

An Enforcement Update from OIG

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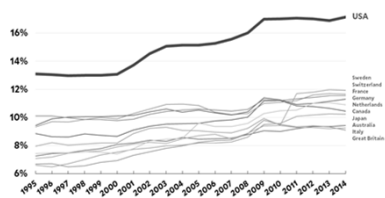
DALLAS REGIONAL OFFICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES, OIG

Overview

- An overview of recent enforcement actions and priorities
- A closer look at: Home Health fraud schemes
- A closer look at: Genetic Testing fraud schemes

Health Care Spending as % of GDP
1995-2014



Source: World Bank

Mother Jones

Medicare and Medicaid

1 in 3
Americans



2/12/2018

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OIG Statistics FY 2017

Criminal Actions	881
Civil Actions	826
Exclusions	3,244

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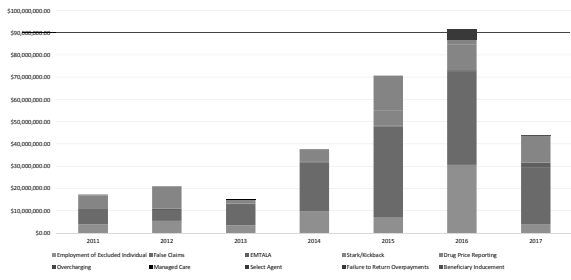
DOJ Statistics FY 2017

Healthcare Fraud Recoveries:
\$2.4 Billion

More than 669 Qui Tams Filed
(~12 a week)

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OIG CMP Recoveries



Notable OIG Reports

OIG uncovered over 100 instances of potential abuse or neglect of Medicare beneficiaries in skilled nursing facilities (SNFs).

OIG identified more than \$700 million in improper Medicare incentive payments designed to promote the adoption of electronic health records (EHR).

OIG found that the Medicare Shared Savings Program (MSSP) shows potential to reduce spending and improve quality.

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

Notable Civil Cases

eClinicalWorks

Life Care Centers of America Inc.

Vitas Hospice Services LLC

Mylan Inc.

Notable Criminal Cases

Fiango Home Healthcare Inc.

Esformes Network

Greater Miami Behavioral Health Center

Jacques Roy, MD

Dallas Regional Office



HHA – ongoing area - unnecessary services, kickbacks

Hospice – growing area-unnecessary services, kickbacks

Labs – Urine testing, genetic testing w/PII breached from hospitals, kickbacks

Adult Day Care – “one stop shop” for a variety of providers billing for services not rendered; kickbacks

Migration of schemes

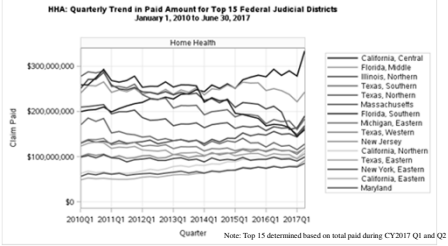
Miami ⇄ Houston ⇄ Baton Rouge ⇄ Dallas ⇄ San Antonio

A closer look at:

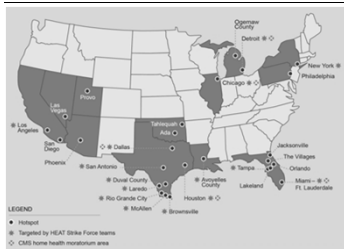
Home Health Fraud Schemes



HHA Payment Trends by Federal Judicial District



Questionable Billing: Home Health Fraud Hot Spots



- High percentage of ...
1. Episodes for which the beneficiary had no recent visits with the supervising physician
 2. Episodes that were not preceded by a hospital or NH stay
 3. Episodes with a primary diagnosis of diabetes or hypertension
 4. Beneficiaries with claims from multiple HHAs
 5. Beneficiaries with multiple home health readmissions in a short period of time

Alert: Improper Arrangements and Conduct Involving Home Health Agencies and Physicians (June 22, 2016)

- Cautionary alert to home health agencies (HHAs) and physicians who refer to them about direct or indirect payments for referrals
- Must ensure arrangements and the payments under compensation arrangements between HHAs and physicians are fair market value and commercially reasonable in the absence of Federal health care program referrals

https://oig.hhs.gov/compliance/alerts/guidance/HHA_%20Alert2016.pdf

Home Health Fraud – Fiango Home Healthcare, Inc.

- Patient recruitment and kickbacks
- Referral of patient from home health agency to physicians
- Physician certification of unqualified patients
- HHA falsifying paperwork and billing for home health services (skilled nursing and physical therapy)
- Scheme repeats for several episodes of care

Home Health Fraud – Jacques Roy

- Patient recruitment and kickbacks
- Referral of patient from home health agency to physician
- Physician certification of unqualified patients
- Physician billing for home visits and unnecessary testing
- HHA falsifying paperwork and billing for home health services
- Scheme repeats for several episodes of care

Current Home Health Fraud Trends

- Certifying physicians who work for large medical entities, hospitals, skilled nursing facilities
- Home health agencies working with multiple physicians
- Nominee owners
- Nurse Practitioner and Physician Assistant home visits with unrelated physician authorization
- Home health agency seeking initial claim without filing final claim for additional reimbursement – short term scheme
- Home health agencies targeting beneficiaries in halfway houses, drug rehabilitation programs, group homes

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A closer look at:

Genetic Testing
Fraud Schemes



According to CBS News...

60,000 genetic testing products on the US Market as of 6/9/2016;

Up from 30,000 in 2013;

"About 10 new genetic tests enter the market every day..."

