Managed Care Enforcement

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Overview from HHS-OIG

- OIG – who we are
- OIG Priorities
- Managed Care Top Management Challenge
- Risk Areas and OIG Action
- Coordination with Key Stakeholders

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
FDA
U.S Food and Drug Administration
INDIAN HEALTH SERVICE · PHS · 1955
DEPARTMENT OF HEALTH & HUMAN SERVICES · USA
U.S. PUBLIC HEALTH SERVICE · 1798
NIH
U.S. Department of Health and Human Services
HRSA
Health Resources and Services Administration
CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION
ADMINISTRATION FOR CHILDREN & FAMILIES

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OIG Mission

Mission: To protect the integrity of HHS programs and the welfare of the people they serve.

Vision: To drive positive change in HHS programs and in the lives of the people served by these programs.

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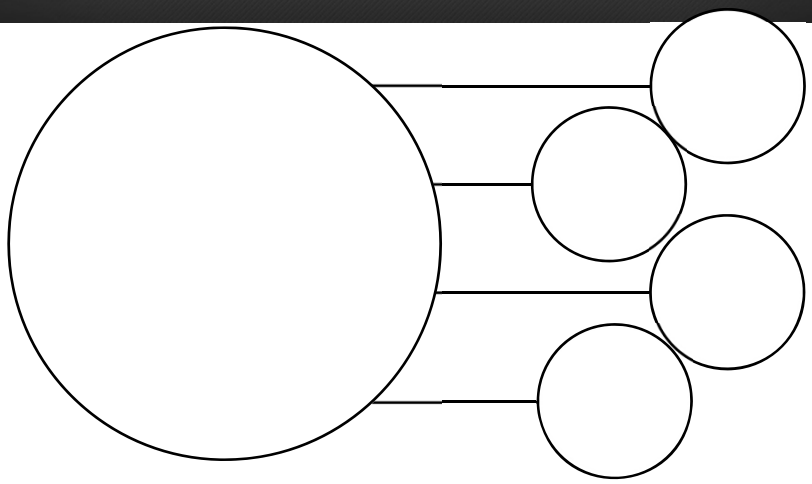
OIG Components



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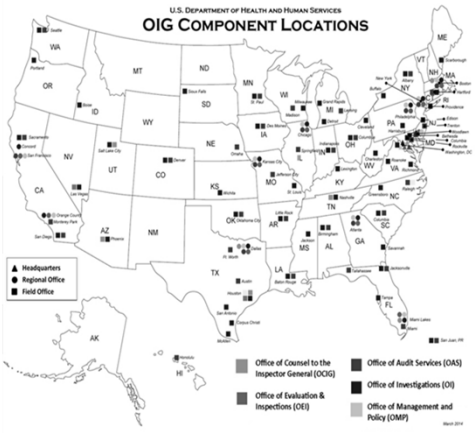
OIG Locations

1,550+ employees



70+ offices

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OIG's Unique Role

- Identify
- Educate
- Enforce

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OIG By The Numbers

- Oversee the $1.1 trillion HHS budget
- $700M oversight per employee
- FY 17 OIG ROI = $13:$1

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OIG by the Numbers FY14-18

- $23.3 billion in expected recoveries
- 1,371 reports issued
- 4,485 criminal actions
- 3,562 civil actions
- 17,720 exclusions

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OIG by the Numbers FY18

- Expected recoveries of +$3.43 billion
- 764 criminal actions
- 813 civil actions
- 2,712 exclusions
- $66M in Civil Monetary Penalties and assessments

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Desired Outcomes

- Healthier People
- Lower Costs
- Better Care
- More Efficient System

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Identifying Risk Areas

- Program Vulnerabilities
- Data Analytics
- Hotline, Qui Tams, Tips
- OIG Collaboration

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OIG-Identified Risks

- HHS Top Management Challenges
- Work Plan
- Semi-Annual Report, HCFAC Report
- Audits, Evaluations, Investigative Results
- Website – oig.hhs.gov

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Opioids

- OIG Role
- HHS Program Improvement
- Identify and Hold Wrongdoers Accountable
- Share/Collaborate with Partners

