An Enforcement Update from OIG

KA REN GLASSMAN
SENIOR COUNSEL
DEPARTMENT OF HEALTH AND HUMAN SERVICES, OIG

LATISHA CLEVELAND
ASSISTANT SPECIAL AGENT IN CHARGE
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
Medicare and Medicaid

1 in 3 Americans

OIG Statistics FY 2017

<table>
<thead>
<tr>
<th>Type</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criminal Actions</td>
<td>881</td>
</tr>
<tr>
<td>Civil Actions</td>
<td>826</td>
</tr>
<tr>
<td>Exclusions</td>
<td>3,244</td>
</tr>
</tbody>
</table>

DOJ Statistics FY 2017

Healthcare Fraud Recoveries: $2.4 Billion

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

Alert: Improper Arrangements and Conduct Involving Home Health Agencies and Physicians

- 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

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
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

Categorization of Genetic Testing By Purpose

**Diagnostic Testing:** identifies whether an individual has a certain genetic disease. This type of test determines whether a specific gene alteration exists 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 factors (e.g., environmental, lifestyle).

**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 VULNERABILITIES

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
- Nordic: CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing (L15472)
- Pathnet: CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing (L15495)
- CES NAHDR: CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing (L15332)
- Cahaba Pathology and Laboratory: CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing (L15305)
Kickbacks
Long a part of the lab industry:

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.”

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 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.

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
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
Risk Effectiveness Guidance: What It Is

Structured Around HCFA 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?