HEALTHCARE REGULATION IN AN AGING UNITED STATES

FRIDAY, JUNE 10, 2016
HCCA - SEATTLE, WASHINGTON

ENFORCEMENT INCREASING - WHY?

65+  Costs  Enforcement

Source: Average of AARP and Pew statistics, aarp.org/personal-growth, pewresearch.org/daily-number

FCA  AML  ACA  RICO  AKS  Stark  Fraud  Anti-trust

DEMOGRAPHY

Population Aging

- By 2050, 111% ↑ in US population > 65
- Approximately 9,000 people per day turn 65

Source: Average of AARP and Pew statistics
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5 Washington D.C.s per year 2011 - 2029 (19 years)

DEMOGRAPHY

1. Age 65+ Growth - Increasing NHE from $2.8 T ($8915 per capita)
2. Medicaid – Expansion added 17M and 3% growth per annum


2012 US GDP

By 2020

All HC spending from gov’t programs 2020

FRAUD, WASTE AND ABUSE ABOUNDS

<table>
<thead>
<tr>
<th>Service Type</th>
<th>Improper Payment Rate</th>
<th>Improper Payment Amount ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient Hospitals</td>
<td>5.2%</td>
<td>$7.6B</td>
</tr>
<tr>
<td>Durable Medical Equipment</td>
<td>29.3%</td>
<td>$3.2B</td>
</tr>
<tr>
<td>Physician/ Lab Services</td>
<td>12.7%</td>
<td>$11.0B</td>
</tr>
<tr>
<td>Non-inpatient Hospital Facilities</td>
<td>11.7%</td>
<td>$21.7B</td>
</tr>
<tr>
<td>Total</td>
<td>12.1%</td>
<td>$40.3B</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Error Category</th>
<th>Percent of 2011 National Snapshots Percent Rate</th>
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</thead>
<tbody>
<tr>
<td>No Documentation</td>
<td>1.8%</td>
</tr>
<tr>
<td>Inflatable Document</td>
<td>0.4%</td>
</tr>
<tr>
<td>Medical Necessity</td>
<td>10.9%</td>
</tr>
<tr>
<td>Account Coding</td>
<td>10.9%</td>
</tr>
<tr>
<td>Other</td>
<td>3.2%</td>
</tr>
<tr>
<td>Total</td>
<td>100.0%</td>
</tr>
</tbody>
</table>
OUTCOMES: DME PAYMENT TRENDS
SUSTAINED DECLINES IN MEDICARE PAYMENTS HAVE FOLLOWED FEDERAL ENFORCEMENT AND OVERSIGHT ACTION

- Medicare payments for DME in Miami peaked at more than $60 million per quarter in 2006
- In 2007, numerous federal oversight and administrative initiatives were launched by CMS, OIG and others, including the Medicare Fraud Strike Force in May 2007
- Miami-area DME payments decreased from over $40 million per quarter in 2007 — before the Strike Force’s first takedown — to $15 million per quarter in 2011 (e.g., approximately $100 million in annual savings thereafter)
FCA OVERVIEW

Knowingly presenting a false claim for payment or approval.
Knowingly making or using a false record or statement material to a false claim.
Improperly avoiding or decreasing an obligation to pay the government (reverse false claim).

What is a "claim"?

"any request" for money “whether or not the United States has title to the money or property” that –
– Is made to a contractor or other recipient if the money is to be spent or used on the government’s behalf or to advance a government program of interest and if the United States
  • Provides any of the money requested; or
  • Will reimburse such contractor/recipient for any portion of the money requested

ANTI-KICKBACK STATUTE

Elements of the Prohibition
Knowing and willful
Solicitation, receipt or offer of payment
Of remuneration
In return for referring a Federal program patient, or
To induce the purchase, leasing, or arranging for or recommending or leasing items or services paid by a Federal program
**TO WHOM DOES IT APPLY?**

- Very broad application – it applies to everyone, not just physicians and their practices
  
  “[O]ne does not have to be a ‘provider’ or make an actual ‘referral’ to be covered by the anti-kickback statute. The statute covers any persons who offer, pay, solicit, or receive any unlawful remuneration. The scope of prohibited conduct includes not only that which is intended to induce referrals, but also that which is intended to induce the purchasing, leasing, ordering or arranging for any good, facility, service or item paid for by Medicare or Medicaid.”


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**INTENT UNDER AKS**

Pre-ACA:
- An individual must have actual knowledge of, and the specific intent to, violate the AKS

Post-ACA:
- A person need not have actual knowledge of the AKS or have a specific intent to commit an AKS violation; still requires knowing and willful
  
  – Current standard

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**AKS DEFINITIONS**

Remuneration:
- Anything of value
  
  – A reduction or discount
  
  – Direct payment of cash or loans
  
  – Free items or services

Federal Program Business:
- Medicare, Medicaid, TRICARE, Veterans Administration, etc.

Remedy:
- Criminal liability and civil penalties
**STARK**

Elements of the Prohibition:
- A physician may not make a referral to an entity for the provision of DHS for which Medicare payment may be made (and the entity may not present a claim for services provided as a result of such referral) if the physician or an immediate family member has a financial relationship with the entity unless either the referral or the financial relationship is “excepted” from the Law’s coverage.

