30 days of receipt. Failure to do so may result in my account being forwarded to collections and reported to a credit bureau.

Patient Signature: Date:

AUTHORIZED HEALTH CARE
PROVIDER SIGNATURE: **Date:**
I acknowledge that documentation to support medical necessity for all tests are recorded in the patient's chart. If not signed, Authorized Health Care Provider affirms that test orders are placed in patient file with provider signature and will be available upon request.*
**OIG requires documentation in patient medical chart including date of service, tests ordered and documentation to support medical necessity.* 7-29-16 ABSPLL001

A Custom Test Order *You must select an option below - if you have not established a custom test order, the Lab will perform tests as ordered below.*

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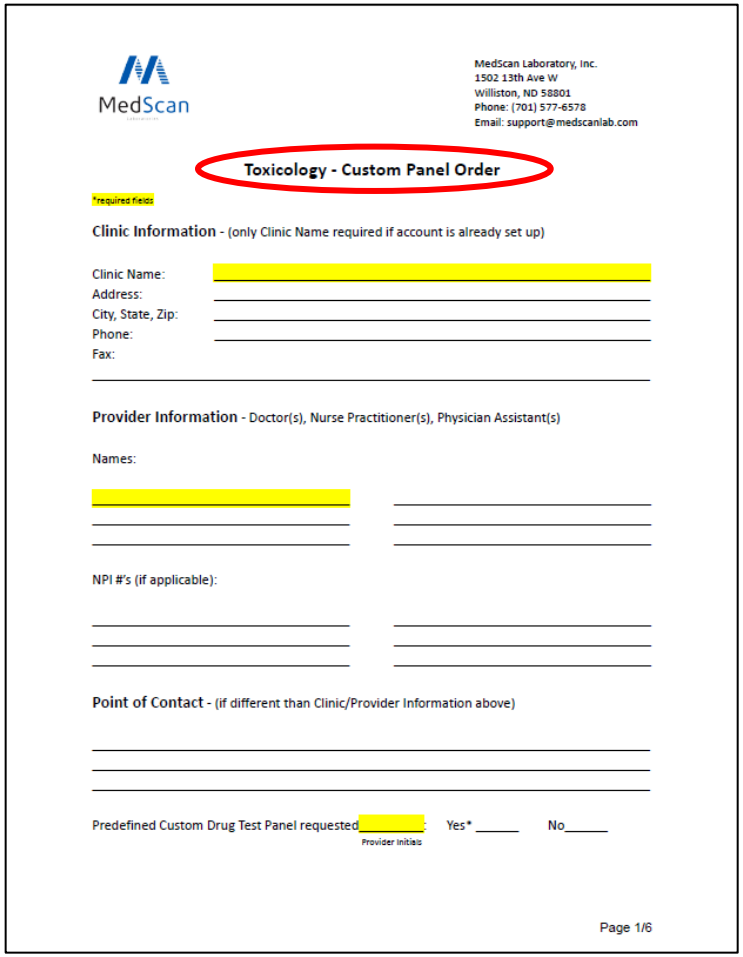
**OIG requires documentation in patient medical chart including date of service, tests ordered and documentation to support medical necessity.* 7-29-16 ABSPLL001

Custom Profile Example 3:



MedScan

MedScan Laboratory, Inc.
1502 13th Ave W
Williston, ND 58801
Phone: (701) 577-6578
Email: support@medscanlab.com

Toxicology - Custom Panel Order

*required fields

Clinic Information - (only Clinic Name required if account is already set up)

Clinic Name:
Address:
City, State, Zip:
Phone:
Fax:

Provider Information - Doctor(s), Nurse Practitioner(s), Physician Assistant(s)

Names:

NPI #'s (if applicable):

Point of Contact - (if different than Clinic/Provider Information above)

