


Health Care Compliance Association

Compliance Institute


March 30, 2020

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SONIC HEALTHCARE USA




THE LABORATORY RISK ASSESSMENT:

THE PROCESS,

THE TOP RISKS, AND

WHAT TO AUDIT


1




Sonic Healthcare

At a Glance

Third largest medical diagnostic company GLOBALLY




Market Leader position in eight countries




Number one in Australia, Germany, United Kingdom and Switzerland

1


More than 115M patients per year, 31M in the US




Ranked among Top 50 Companies on Australian Securities Exchange




Laboratory medicine, imaging and clinical services



Medical centers in Australia housing 2,900 primary care providers



37K employees worldwide, more than 8K in the US



2



Why do a Compliance Risk Assessment?

- Federal sentencing guidelines and other authorities require/recommend
 - Guidelines, § 8B2.1(c)) – “ In implementing subsection (b), the organization shall periodically assess the risk of criminal conduct and shall take appropriate steps to design, implement, or modify each requirement set forth in subsection (b) to reduce the risk of criminal conduct identified through this process.”
 - “Prosecutors should also consider “[t]he effectiveness of the company’s risk assessment and the manner in which the company’s compliance program has been tailored based on that risk assessment” and whether its criteria are “periodically updated.” April 2019 Department of Justice, Criminal Division
 - Examples of NY OMIG citations:
 - There was no system for evaluation of potential or actual non-compliance as a result of self-evaluations and identified by external or internal audits.
 - For a large enterprise, there is no system in place at the regional level or routine identification of compliance risk areas specific to the provider’s service type(s).
- **Performing a Risk Assessment will impact the effectiveness of the entire compliance program.**

3




Three “Fundamental Questions”

1. Is the corporation’s compliance program well designed?
2. Is the program being applied earnestly and in good faith? Is the program being implemented effectively?
3. Does the corporation’s compliance program work in practice?



4



Structural Risk Assessment Example

(included as a hand-out)

To determine if the Compliance Program has the right structure and autonomy to implement the program effectively.

Strength Rating	
Weak	1
Medium	2
Strong	3



CREATED FOR ILLUSTRATION ONLY

Compliance Program Structural Risk Assessment


A Compliance Program "best practice" is to conduct periodic Risk Assessments. Both a 1) Structural and 2) Substantive. The Structural component includes the framework necessary to build and operate an effective compliance program including the OIG necessary elements of a compliance program and the U.S. Sentencing Guidelines. The Substantive component relates to the specific body of substantive law (Medicare, Medicaid, Anti-kickback, Stark, Privacy, etc.) and will be presented for discussion separately. Please maintain documentation of this completed assessment in your files.

Effective Date: _____

Description	Current Strength Rating	Assessment			Explanation of "Yes" including documentation references	Note/Action
		Yes	No	N/A		
Item 1: Written Policies and Procedures						
1.01 An assessment of key risks that could impact the organization has been completed.						
1.02 Policies address issues identified in guidance documents (e.g. OIG, Fraud alerts, CJA's, etc.) or enforcement actions by the OIG and other government agencies with enforceable legal consequences.						
1.03 Policies address previously identified serious weaknesses in its practices, audits, investigations, Exit Interviews.						
1.04 Policies describe how the organization's compliance program operates and the consequences of noncompliance.						
1.05 A Code of Conduct has been distributed to all employees and a signed acknowledgment is tracked and maintained.						
1.06 Policies include the duty to report and reporting outlets.						
1.07 Policies are in place to promptly address and rectify employee noncompliance.						
1.08 Policies and Procedures are periodically reviewed and are updated to reflect changes in laws, regulations, or practices.						
1.09 Policies and Procedures are reviewed at regular intervals.						
1.10 Does a written policy provide guidance to employees on how potential compliance problems are investigated and resolved?						
1.11 Compliance Policies and Procedures are distributed to employees upon hire.						
Item 2: Education and Training						
2.01 Is training and education provided to all employees, contractors, temps, etc on expectations of the compliance program and potential compliance issues?						





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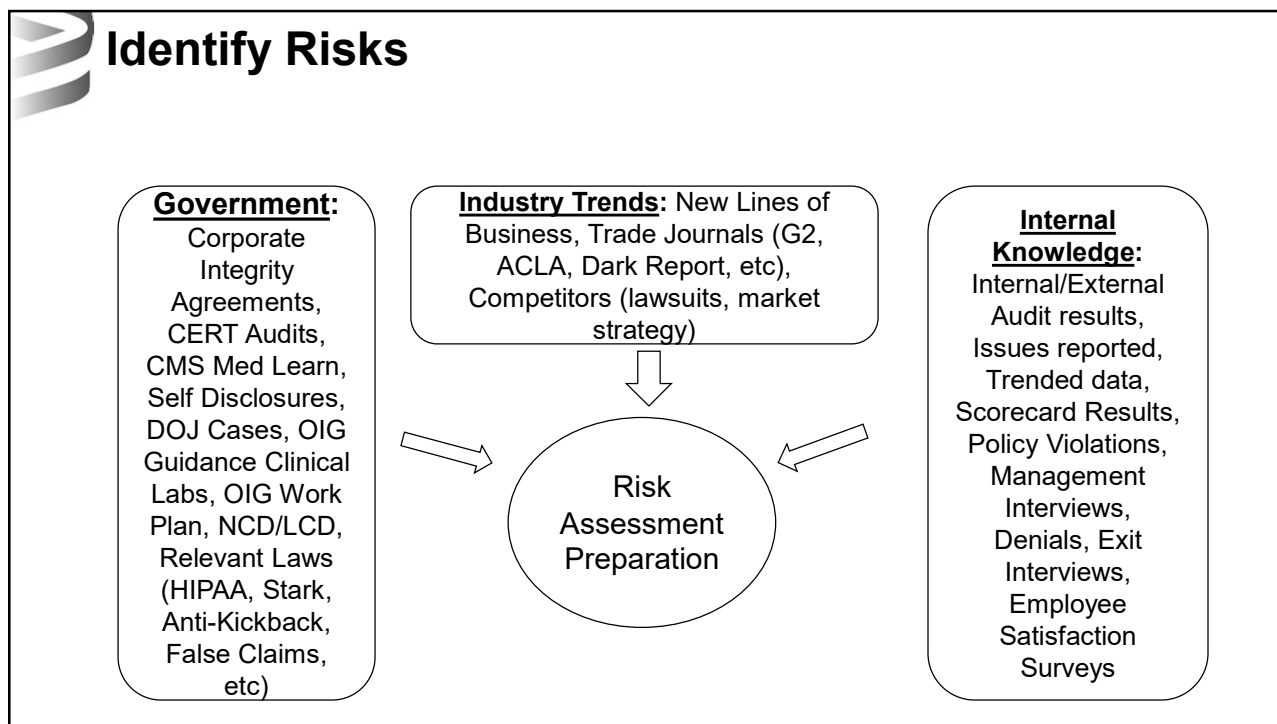