"Questionable tactics used to profit from genetic testing boom" at
<https://www.cbsnews.com/news/cbs-news-investigation-genetic-testing-scam-call-kirk-zajac-craigslis/>

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Categorization of Genetic Testing By Purpose

Diagnostic Testing: identifies whether an individual has a certain genetic disease. This type of test commonly detects a specific gene alteration but is often not able to determine disease severity or age of onset.

Predictive/Presymptomatic Testing: used to determine whether an individual has an increased risk for a particular disease. Results from this type of test are usually expressed in terms of probability since disease susceptibility may also be influenced by other genetic and nongenetic (e.g. environmental, lifestyle) factors.

Pharmacogenomic Testing: used to determine the influence of genetic variation on drug response.

Carrier Testing used to identify people who carry one copy of a gene mutation that, when present in two copies, causes a genetic disorder.

sequencing: examines the entire genome or exome to discover genetic alterations that may be the cause of disease.

GENETIC TESTING VULNERABILITES

Overutilization

Kickbacks

Medically unnecessary testing

Overutilization

Repeat Genetic Testing

- Repeat testing by same lab
- Repeat testing by multiple "connected" labs
- Repeat testing by wholly different labs (potential fraud and abuse issue for physician, general issue for industry)

"Swabbing" Fairs

- "Health fairs"
- Going into Skilled Nursing Facilities, Adult Day Cares, and Extended Care facilities

Medically Unnecessary Testing

Nutrigenomic testing

Pharmacogenetic testing

- Warfarin NCD 90.1: coverage with evidence development

Many Medicare Administrative Contractors adopting LCDs

- Noridian Genetic Testing (L24308)
- Noridian CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing (L35472)
- Palmetto MoIDX: CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing (L34499)
- CGS MoIDX: CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing (L35332)
- Cahaba Pathology and Laboratory: CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing (L35306)

Office of Evaluations and Inspections Reports

Coverage and Payment for Genetic Laboratory Tests



APRIL 2016

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Kickbacks

Long a part of the lab industry;



Special Fraud Alert: Laboratory Payments to Referring Physicians

June 25, 2014

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FCA Settlements

Pathway Genomics

- Paid \$4+ million in December, 2015
- "As alleged, Pathway offered physicians and medical groups reimbursements of up to \$20 for each saliva kit they collected and submitted to Pathway for testing. The United States alleges that individual physicians received as much as \$13,534 in reimbursements from Pathway and that most of the physicians had never ordered these costly genetic tests before enrolling in Pathway's reimbursement program."
- <https://www.fbi.gov/contact-us/field-offices/sandiego/news/press-releases/san-diego-genetics-laboratory-pays-4-million-to-settle-federal-kickback-allegations-in-connection-with-patient-referrals>

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FCA Settlements

- Mitchell Ray Edland, former Ceo/Founder of DNA Stat (marketing company in Addison, Texas)
- Agreed to pay \$270,000 and be excluded for 5 years on October 17, 2017 for:
 - (1) paying physicians to participate in a clinical study, which was not a legitimate clinical study, to induce those physicians to order pharmacogenetic tests from Primex;
 - (2) paying physicians based on the volume of referrals made to Primex for PGX Tests to induce those physicians to order pharmacogenetic tests from Primex;
 - (3) providing physicians with in-office medical technicians to induce those physicians to order PGX Tests from Primex to induce those physicians to order pharmacogenetic tests from Primex;
 - (4) entering into a marketing arrangement with Primex that took into account the volume or value of referrals with the intention of inducing the referrals of PGX Tests to Primex; and
 - (5) entering into marketing agreements with individual marketers that took into account the volume or value of referrals with the intention of inducing referrals of PGX Tests to Primex.

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FCA Settlements

Primex Clinical Laboratories

- FCA Settlement and CIA resolved in December 2017
- Allegations based on same conduct as Edland FCA case, but also included medical necessity allegations
- Paid \$3.5 million

FCA Settlements

Prestige Healthcare

- Paid \$995,500 in April 2017
- Nursing Home Operator
- Contracted with a lab for genetic testing
- Agreed to ensure that lab had all necessary information to bill federal health care programs, including physician orders
- Prestige caused false claims to be submitted for medically unnecessary genetic tests

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Millennium Health, LLC FCA Settlement

October 16, 2015;

Settlement agreement includes allegations pertaining to the medically unnecessary use of pharmacogenetic testing.

OCIG Cases on Molecular Pathology Consultations

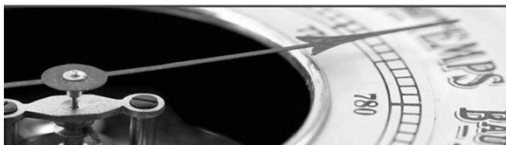
Molecular Pathology (i.e., Genetics) Consult Cases: CPT Code G0452

- Settlement with 29 physicians in 24 physician practices and with one lab
- \$871,435.88 total recoveries; low payment code
- Pain Management MDs, Internal Medicine MDs, Cardiologists, etc.
- In many cases, no attempt to comply with billing code requirement, in some cases cosmetic attempts

Measuring Compliance Program Effectiveness: A Resource Guide

ISSUE DATE: MARCH 25, 2017

HCCA-OIG Compliance Effectiveness Roundtable
Roundtable Meeting: January 17, 2017 | Washington, DC



Risk Effectiveness Guidance: What It Is

Structured Around HCCA Seven Elements
Compilation of Questions Used by Experienced Compliance Professionals
A ToolKit
Stimulus

Risk Effectiveness Guidance: What It Is Not

NOT a Checklist
NOT a Standard
NOT a Guarantee

Risk Assessment Guidance: Ways to Use

By Element or Sub-element
◦ Pick and Choose
– Not All Questions Will Be Applicable.
◦ Refine: Hone In On Key Areas

By Theme
◦ Culture
◦ Retaliation
◦ Oversight
◦ Independence

Questions?