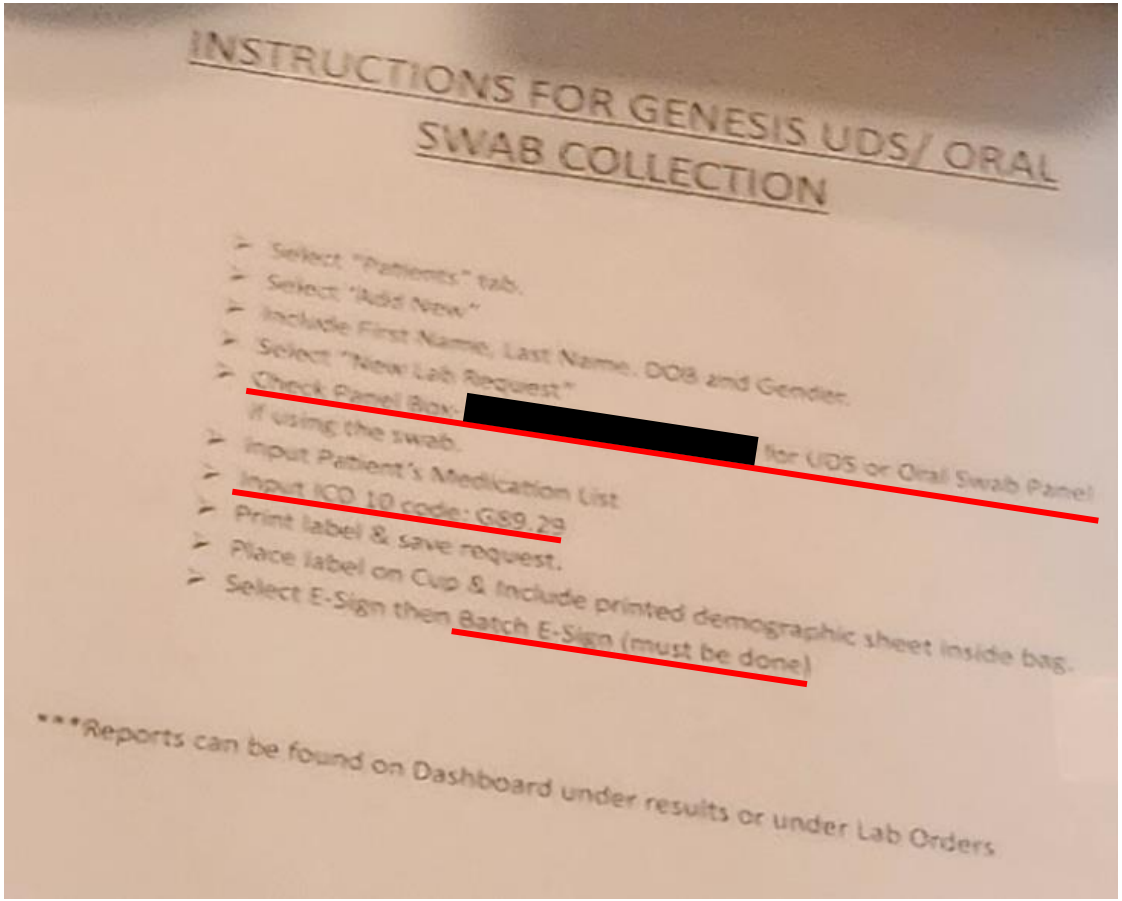
Predefined Custom Drug Test Panel requested_____: Yes* _____ No_____
Provider Initials

Page 1/6

4) When ordering tests for which Medicare reimbursement will be sought, the provider(s) understands that only tests which are medically necessary for each patient should be ordered, and that using a custom test panel may result in the ordering of tests which Medicare or other federally funded healthcare programs may deny payment;
5) The provider(s) knows of the office of Inspector General's position that a person who orders or influences the ordering of non-medically necessary test which Medicare and Medicaid reimbursement is claimed may be subjected to civil penalties under the False Claims Act;

I authorize **MedScan Laboratory Inc.** to follow the protocol listed above when conducting tests on patient samples sent to their lab from my clinic(s) unless I instruct otherwise on a signed requisition form. I believe this protocol to be medically necessary and reasonable for my patients, and I acknowledge that **MedScan Laboratory Inc.** has provided me with information regarding its policies and guidelines for qualitative and confirmatory drug screening. The signatories hereto understand there may be applicable National Coverage Determinations and Local Coverage Determinations for Clinical Laboratory Qualitative and Quantitative Drug Testing and Drugs of Abuse Testing. The start date for the ordering of this custom test panel is_____and will continue until_____or upon the creation of a new custom test panel order.