Substantive Risk Assessment Process Example

- I. Make a Plan
- II. Determine the Team(s)
- III. Identify Potential Risks
- IV. Assess and Prioritize Potential Risks
- V. Manage and Monitor
 - I. Create Work Plan
 - II. Implement Policies
 - III. Proactively Train
 - IV. Audit
 - V. Revise the Program



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~~Reactive~~
 Proactive

- CLAIMS
- ARRANGEMENTS/ RELATIONSHIPS
- MARKETING

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SEVEN FUNDAMENTAL ELEMENTS

1. WRITTEN POLICIES AND PROCEDURES
2. COMPLIANCE PROFESSIONALS
3. EFFECTIVE TRAINING
4. EFFECTIVE COMMUNICATION
5. ENFORCEMENT OF STANDARDS
6. INTERNAL MONITORING
7. PROMPT RESPONSE



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FRAUD AND ABUSE STATUTES, ADMINISTRATIVE AUTHORITIES, AND SELF-DISCLOSURES

1. THE FALSE CLAIMS ACT
2. CIVIL MONETARY PENALTIES LAW
3. THE ANTI-KICKBACK STATUTE
4. THE PROHIBITION ON CERTAIN PHYSICIAN REFERRALS (STARK)
5. THE INSPECTOR GENERAL'S EXCLUSION AUTHORITY
6. THE SELF-DISCLOSURE PROCESS

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CIVIL CASES

<p><u>RELATIONSHIPS</u></p> <ul style="list-style-type: none"> • ANTI-KICKBACK STATUTE • PROHIBITION ON CERTAIN PHYSICIAN REFERRALS (STARK) • FALSE CLAIMS ACT • CIVIL MONETARY PENALTIES LAW • EXCLUSION 	<p><u>BILLING</u></p> <ul style="list-style-type: none"> • FALSE CLAIMS ACT • CIVIL MONETARY PENALTIES LAW • EXCLUSION
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ARRANGEMENTS/RELATIONSHIPS

<p><u>THE ANTI-KICKBACK STATUTE</u> <u>42 U.S.C. § 1320A-7B(B)</u></p> <ul style="list-style-type: none"> • OFFER, PAYMENT, SOLICITATION, OR RECEIPT • REMUNERATION • REFERRALS • KNOWINGLY AND WILLFULLY • SAFE HARBORS 	<p>• <u>PROHIBITION ON CERTAIN PHYSICIAN REFERRALS</u> <u>42 U.S.C. § 1395NN (STARK LAW)</u></p> <ul style="list-style-type: none"> • REFERRAL BY A PHYSICIAN • MEDICARE DESIGNATED HEALTH SERVICE (DHS) • PHYSICIAN HAS A FINANCIAL RELATIONSHIP WITH THE ENTITY FURNISHING DHS • EXCEPTIONS
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POTENTIAL ARRANGEMENTS ISSUES



COMMON OWNERSHIP THAT DOESN'T FIT INTO A SAFE HARBOR/EXCEPTION



FREE SERVICES



SPECIMEN COLLECTORS GOING BEYOND THE SCOPE
MANAGERIAL SERVICES
PATIENT MANAGEMENT SERVICES



FREE OR DISCOUNTED ITEMS

GIFTS/MEALS
SUPPLIES
ELECTRONIC HEALTH RECORDS SYSTEMS

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MORE POTENTIAL ARRANGEMENTS ISSUES

CONSULTING FEES

SPEAKER FEES

RENTAL AGREEMENTS



PROCESSING AND HANDLING FEES

CLINICAL TRIALS



ADVICE TO REFERRAL SOURCES RELATED TO BILLING

OPPORTUNITY TO CHARGE

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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

**SPECIAL FRAUD
ALERT – PAYMENTS
TO REFERRING
PHYSICIANS**

WWW.OIG.HHS.GOV/FRAUD/DOCS/ALERTSANDBULLETINS/2014/OIG_SFA_LABORATORY_PAYMENTS_06252014.PDF

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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

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**COMPLIANCE
RESOURCE PORTAL**