Remedy:
- In addition to civil penalties, a refund of every payment received for services that were referred in violation of the law.

**DO MCO CLAIMS QUALIFY?**

- **Anti-Kickback Statute**
  - *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659, F.3d 295, 315 (3d Cir. 2011)
    - Applies AKS to Part C plan

- **Stark**

**CMS GUIDANCE**

More Information:
- Fraud and Abuse in Medicare Part C and Part D and Medicaid
- The fraudulent conduct addressed by these laws also is prohibited in Medicare Part C and Part D and in Medicaid. For more information, refer to the "Medicare Parts C and D Fraud, Waste, and Abuse Training" in the Downside furnace at My CMS.gov/Outreach-and-Education/Medicare-Learning-Network/Medicare-Learning-Network-Provider-Compliance/Help-on-the-Centers-for-Medicare-and-Medicaid-Services (CMS) website.
STATE LAW

- 37 states have statutes that parallel either AKS or Stark
  - Anti-fee splitting
  - Provider conflict of interest
  - Unfair and deceptive trade practice

STATE LAW (EXAMPLES)

- California
  - California Business & Professions Code Section 650
  - More expansive than FCA, applies to claims submitted to commercial plans and Workers Compensation
  - Private cause of action
- Florida
  - Florida’s Deceptive and Unfair Trade Practices Act (Fla. Stat. § 501.201 et seq.)
  - Also applies to claims submitted to commercial plans
  - Private cause of action

RECOVERIES CONTINUE TO RISE!

- HCFAC budget doubled
  - Expected to generate $5.4B
  - Expected to generate an 800% ROI
- Relators incentivized
  - $600M paid to relators in 2015
AREAS OF FOCUS - MEDICARE PART A

- Medically unnecessary invasive procedures
  - Cardiology
  - Orthopedic Surgery (knees, hips, shoulders)
- “Customized” Health Care
  - Costly and customized oncology treatment
  - Genetic analysis
- Aging population & high cost patients
  - Alzheimer’s, Dementia, Parkinson’s, Diabetes

TECHNOLOGICAL ADVANCES

- Medically unnecessary diagnostic laboratory and radiology services
- Mobile health apps and wearable devices
- Telemedicine
- PHI data security
- Security of electronic medical devices

HOSPICE

- Early or false diagnosis of terminal illness
- Continuous care in alleged crisis situation
- Unqualified providers and facilities
- Patient or family involvement in the fraud scheme
- Lucrative medical director contracts/kickbacks
AREAS OF FOCUS - PART B

- Diagnostics
- Ambulance
- Therapy Services
- Dermatology

DIAGNOSTICS

- Social targeting
  - Mall kiosks, health fairs, flea markets, and churches
  - Sleep studies, allergy testing
- High cost genetic testing
  - Medically unnecessary
  - Cheek swabs for drug sensitivity and STDs

DIAGNOSTICS

- Kickbacks between labs and physician offices
  - Labs renting closets at MD offices to avoid kickback scrutiny
- Lab billing issues
  - Inflated charges
  - Urine drug screens and quantitative and qualitative tests
- Expensive diagnostics
  - CAT scans, MRI, Nerve Conduction, Stress Tests
**AMBULANCE**
- Medically unnecessary transports in connection with dialysis services, mental health services, and assisted living facilities
  - Patient co-conspirators
  - $2000 sign-on bonus for co-conspirator patients, then $300-$500 a month
- Air Ambulance

**THERAPY SERVICES**
- Physical Therapy
  - Massage therapy billed as PT
  - Diagnostic and therapeutic ultrasound
  - Unlicensed personnel
- Chiropractic Services
  - Instrument Assisted Soft Tissue Manipulation (IASTM)
    - Reimbursed at higher rate than manual manipulation

**DERMATOLOGY**
- Dermatology
  - False cancerous growth diagnosis and unnecessary minor surgery
  - Misrepresentation of cosmetic procedures
DURABLE MEDICAL EQUIPMENT (DME)

- Wheelchairs
- Custom Orthotics & Ortho Kits
  - Fraud schemes linked to “arthritis kits”
- Oxygen & CPAP Machines
- Aging Supplies
  - Nutrition Supplies
  - Adult Diapers
- Diabetic Testing Strips

YATES MEMO

- “Absent extraordinary circumstances, no corporate resolution will provide protection from criminal or civil liability for any individuals.”

CORPORATE INTEGRITY AGREEMENTS

1. Corporate
   1. Executive Financial Recoupment Program. DeVia shall establish no later than December 31, 2014, and maintain throughout the CSA Period, a financial recoupment program that puts at risk forfeiture and recoupment an amount equivalent to up to three years of annual performance pay (e.g., annual bonus, incentives) for a Covered Executive who is discovered to have been involved in any significant misconduct (Executive Financial Recoupment Program). This financial recoupment program shall apply both to Covered Executives who are current DeVia employees and to Covered Executives who are former DeVia employees at the time of a Recoupment Determination. The specific terms and conditions of the Executive Financial Recoupment Program are set forth in Appendix D to the CSA. DeVia shall maintain an Executive Financial Recoupment Program consistent with the terms of Appendix D for at least the duration of the CSA, absent agreement otherwise by OR.