Custom Profile Example 4:



INSTRUCTIONS FOR GENESIS UDS/ ORAL SWAB COLLECTION

- Select "Patients" tab.
- Select "Add New."
- Include First Name, Last Name, DOB and Gender.
- Select "New Lab Request"
- Check Panel Box: [redacted] for UDS or Oral Swab Panel if using the swab.
- Input Patient's Medication List
- Input ICD 10 code: G89.29
- Print label & save request.
- Place label on Cup & Include printed demographic sheet inside bag.
- Select E-Sign then Batch E-Sign (must be done)

***Reports can be found on Dashboard under results or under Lab Orders

Copies can also be obtained by contacting the Office of Public Affairs.

Medicare Could Have Saved up to $216 Million Over 5 Years if Program Safeguards Had Prevented At-Risk Payments for Definitive Drug Testing Services

02-27-2023 | A-09-21-03006 | Complete Report | Report in Brief

Why OIG Did This Audit

Drug testing is generally used to detect the presence or absence of drugs in patients undergoing treatment for pain management or substance use disorders. Medicare payments for definitive drug testing services increase based on the number of drug classes tested. The Centers for Medicare & Medicaid Services (CMS) identified overpayments for the definitive drug testing service with the highest reimbursement amount (procedure code G0483, definitive drug testing for 22 or more drug classes) due to noncompliance with Medicare requirements. In addition, a prior OIG report on drug testing services identified that payments for G0483 were at risk for overpayments.

Our objective was to identify Medicare Part B payments for definitive drug testing services that were at risk for noncompliance with Medicare requirements.

How OIG Did This Audit

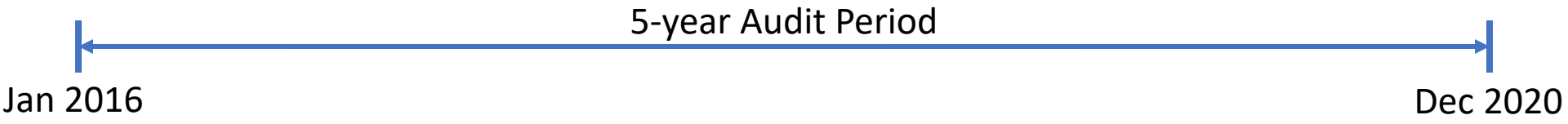
Our audit covered $3 billion in Medicare Part B payments for definitive drug testing services with dates of service from January 2016 through December 2020 (audit period). These payments were made to 1,062 "at-risk providers," which routinely billed procedure code G0483 (for 75 percent or more of their definitive drug testing services), and 4,227 "other providers," which did not routinely bill this service. We compared characteristics of the at-risk providers and other providers.

What OIG Found

For the 5-year audit period, Medicare paid $704.2 million for definitive drug testing services that were at risk for noncompliance with Medicare requirements. Specifically, these payments were for the definitive drug testing service with the highest reimbursement amount (procedure code G0483). These payments were made to 1,062 at-risk providers that routinely billed this procedure code and may not have been reasonable and necessary. We determined that presumptive drug testing preceded most definitive drug testing services billed by both the at-

OIG.HHS.GOV/OAS/REPORTS/REGION9/92103006.ASP

Understanding the Headline:



$3 billion Medicare payments for Definitive Drug Testing
17.1 million definitive drug tests
8,663 providers*

At-Risk Providers	Other Providers
• 1,062 Providers*	• 4,227 Providers*
• Routinely (>75%) billed G0483	• Did not routinely (<75%) bill G0483
• $760.8M paid for 3.4M Drug Tests	• $2.2B paid for 13.7M Drug Tests
• Total paid for G0483: $704.2M	• Total paid for G0483: $676M

* - The report focused on the At-Risk Providers (1,062) and Other Providers (4,227). The remaining 3,374 providers were removed because they did not receive at least $5,000 for definitive drug testing during the audit period. The total paid to these not included providers was $3.6 million.