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RESOURCE-PORTAL/**



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Compliance Resource Portal

Highlights from Principal Deputy JG Joanne Chiedi's 2019 HCCA Compliance Institute Remarks

- Toolkits +
- Provider Compliance Resources and Training +
- Advisory Opinions +
- Voluntary Compliance and Exclusions Resources +
- Special Fraud Alerts, Other Guidance, and Safe Harbor Regulations +
- Resources for Health Care Boards +
- Resources for Physicians +
- Accountable Care Organizations +

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**CORPORATE
INTEGRITY
AGREEMENTS**

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COMPLIANCE/
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AGREEMENTS/CIA-
DOCUMENTS.ASP**



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Corporate Integrity Agreement Documents

i 02-21-2020
Last Updated

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Related Information

- Corporate Integrity Agreement Enforcement
- Quality of Care Clia

Recent Updates

New Cases	City	State	Effective	Press
Diversicare Healthcare Services, Inc.	Brentwood	TN	02-14-2020	

Complete CIA List

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

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ADVISORY OPINIONS

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UTC LABORATORIES, INC. A/K/A RENRX

[WWW.JUSTICE.GOV/
OPA/PR/GENETIC-
TESTING-COMPANY-AND-
THREE-PRINCIPALS-AGREE-
PAY-426-MILLION-RESOLVE-
KICKBACK](http://WWW.JUSTICE.GOV/OPA/PR/GENETIC-TESTING-COMPANY-AND-THREE-PRINCIPALS-AGREE-PAY-426-MILLION-RESOLVE-KICKBACK)

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**BOSTON HEART
DIAGNOSTICS
CORPORATION**

**WWW.JUSTICE.GOV/OPA/
PR/LABORATORY-PAY-2667-
MILLION-SETTLE-FALSE-CLAIMS-
ACT-ALLEGATIONS-ILLEGAL-
INDUCEMENTS-REFERRING**

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JUSTICE NEWS

Department of Justice
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FOR IMMEDIATE RELEASE Tuesday, November 26, 2019

Laboratory to Pay \$26.67 Million to Settle False Claims Act Allegations of Illegal Inducements to Referring Physicians

Laboratory Boston Heart Diagnostics Corporation (Boston Heart), of Framingham, Massachusetts, has agreed to pay \$26.67 million to resolve False Claims Act allegations involving payments for patient referrals in violation of the Anti-Kickback Statute and the Stark Law, as well as claims otherwise improperly billed to federal healthcare programs for laboratory testing, the Department of Justice announced today.

The settlement announced today resolves allegations that Boston Heart conspired with others to pay doctors kickbacks disguised as investment returns. From 2012 to 2017, Boston Heart allegedly agreed to provide laboratory testing services to small Texas hospitals in exchange for per-test payments. To generate more referrals for the hospitals and more money for itself, Boston Heart allegedly coordinated with the hospitals' independent marketers, who set up companies known as management service organizations (MSOs), to make payments to referring physicians that were disguised as investment returns but were actually based on, and offered in exchange for, the physicians' referrals. Boston Heart allegedly helped the MSOs identify physician targets, referred interested physicians to the MSOs to secure their business, and participated with the MSOs in sales pitches to offer physicians money in exchange for referrals. As a result, physicians allegedly referred patients to the Texas hospitals and Boston Heart for laboratory tests performed by Boston Heart, which were then billed to Medicare, Medicaid, and TRICARE.

RELATED LINKS

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**INFORM DIAGNOSTICS
F/K/A MIRACA LIFE
SCIENCES, INC.**

**WWW.JUSTICE.GOV/
OPA/PR/PATHOLOGY-
LABORATORY-AGREES-PAY-
635-MILLION-PROVIDING-
ILLEGAL-INDUCEMENTS-
REFERRING**

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JUSTICE NEWS

Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE Wednesday, January 30, 2019

Pathology Laboratory Agrees to Pay \$63.5 Million for Providing Illegal Inducements to Referring Physicians

Pathology laboratory company Inform Diagnostics has agreed to pay \$63.5 million to settle allegations that it violated the False Claims Act by engaging in improper financial relationships with referring physicians, the Justice Department announced today. Inform Diagnostics, formerly known as Miraca Life Sciences Inc., is headquartered in Irving, Texas, and was a subsidiary of Miraca Holdings Inc., a Japanese company, during the period relevant to the case. In 2017, majority ownership of the company changed, and the company was renamed.

"The Department of Justice has longstanding concerns about improper financial relationships between health care providers and their referral sources because these relationships can alter a physician's judgment about the patient's true health care needs and drive up health care costs for everybody," said Assistant Attorney General Judy Hunt of the Department of Justice's Civil Division. "In addition to yielding a substantial recovery for taxpayers, this settlement should deter similar conduct in the future and help make health care more affordable."

The settlement announced today resolves allegations that the company violated the Anti-Kickback Statute and the Stark Law by providing to referring physicians subsidies for electronic health records (EHR) systems and free or discounted technology consulting services. The Anti-Kickback Statute and the Stark Law restrict the financial relationships that health care providers, including laboratories, may have with doctors who refer patients to them. Although regulations adopted by the Department of Health and Human Services (HHS) in 2010 included provisions that allowed laboratories to provide EHR donations to physicians under certain conditions, the United States alleged that the defendant violated those conditions. HHS withdrew those exemptions for laboratories in 2012.

"The well-being and needs of the patient should always be a medical provider's primary considerations," said U.S. Attorney Don Cochran of the Middle District of Tennessee. "The restrictions imposed by federal statutes exist to prevent improper influence on the parties prescribing and providing medical services, including laboratory tests. We will continue to enforce the laws that protect the integrity of federal health care programs."

