# Laboratory Oversight and Enforcement

Kyle Fetter VP & General Manager of Diagnostic Services, XIFIN, Inc.

G2 Intelligence Lab Institute 2017

# Industry Happenings and Regulatory / Compliance Enforcement

PAMA

Toxicology

Pricing & Coding
- GSP/ADLTs
- ADLT

Medical Necessity

Data

Patient Billing

Audits/OIG

# Ongoing Battles

- Bar to demonstrate validity and clinical utility keeps rising and now payors are challenging clinical utility on a claim-by-claim basis
  - Manifested in audits
- Investment and financing in the space continues to be extremely challenging
- Appropriate labs not given “specialty” status

ROI ⬇ while costs ⬆

# Medicare Payments for Lab Tests in 2016: Year 3 of Baseline Data - Summary

- Medicare Part B paid $6.8 billion for lab tests in 2016 (~$0.2B less than 2015)
- The top 25 lab tests totaled $4.3 billion in 2016 (60% of total MCare)
  - 50% of reimbursement for the top 25 tests went to 1% of labs
- Medicare paid 26% less for drug tests & 37% less for molecular tests in 2016 vs. 2015
  - Payment for MAAAs increased by 665%
- OIG estimated savings of $390M in 2018 vs. draft 2018 CLFS estimate of $670M

| In 2018 | 5 years (2016-25) | 10 years (2016-25) |
|---|---|---|
| US$390 million | US$2.3 Billion | US$3.9 Billion |

*Source: September 2016 HHS OIG DATA BRIEF: Second set of annual baseline analysis of payment for the top 25 lab tests*

# Coding and Payment 2018

**Clinical**

- Routine testing sees an 8-10% cut
- Toxicology definitive testing sees a 10% cut

**Molecular**

- NonProprietary – mostly a wash
- Proprietary- mostly increases with some exceptions

**Issues**

- Lower per test revenue and increasing compliance costs decrease availability of testing to patients

# Genomic Sequencing Procedures (GSPs) – Rates Completely Decoupled from Costs

| HCPCS | Descriptor | National Limit |
|---|---|---|
| **81435** | Inherited Colon | $795.95 |
| **81436** | Inherited Colon | $795.95 |
| **81445** | 5-50 genes- solid organ | $597.31 |
| **81450** | 5-50 genes- hematolymphoid | $759.53 |
| **81455** | 51 or greater genes- hematolymphoid or solid organ | $2,919.60 |

*Discrepancies demonstrate the arbitrary nature of the pricing here across the board and labs clearly cant afford to provide the first 4 services on this list

*Source: AMP Publishes Economic Analysis of Genomic Sequencing Procedures to Support Lab, Payor Discussions – 4/20/16*

# Commercial Payor Issues

Documentation becoming more and more critical!

Back-end medical necessity audits increasing, recoupment requests 12-18 months after payments

Appeals work, but only if the documentation supports

- Does more harm than good to appeal a claim for which there is no support, but providers should avail themselves of opportunities when warranted

Narrow networks and new payment models-sanctions on use of OON labs

Prior Authorization requirements

Payors actively recouping payments around uncompliant patient billing policies

# CMS Issues – Labs Targeted

- $7.7 recouped for every $1 spent on anti-fraud activities
- “Guilty until proven innocent”
  - No accountability for adhering to resolution deadlines
  - “Follow the $$” – labs held responsible for issues out of their control, ie physician error
- Heavy ZPIC activity
  - Suspension of PTAN numbers
- 2 attorneys – 6 examples of unprecedented suspensions
  - No opportunities to appeal
  - Seem to be targeting:  PGX, Florida, contracted sales forces

# Nature of the Audits in the Market

**Patient Billing**

- Requests for proof of patient billing coming to labs big and small with requests to see:
  - ➢Proof of collections of patient balances
  - ➢Or in lieu of that, proof of attempt to bill