Urine Drug Testing Tiered Pricing Model

1. Introduced by CMS in 2016
2. Four tiers for payment:
   - G0480 (Tier 1) – 1 to 7 “Drug Classes”
   - G0481 (Tier 2) – 8 to 14 “Drug Classes”
   - G0482 (Tier 3) – 15 to 21 “Drug Classes”
   - G0483 (Tier 4) – 22 or more “Drug Classes”
3. Tiers – Intended to reflect the additional cost with more tests
4. “Drug Classes” are defined by AMA coding book, NOT pharmacologic drug class

   Example 1: All benzodiazepines are one Drug Class

   Example 2: Ordering all pharmacologic opioids would be 8 Drug Classes

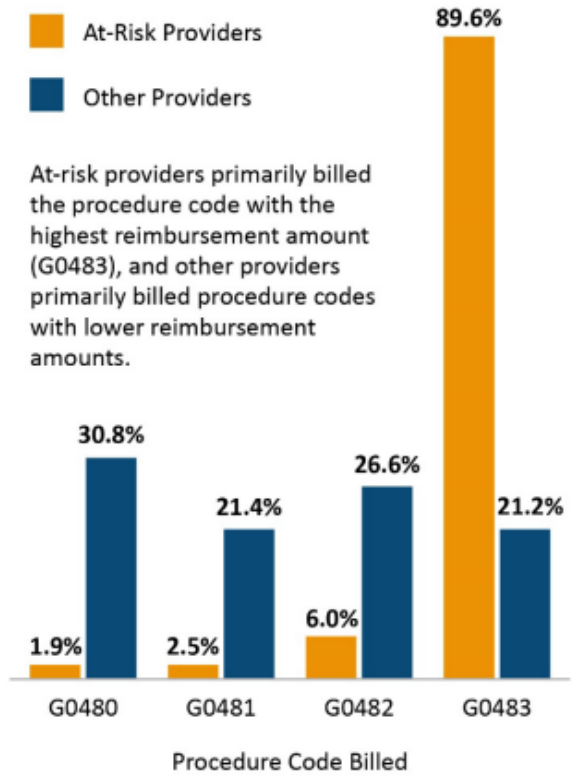
   Example 3: THC, Heroin, Cocaine, Spice, MDMA are individual Drug Classes

Potential Medicare Savings if At-Risk Providers Had Billed the Same Percentage of Definitive Drug Testing Services With Lower Reimbursement Amounts as Other Providers

Figure 5: Potential Medicare Savings if At-Risk Providers Had Billed the Same Percentage of Definitive Drug Testing Services With Lower Reimbursement Amounts as Other Providers

Payments to At-Risk Providers			Revised Payments to At-Risk Providers		
Procedure Code	Total Payments		Procedure Code	Revised Total Payments	
G0480	$6,599,893		G0480	$106,247,325	
G0481	12,145,078	VS	G0481	105,180,977	
G0482	37,897,433		G0482	166,873,489	Potential Medicare Savings
G0483	704,157,430		G0483	166,658,631	
Total	$760,799,834		Total	$544,960,422	$215,839,412

Figure 1: Percentage of Definitive Drug Testing Services That At-Risk and Other Providers Billed to Medicare Using Each Procedure Code



PERCENTAGE OF DEFINITIVE DRUG TESTING SERVICES THAT AT-RISK AND OTHER PROVIDERS BILLED TO MEDICARE USING EACH PROCEDURE CODE