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**OTHER
ARRANGEMENTS
SETTLEMENTS**

TOTAL DIAGNOSTIX

BLACKFLY INVESTMENTS, LLC
D/B/A MOLECULAR TESTING LABS

NEVADA HEART AND VASCULAR
CENTER, LLP

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PARTY	DATE OF AGREEMENT	SETTLEMENT AMOUNT
PARALLAX CENTER, INC.	9/18/2017	\$64,203.30
ADVANCED PAIN MANAGEMENT	9/27/2017	\$186,210.2
ADDICTION MEDICAL CARE OF COLUMBUS, ADDICTION MEDICAL CARE OF NORWALK, PRACTICE MANAGEMENT ASSOCIATES NORWALK, LLC, AND PRACTICE MANAGEMENT ASSOCIATES, LLC	12/5/2017	\$79,880.50
THE PAIN INSTITUTE, INC. D/B/A SPACE COAST PAIN INSTITUTE, STANLEY GOLOVAC, MD AND RICHARD GAYLES, MD	2/28/2018	\$95,302.50
DR. KEVIN DIEI AND AMC – AFFORDABLE MEDICAL CARE F/K/A ANDALUSIA MEDICAL CENTER	4/5/2018	\$40,500.50
RECOVERY PATHWAYS, LLC	5/24/2018	\$64,550.00
MILIND V. TILAK, MD, SUWARNA TILAK, MD, DOCTOR'S INLET PEDIATRICS AND PRIMARY CARE, PA, AND AVENUES PEDIATRICS AND INTERNAL MEDICINE	9/6/2018	\$58,370.00
DR. RONALD BURNS	10/3/2018	\$75,409.15
TULSA PAIN CONSULTANTS, INC., MARTUCCI, MD, AND ANDREAS REVELIS, MD, HKD TREATMENT OPTIONS, PC	12/21/2018	\$98,942.50
ANESTHESIA SERVICES, P.C. D/B/A UNIVERSITY PAIN CLINIC	6/14/2019	\$87,650.00
PHYSICIANS GROUP SERVICES, P.A.	7/12/2019	\$44,900.00
A.R.E.B.A.-CASRIEL, INC.	10/2/2019	\$1,128,615.04
	11/19/2019	\$151,056.75
13 CMP SETTLEMENTS		\$2,175,590.44



**FREE
POINT
OF CARE
TESTING
CUPS**

MILLENNIUM
HEALTH, LLC
F/K/A
MILLENNIUM
LABORATORIES,
INC.

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 U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Office of Inspector General 		
PROCESSING AND HANDLING FEES HEALTH DIAGNOSTIC LABORATORY, INC. AND/OR SINGULEX, INC.		
PARTY	DATE OF AGREEMENT	SETTLEMENT AMOUNT
TIMOTHY MCPHERSON, D.O. AND MCPHERSON MEDICAL AND DIAGNOSTIC, LLC	5/16/2017	\$61,392.00
JONATHON B. SHAFFER, MD, DINA B. WHITE, MD, AND SWEETWATER MEDICAL ASSOCIATES	7/6/2017	\$62,400.00
ALAN D. JUSTICE, M.D. AND OCMULGEE PHYSICIANS, LLC	9/22/2017	\$277,202.00
SCOTT R. EISENBERG, D.O., ROBERT G. KAYSER, JR., M.D., AND CHANGE OF HEART CARDIOLOGY, LLC	10/17/2017	\$208,450.00
DOCTORS OF INTERNAL MEDICINE, DAVID E. GARZA, M.D., & LADAN BAKHTARI, M.D.	11/1/2017	\$53,820.00
RODNEY MALISOS, M.D. AND LIBERTY MEDICAL CENTER	12/4/2017	\$60,839.00
PRIMECARE MEDICAL GROUP AND ANKUR DOSHI, M.D.	3/5/2018	\$53,260.00
REX A. BUTLER, M.D. AND SOUTH CENTRAL MEDICAL CENTER, P.C.	4/5/2018	\$505,030.00
C. DAVID BIRD, M.D., KURT W. LESH, M.D., AND COLORADO SPRINGS FAMILY PRACTICE	4/9/2018	\$152,554.00
ELIZABETH SEYMOUR, M.D. AND ERS MEDICAL ASSOCIATES OF DENTON	8/3/2018	\$54,860.00
HORACE E. WALPOLE, M.D. AND POWERSVILLE INTERNAL MEDICINE	8/3/2018	\$68,500.00
SARAH S. COTTINGHAM, M.D., RUSSELL E. DITZLER, M.D., AND LEXINGTON COUNTY HEALTH SERVICES DISTRICT, INC.		
D/B/A LEXINGTON MEDICAL CENTER	9/19/2018	\$97,784.00
PAUL S. MONIZ, DO, GUY D. ROBERTS, DO, AND MIDWEST HEALTH GROUP, LLC	5/20/2019	\$96,880.00
MIDLAND MEDICAL, INC. AND ITS SUBSIDIARY, MIDLAND MEDICAL-BROWARD, INC.	6/17/2019	\$102,204.00
JOSEPH P. CLANCY, JR., M.D. WALTER P. MILLER, M.D., AND SOUTHERN OCEAN PRIMARY CARE ASSOCIATES, LLC	8/7/2019	\$311,626.00
JOSE R. GONZALEZ, M.D., PEDRO NAM, M.D., AND WELLINGTON MEDICAL CARE ASSOCIATES, LLC	11/12/2019	\$107,260.00
	16 SETTLEMENTS	\$2,274,061.00