**Medical Necessity**

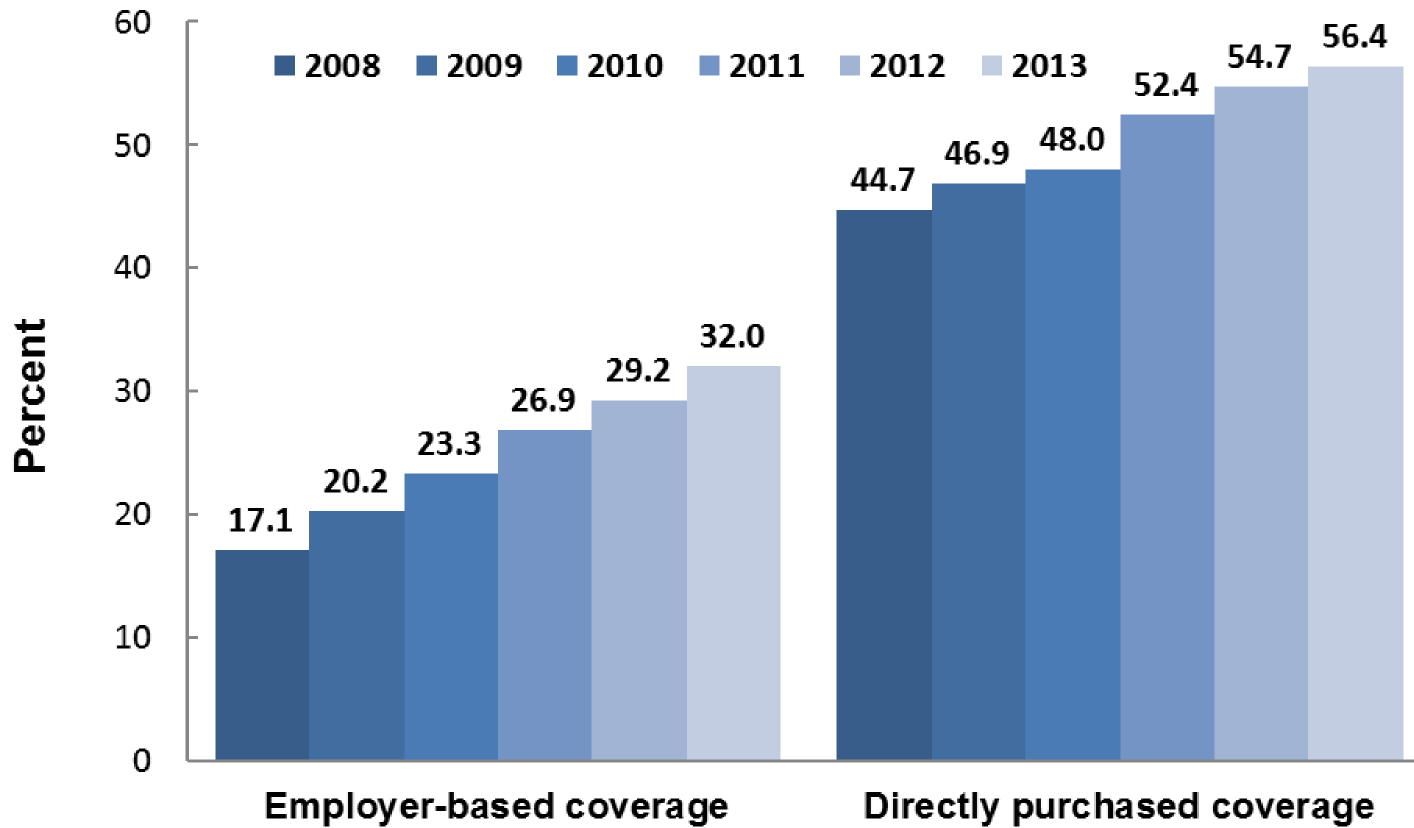
- Requesting medical records where if the physician notes don't document the order correctly, recoupment or request for refund is made
  - ➢Generally coordinated through the ZPIC on behalf of the MACs
  - ➢Routinely coming from Private payors as well
  - ➢Using and E&M visit claims data to determine if they should look more closely at certain lab claims

*Settlements range from hundreds of thousands to hundreds of millions with both commercial and government payors

**Can take months to years to complete depending on the scope of the audit

# Medicare Overpayment Rule

- Medicare Reporting and Returning of Self-Identified Overpayments CMS 6037-F Final Rule
- The Centers for Medicare & Medicaid Services (CMS) has published a final rule that requires Medicare Parts A and B healthcare providers and suppliers to report and return overpayments by the later of the date that is 60 days after the date an overpayment was identified, or the due date of any corresponding cost report, if applicable.




- Leading to compliance issues re: patient shares of cost
- Salaries not keeping pace with increasing out of pocket costs

# 3rd Party Lab Benefit Management Services

- Highmark using eviCore: front end prior auths and back end medical necessity
- BCBS of NC/SC using Avalon: handling adjudication and benefits
- UHC using Beacon: requires physician to select test/lab and get the authorization directly
- Empire using AIM: benefit management and prior authorization

https://www.highmarkblueshield.com/health/pdfs/pubs/tm-hbs-evicore-lab-management-program-062416.pdf