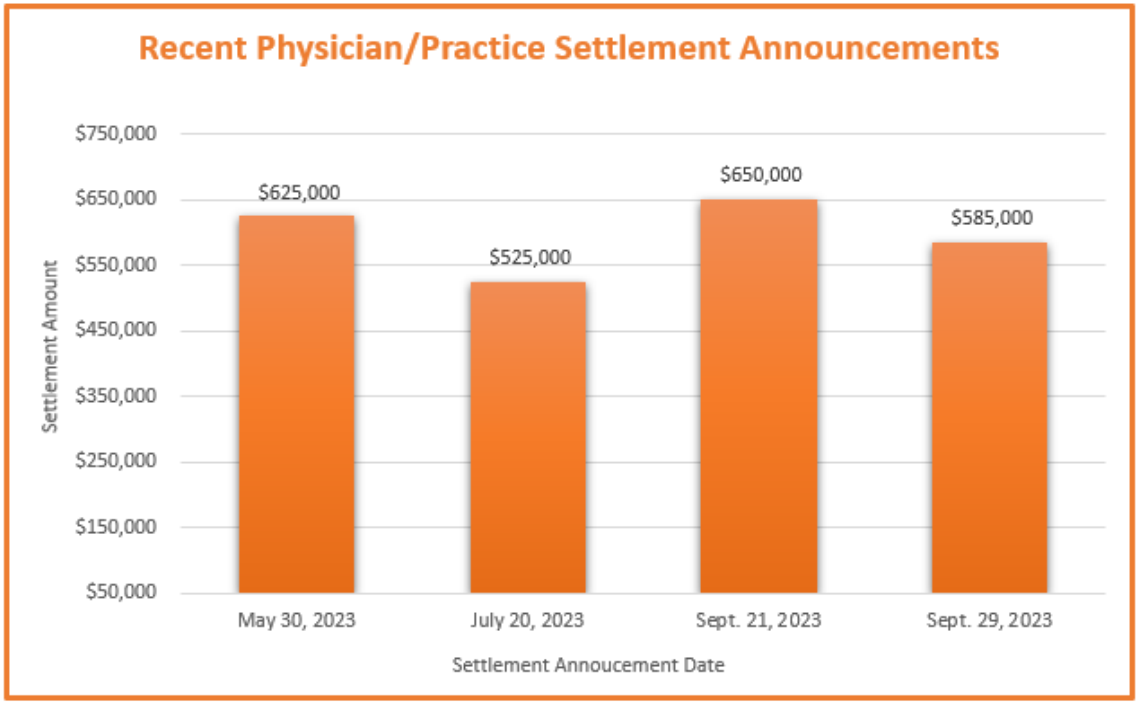
AT-RISK PROVIDERS MAY NOT HAVE ALWAYS USED PRESUMPTIVE DRUG TESTING TO DETERMINE THE NUMBER OF DRUG CLASSES THAT NEEDED TO BE TESTED USING DEFINITIVE DRUG TESTING SERVICES

Appendix 7:
Lab Kickback Issues

Observed Kickback Schemes:

- Lab collector performs office staff services
- Payments to a practice or provider disguised as office space rental
- Free or significantly discounted point of care collection cups
- Free, discounted, or waived testing fees for practices or patients
- Sports camps for children of practice personnel
- 1099 Sales Reps
- Lab-provided free office equipment not necessary for drug testing

Four Recent Practice/Physician Settlements:



Issues:

1. Payments disguised as “investment returns”
2. Payments disguised as “consulting” or “medical director” fees
3. Lab personnel providing office staff services
4. Office rental payments