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BILLING ADVICE TO REFERRAL SOURCES MOLECULAR PATHOLOGY CONSULTATION (G0452)		
PARTY	DATE OF AGREEMENT	SETTLEMENT AMOUNT
DENNIS C. FORD, MD AND THE FORD CENTER FOR PAIN MANAGEMENT, PLLC	9/17/2015	\$32,184.71
KARL T. CHEN, MD AND KARL T. CHEN, LLC	9/17/2015	\$25,937.72
THE MEDICINE CLINIC, LLC AND JESUS J. FONSECA, MD	9/17/2015	\$17,925.24
TAJUL CHOWDHURY, MD, & THE CENTER FOR PAIN MANAGEMENT, PLLC	10/30/2015	\$26,587.20
DR. RENAUD RODRIGUE	10/30/2015	\$22,807.06
DR. EDWIN GAR-EL	10/30/2015	\$11,954.86
FRANK AGNONE, M.D.	12/16/2015	\$28,863.14
ROBERTO DIAZ, M.D.	12/16/2015	\$13,418.56
MARTIN E. GILLILAND, MD	1/27/2016	\$49,041.58
ROGER C. WILLETTE, MD	1/27/2016	\$44,120.14
BENJAMIN H. VENGER, MD	2/5/2016	\$15,956.74
RONALD DALE PARKER, M.D.	2/22/2016	\$15,036.50
MICHAEL BAKER, M.D.	2/22/2016	\$13,238.16
JAMES RAY HIGGINS, MD	3/4/2016	\$10,346.96
EDUARDO MONTES, DPM, AND EDUARDO MONTES, DPM, PLLC	5/5/2016	\$10,887.60
KOYIA LATRECE FIGURES, MD, AND ALLIANCE SENIOR HEALTH, PLLC	5/27/2016	\$15,071.20
FRANCES GLICKSMAN, MD AND FRANCES GLICKSMAN, MD PA	6/17/2016	\$12,613.72
WILLIAM BOULWARE, MD, AND BOULWARE MEDICAL CLINIC, LLC	7/20/2016	\$10,653.54
DR. MANITH MANN, M.D.	8/12/2016	\$66,513.50
LEXINGTON CARDIOLOGY ASSOCIATES, LLC, ROBERT D. MALKIN, M.D., ROBERT BORKOWSKI, M.D., MANNY-KATSETOS, M.D., AND JAMES ST. PIERRE, M.D.	8/24/2016	\$30,849.14
HAROLD J. PEAN, M.D., MIHAELA SHUAIB, M.D., AND MISSION INTERNAL MEDICINE, P.A.	8/24/2016	\$28,757.18
NORTHERN OCEAN COUNTY MEDICAL ASSOCIATES, P.C., JOHN G. CICIARELLI II, MD AND JASON ARASH NEHMAD, MD	9/21/2016	\$36,850.38
GENOPTIX, INC.	10/11/2016	\$218,744.92
DR. A. CLARK RUTTINGER, D.O., AND HIS PRACTICE, A. CLARK RUTTINGER DO PLLC	11/2/2016	\$52,961.20
LAWRENCE C. ANTONUCCI, M.D., HIS PRACTICE, LAWRENCE C. ANTONUCCI, MD LLC, AND DR. CLIFFORD SEBASTIAN, M.D.	11/15/2016	\$60,884.90
	25 SETTLEMENTS	\$871,705.85

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Lab Relationship Risks

Department(s)	Topic	Risk	Analysis
Sales, Compliance, Finance, Executives	Provider Compensation Arrangements	Compensation Arrangements with Referral Sources could implicate Fraud and Abuse Laws if they do not meet an allowable exception, are at Fair Market Value (FMV), have an agreement and the terms followed and is in no way intended to solicit their referrals.	1. Is a process in place to determine which contracts are focused arrangements? A. Between lab and source of referrals that involves, directly or indirectly, the offer, payment or provision of anything of value; B) Between the lab and any physician who makes a referral to the lab for designated health services; or C) Between entity and any physician (or physician's immediate family member or medical practice that involves, directly or indirectly, the offer, payment or provision of anything of value in anticipation of that physician becoming an actual source of healthcare business or referrals. 2. Is a contract in place signed by both parties PRIOR to the beginning of payment? 3. Are the contracts and terms maintained in a database or contract management system? 3. Does the process ensure FMV determination and documentation maintained? 4) Is Compliance part of the approval process to ensure proper handling of this high risk arrangement? 5. If being paid for time related activity ensure checks and balances are in place.
Finance, Sales	Panel Pricing (Clients)	Pricing of panels billed directly to Clients could inappropriately lead to the over ordering of medically unnecessary tests to Medicare and Medicaid if not properly addressed.	1)Is a process in place to ensure client priced tests are above fair market value and cost? 2)Are the tests priced in a panel priced the same individually as to ensure clients are not getting "a better deal" by ordering a panel/profile?
Sales, Billing	Professional Courtesy Testing to Providers	Items and services of value should not be given to a current or potential referral source or Fraud and Abuse Laws could be implicated:	Are controls in place to ensure this does not occur? What is the process to approve test write-offs?
Sales	Sales Representatives earning commission from family member Doctors	Sales Reps earning commission from doctors who are an immediate family member could implicate the Stark Law.	Are Sales Reps prohibited from including family members in their book of business?

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Lab Relationship Risks

Sales, Account Set up, Human Resources, Billing, Finance	Excluded Provides, Employees and Vendors	Billing Medicare for tests ordered by an individual excluded from participating in Medicare could lead to a False Claim. As an entity who bills government payors we cannot employ or do business with an entity or person on the LEIE exclusion list.	1. Are clients who order tests vetted against the LEIE list? A. At what frequency, Monthly, Annually, etc.? Are they checked prior to performing tests ordered? 2. Are employees checked prior to hire? Vendors prior to hire? Thereafter and at what frequency?
Information Technology	Computer related Equipment	The lab can only provide equipment and services that are directly related to our lab testing. If computers, fax, printers, scanners, etc are provided they should be locked down and only used for lab testing needs and should be retrieved upon client separation. An exception process that includes a monitoring plan to ensure proper use may be permitted in some cases.	Is there an inventory tracking method in place to ensure equipment is properly accounted for and retrieved upon client separation? 2) Is there a method to ensure the equipment provided is locked down for only our purposes? Is there an exception process that includes a monitoring plan and compliance oversight?
Sales, Phlebotomy, Finance, Legal	Leases with Providers	(A Provider Compensation Arrangement)- Rental Arrangements for Space in Physician Offices are suspect as an Anti-Kickback violation based on 1)the Appropriateness of a Rental Agreement 2)The Rental Amount and 3)Time and Space considerations.	Is there a process that includes the Provider Compensation Arrangement info above? Is there a process to ensure the space being leased does not appear to be payment for space that should be provided at no cost as in an IOP arrangement? Is there a method for Fair Market Value calculation and a review of the square footage being leased? Is there an agreement process
Marketing	Marketing Materials	Business leaders should not provide clinical guidance. Marketing materials that include clinical information should accurately reflect the Chief Medical Officer's guidance regarding the proper use of and medical necessity of testing.	Is a review and approval process in place for marketing material that includes Clinical and Compliance?
Sales, Finance	Client Entertainment & Gifts	OIG Fraud Alert regarding Kickbacks: "A payment or gift may be considered improper if it is made to a person in a position to generate business for the paying party; related to the volume of business granted; and more than nominal in value or exceeds fair market value of any legitimate service rendered to the payer, or is unrelated to any service at all other than referral of patients.	Are controls in place to oversee Sales expense reports to ensure improper gifts, service, or payments are not provided?

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Lab Relationship Risks

Admin, Finance	Charitable and Political Contributions	Charitable and Political Contributions could lead to or be perceived to induce referrals and could be a "thing of value" implicating Fraud and Abuse laws.	Are controls in place to ensure the charities are aligned with our values? That a client or potential client will not benefit directly or indirectly from the charitable donation.
Sales, Finance	Client Entertainment & Gifts	The Stark law allows non-monetary compensation to physicians up to \$416 if 1.) It is not determined in any manner the volume or value of referrals 2) Cannot be solicited by physicians or their staff 3) It does not violate the Anti-Kickback statute (see above). If the Anti-Kickback Statute or Stark law are implicated, tests billed to government payors for those providers could be False Claims.	Are controls in place to ensure all expenses to providers are related to clinical lab testing, not related to the volume or value of referrals, and not solicited by the client? Are they tracked and tallied to ensure it is below the limit per NPI?
Supply Distribution	Client Supplies	Giving an item or service for free or less than fair market value to a referral source creates an inference that it is to induce the referral of business, potentially impacting the Anti-Kickback statute.	Are controls in place to ensure that only supplies that are directly related to our lab testing being provided? Are controls in place to ensure clients are not using lab supplies for their own purpose?
Phlebotomy	Phlebotomy Duties	Phlebotomists performing duties that are not directly related to our lab testing could implicate the Anti-Kickback statute.	Are controls in place to ensure Phlebotomists placed in provider offices are not performing duties on behalf of the client such as taking vitals, performing clerical services, etc.

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CLAIMS-RELATED ISSUES

- MEDICAL NECESSITY
- CORRECT CODING
- REFERRAL FORMS
 - À LA CARTE SELECTIONS INSTEAD OF PANELS
 - DIAGNOSIS CODES/EXPLANATIONS
- PATIENT ENCOUNTERS
 - REPEATED GENETIC TESTING
 - MULTIPLE UNITS
- REFLEX TESTING

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GENETIC TESTING FRAUD ALERT

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FRAUD/CONSUMER-
ALERTS/ALERTS/
GENETICSCAM.ASP



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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

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COMPLIANCE RESOURCE PORTAL

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COMPLIANCE/
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RESOURCE-PORTAL/

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CORPORATE INTEGRITY AGREEMENTS

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COMPLIANCE/
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AGREEMENTS/
CIA-DOCUMENTS.ASP





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GENOMEDX BIOSCIENCES CORP.


WWW.JUSTICE.GOV/OPA/PR/GENETIC-TESTING-COMPANY-AGREES-PAY-199-MILLION-RESOLVE-ALLEGATIONS-FALSE-CLAIMS-MEDICARE

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LABTOX, LLC

WWW.JUSTICE.GOV/USAO-EDKY/PR/LEXINGTON-LABORATORY-AGREES-PAY-21-MILLION-RESOLVE-ALLEGATIONS-FALSE-CLAIMS-URINE-DRUG





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CLINICAL SCIENCE LABORATORY, INC.