Appendix 8:
Compliance Measures

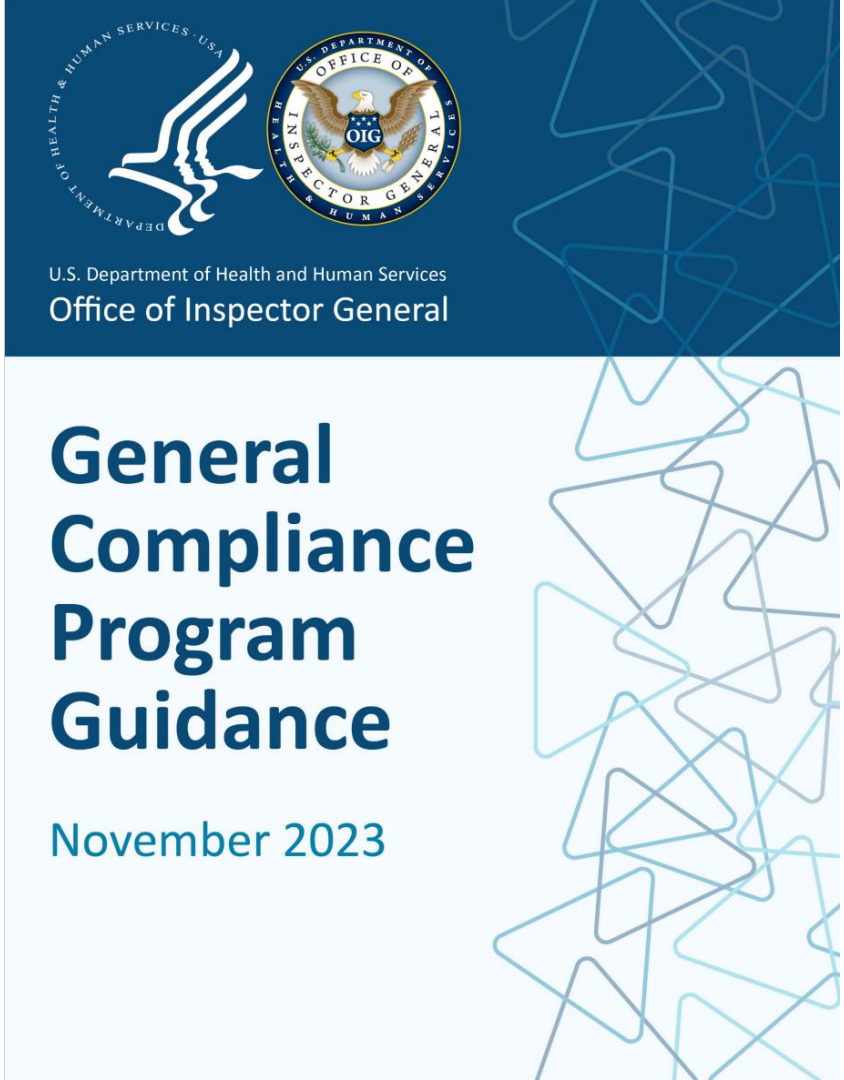
CLAIMS-RELATED COMPLIANCE INITIATIVES

- POLICIES AND PROCEDURES
- TRAINING
- INTERNAL MONITORING
- CLINICAL OVERSIGHT OF TESTING AND BILLING
- TRACKING OF REFERRAL SOURCES
- OPPORTUNITIES TO CONNECT WITH REFERRAL SOURCES
- REVIEW AND UPDATE OF REQUISITION FORM

ARRANGEMENTS-RELATED COMPLIANCE INITIATIVES

- POLICIES AND PROCEDURES (E.G. PHLEBOTOMISTS/SPECIMEN COLLECTORS, SPEAKERS, LEASES)
- TRAINING (E.G. SALES FORCE)
- INTERNAL MONITORING (E.G. ARRANGEMENTS TRACKING; COMPLIANCE RIDE-A-LONGS)
- CLINICAL OVERSIGHT OF MARKETING, MESSAGING, AND REQUISITION FORMS
- TRACKING OF REFERRAL SOURCES
- OPPORTUNITIES TO CONNECT WITH REFERRAL SOURCES
- REVIEW AND UPDATE OF REQUISITION FORM

Appendix 9:
OIG Resources


U.S. Department of Health and Human Services
Office of Inspector General
General Compliance Program Guidance
November 2023

COMPLIANCE RESOURCE PORTAL - OIG.HHS.GOV/COMPLIANCE/COMPLIANCE-RESOURCE-PORTAL/

INTEGRITY AGREEMENTS - OIG.HHS.GOV/COMPLIANCE/CORPORATE-INTEGRITY-AGREEMENTS/CIA-DOCUMENTS.ASP

ADVISORY OPINIONS - OIG.HHS.GOV/COMPLIANCEADVISORY-OPINIONS/INDEX.ASP

ENFORCEMENT ACTIONS - OIG.HHS.GOV/FRAUD/ENFORCEMENT/

OEI REPORTS - OIG.HHS.GOV/REPORTS-AND-PUBLICATIONS/OEI/L.ASP#LABORATORIES

SELF-DISCLOSURE - OIG.HHS.GOV/COMPLIANCE/SELF-DISCLOSURE-INFO/INDEX.ASP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