WWW.JUSTICE.GOV/USAO-
CT/PR/
MASSACHUSETTS-
LABORATORY-AND-ITS-
OWNERS-PAY-OVER-1.5-
MILLION-SETTLE-FALSE-
CLAIMS-ACT

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MULTIPLE UNITS BILLED FOR A SINGLE PATIENT ENCOUNTER


G0431/G0434

PARTY	DATE OF AGREEMENT	SETTLEMENT AMOUNT
C.F. HEALTH MANAGEMENT, INC., D/B/A GAINESVILLE PAIN MANAGEMENT	5/17/2013	\$1,577,597.00
MEDICUS LABORATORIES, LLC	2/14/2014	\$5,000,000.00
NABIL ATTALLA BARSOU, M.D.	7/25/2014	\$334,528.90
FLORIDA FAMILY LABORATORY, INC	8/5/2014	\$197,400.09
PAIN SPECIALISTS OF GREATER CHICAGO	9/10/2014	\$590,763.45
CLINICAL LABORATORY PARTNERS	9/29/2014	\$145,789.34
DENNIS CONRAD HARPER, M.D.	1/20/2015	\$305,168.54
ALAN J. WAYNE, M.D. AND STEVENSON MEDICAL CENTER, INC.	2/24/2015	\$225,000.00
AMERICAN INSTITUTE OF TOXICOLOGY	7/20/2015	\$229,924.74
DAVID IRVING STEIN, M.D. AND MILWAUKEE PAIN TREATMENT SERVICES	8/14/2015	\$374,864.78
JAHAN IMANI, M.D. AND INTERMOUNTAIN MEDICAL MANAGEMENT, P.C.	7/21/2017	\$399,895.92
MOHAMMAD SIDDIQUE, M.D AND SHOALS MEDICAL GROUP, LLC	8/29/2016 ALJ ORDER UPHOLDING DEMAND	\$2,767,651.67 CMPS AND ASSESSMENTS AND 10 YEARS EXCLUSION
11 SETTLEMENTS AND 1 DEMAND		\$12,148,584.43 AND 10 YEARS EXCLUSION

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SPECIMEN VALIDITY TESTING 81000, 81001, 81002, 81003, 81005, 82570, 83986, 84311		
PARTY	DATE OF AGREEMENT	SETTLEMENT AMOUNT
NORTHERN KENTUCKY CENTER FOR PAIN RELIEF, LLC	1/24/2019	\$126,799.90
MOHAMMAD MOUHIB KALO, M.D. AND WHEELERSBURG INTERNAL MEDICINE GROUP, INC.	2/6/2019	\$111,706.00
VERRALAB JA, LLC	3/13/2019	\$125,983.16
MEDICAL SPECIALIST OF KENTUCKIANA, PLLC	3/13/2019	\$69,776.24
COMMONWEALTH PAIN ASSOCIATES, PLLC	5/31/2019	\$88,214.88
SOUTHEASTERN INTEGRATED MEDICAL, PL	6/6/2019	\$62,727.88
ETHOS LABORATORY	6/28/2019	\$1,345,959.74
DISCOVER DIAGNOSTIC LABORATORY, LLC	8/7/2019	\$95,882.36
PREMIERTOX 2.0 INC.	8/7/2019	\$99,157.00
AMERICAN CLINICAL SOLUTIONS, LLC	8/22/2019	\$61,546.31
OHIO RIVER LABORATORIES, LLC	10/4/2019	\$49,493.48
AMERICAN TOXICOLOGY LAB, LLC	12/12/2019	\$175,889.72
13 AGREEMENTS		\$2,643,822.49

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 Claim Risks			
Phlebotomy, Specimen Processing, Billing	Diagnosis Codes	Dx codes drive reimbursement. Billing for tests with a false/inaccurate dx code could be considered a False Claim. (A lab may translate narrative dx into Code if done properly.)	Are there controls in place to ensure: 1)Diagnosis are given from the provider, specific to the patient for that date of service 2) Methods to properly translate narrative dx to Code 3)"Covered" codes are not suggested, etc. 4)"Standing" dx codes are not being used outside the proper Standing Order process. Is the original order versus lab req audited?
Phlebotomy, Sales	Test Order	Billing for tests that were not ordered by an Authorized Provider could be a false claim	Are their controls to ensure that tests ordered by Non-Physician Practitioners (psychologist, midwives, Nurse Practitioners, Physician Assistants, Social Workers, etc) are acting within their authority under state law within the scope. Is there a process to ensure accounts are set up only for those authorized to order lab testing in that state?
Lab, Phlebotomy	Test Order	Verbal Orders- If an order is received by phone both the treating provider and the testing facility must document the call in their records including the test request, the date, and requestor. 2)A lab should confirm the verbal order within 30 days.	1)Is there a process to send written acknowledgement to clients of verbal orders? 2)Is there a method of documentation that a verbal order was received and by whom?(the acknowledgment does not have to be returned to the lab.)
Phlebotomy, Lab, Billing, (Sales?)	Test Order	Performing and Billing for tests that were not ordered could lead to a False Claim and impact patient care.	Are controls in place to address: 1) Ambiguous Orders with Phlebotomy and the lab? 2)To ensure the order input into the Ordering System is a match with the Original Provider Order 3)Are controls in place to ensure the tests being performed match the provider's order? 3) The tests that were performed are properly billed? Are original orders retrievable and maintained?

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Claim Risks

Sales, Billing	Co-Pays & Deductibles	Waiving Patient Co-Pays and Deductibles could implicate Fraud and Abuse Laws.	Are controls in place to ensure patient co-pays and deductibles are not routinely waived? Is a collection process attempted and/or a process in place for Indigent patients which would be an allowable exception.
Quality, Clinical	Specimen Integrity	(As billing for poor Quality can implicate the False Claims Act, Compliance should be aware of the QA process.) Some test results may be impacted if the specimen was not handled properly. Such as test date versus the collection date, refrigeration, etc.	Does the lab have protocols in place and to ensure proper specimen integrity such as time limitations on testing based on the collection date, and specimen handling instructions. Is Compliance involved in the Quality process?
Lab, Sales, Phleb, Finance	Custom Profiles-Client Acknowledgement	Custom Profiles can lead to the over-ordering of medically un-necessary tests. The OIG designates the lab to educate providers on the proper use of clinical lab testing and to ensure appropriate offering of tests both electronically and on requisitions.	1)If Custom Profiles are permitted, is there a process for the provider to sign the requested grouping of tests? 2)Is it confirmed annually? 3)Are the protocols followed for electronic ordering systems?
Lab, Sales, Phleb, Finance	Profiles (Panels) offered by the Lab	The grouping of tests can lead to the over-ordering of medically unnecessary tests. Failure to properly disclose components of panels and to market the individual tests equally to profiles could be seen by the government as inappropriate marketing leading to over-ordering.	1)Is there a process to review test groupings offered to ensure they are medically appropriate? 2) Are the individual components disclosed on the req/electronically? 3)Is clinical involved in the review/approval of the offering?

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Claim Risks

Compliance	Profiles/Panels including Custom Panels/Profiles	The OIG states the Lab should educate providers on the proper use of lab testing. An Annual Disclosure Letter should be sent to providers reminding them of the panel content and preferably their frequency of ordering and the Medicare Reimbursement of each test.	Are Annual Disclosure Letters sent to providers who use 1)Custom Panels 2) Lab Panels/Profiles
Marketing, Clinical, Compliance	Requisition Review	During Operation Labscam the FBI deemed the Requisition the "tool of the crime" because of how panels were marketed and limiting test order options to high reimbursement tests. Requisitions and the Test Menu should have Clinical oversight to ensure appropriate Medical Necessity test offerings.	Is there a clinical review of Requisition changes? Is it designed to ensure providers can choose tests that are medically necessary? Does it contain a statement to address Medical Necessity and proper Reflex Testing? See notes on Panels/Profiles
Lab, Billing	CPT Code Assignment	Payment is derived by the CPT Code Assigned. An inappropriate Code assigned to a test could lead to inappropriate reimbursement and a False Claim.	Is there a process for CPT code assignment? Is Clinical involved in the assignment? If a method or test changes does the process ensure it is communicated to Billing and Ordering Systems? When is the last time a Chargemaster review was performed?
Phlebotomy	Standing Orders	Should be used in connection with an extended course of treatment, in writing or electronically, include a duration, frequency, diagnosis and should be in place for no longer than 1 year or less per state law. A physician signature is recommended. CLIA and the Social Security Act require that a valid, written order be obtained for all laboratory services. Billing government payors without a valid order could lead to a False Claim.	Are controls in place to ensure the proper attainment and handling of Standing Orders? Is there a filing system in place to ensure proper control of active and expired standing orders?

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Claim Risks

Phlebotomy/Specimen Collection	Blanket Orders	Blanket Orders Defined-set up at the client level and are not specific to a patient and should be prohibited. They are common with toxicology labs as in "Dr. Smith's New Patient Panel".	Are such orders prohibited ?
Phlebotomy	Cheat Sheets	Billing the government for tests that were not ordered by an authorized provider could lead to a False Claim. Cheat sheets indicate unclear orders were received.	Are controls in place to prevent and detect the use of Cheat Sheets and to ensure only those tests ordered by an authorized provider are performed.
Sales, Account Set up	Account Restrictions	ESRD, Hospital, Research, Skilled Nursing, Long Term Care, Hospice, Transplant, Prison Accounts all should be categorized upon set up such that their unique billing requirements are met. Many of the facilities in this category are paid for the lab testing as part of the patients treatment/stay and should be client billed in order to prevent False Claims.	Is there a way to categorize the special account types to ensure proper billing?

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Self-Disclosure Information

The Office of Inspector General (OIG) has several self-disclosure processes that can be used to report potential fraud in Department of Health and Human Services (HHS) programs. Choose the one that applies to you from the following descriptions to learn more.

Self-disclosures should not be reported to the OIG Hotline.

Health Care Provider Self-Disclosures

> Health care providers, suppliers, or other individuals or entities subject to Civil Monetary Penalties can use the Provider Self-Disclosure Protocol, which was created in 1998, to voluntarily disclose self-discovered evidence of potential fraud. Self-disclosure gives providers the opportunity to avoid the costs and disruptions associated with a Government-directed investigation and civil or administrative litigation. Visit the [Provider Self-Disclosure Protocol](#) webpage for more information.

HHS Contractor Self-Disclosures

> Contractors are individuals, businesses, or other legal entities that are awarded Government contracts, or subcontracts, to provide services to the Department of Health and Human Services (HHS). OIG's contractor self-disclosure program enables contractors to self-disclose potential violations of the False Claims Act and various Federal criminal laws involving fraud, conflict of interest, bribery or gratuity. This self-disclosure process is available for those entities with a Federal Acquisition Regulation-based contract. Visit the [Contractor Self-Disclosure](#) webpage for more information.

HHS Grant Self-Disclosures

> HHS grant recipients or subrecipients must disclose evidence of potential violations of Federal criminal law involving fraud, bribery, or gratuity violations, potentially affecting the Federal award. Federal regulation, 45 C.F.R. § 75.111, mandates disclosures of criminal offenses that non-Federal entities must make with respect to HHS grants.

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