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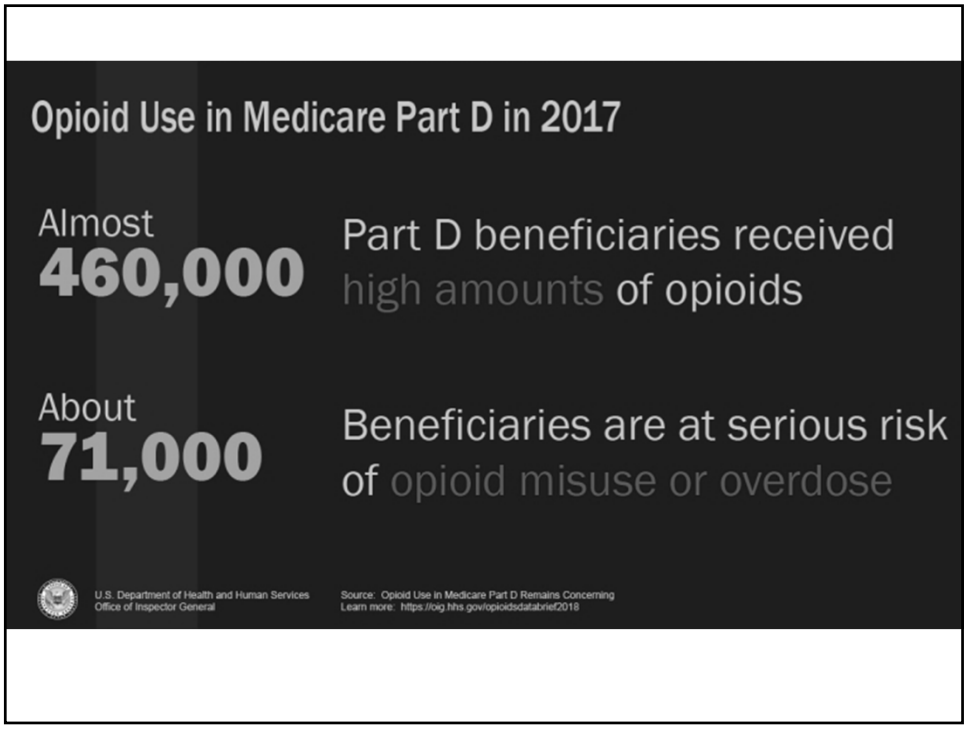

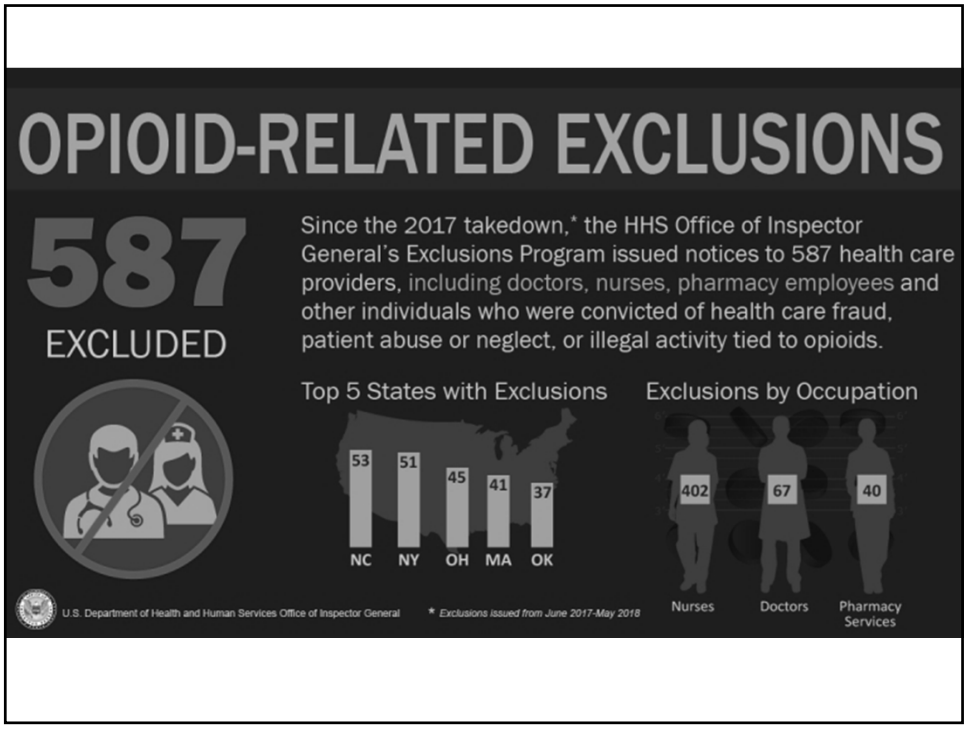

Opioids

Toolkit:

Using Data Analysis To Calculate Opioid Levels and Identify Patients At Risk of Misuse or Overdose

Home and Community Based Services

- Home Health
- Hospice
- Group Homes
- Personal Care Services

Home Health

- Vulnerable Area
  - Medical Necessity
  - Kickbacks
- OIG Multi-Disciplinary Approach
- OCIG Industry Outreach
- Focus on Geographic Hot Spots

Hospice

Portfolio:

Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity

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Joint Report

U.S. Department of Health and Human Services
Office of Inspector General,
Administration for Community Living, and
Office for Civil Rights

Ensuring Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight

January 2018

Personal Care Services

- MFCU focus
  - 38% of MFCU indictments involve PCS providers or attendants
- Beneficiary abuse and neglect
- Financial fraud

Managed Care: Top Management Challenge

Managed Care: Top Management Challenge

Ensuring Value and Integrity in Managed Care:

- Combatting provider fraud and abuse
- Fostering compliance by managed care organizations

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Managed Care: Top Management Challenge

What needs to be done:

- Ensure comprehensive data
- Identify fraud and abuse
- Make referrals to law enforcement
- Ensure access to care
- Enhance oversight of MCO contracts

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Risk Area: Fraud by Providers

- Challenges to oversight
- Shared program integrity obligations
  - CMS, plans, States, and contractors
- Detection of suspected provider fraud varies widely

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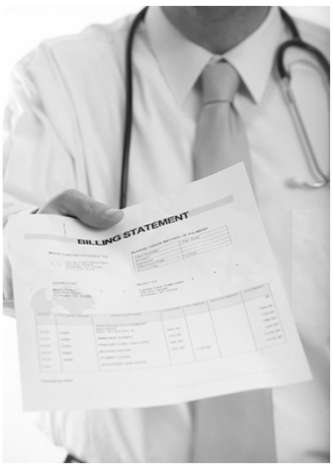
Risk Area: Fraud by Providers

- Limitations in MA and Medicaid MCO encounter data pose a challenge to effective oversight of the programs.
- Lack of complete data



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OIG Report: Weaknesses Exist in Medicaid MCO's Efforts to Identify Fraud and Abuse

- Medicaid MCO identification of fraud and abuse by network providers
- Some MCOs identified and referred only a few providers suspected of fraud or abuse
- Not all MCOs used proactive data analysis
- MCO did not inform states of action taken against providers suspected of fraud

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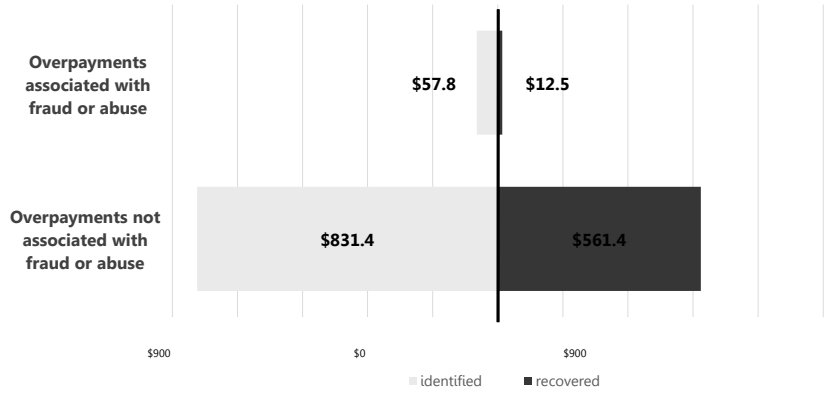
MCOs did not always identify and recover overpayments
(dollars in millions)_



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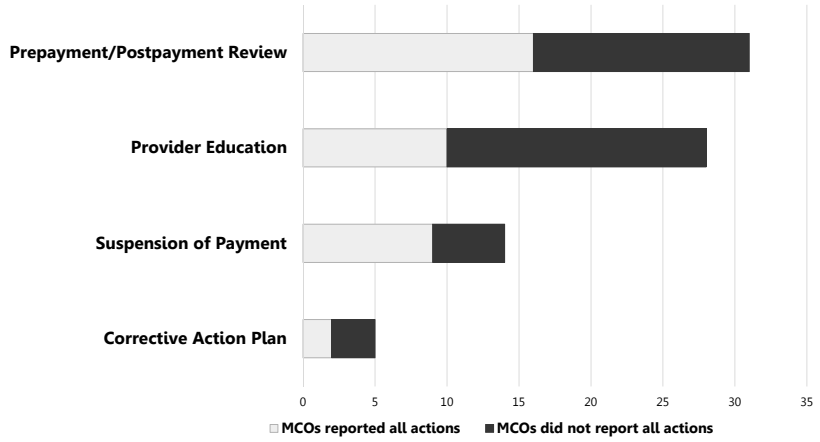
MCOs took corrective actions but did not always report these actions to the State.



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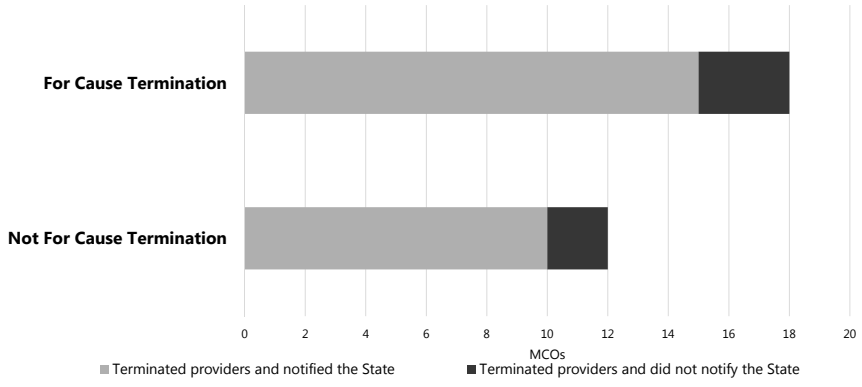
MCOs sometimes terminated suspected providers but did not always notify the State



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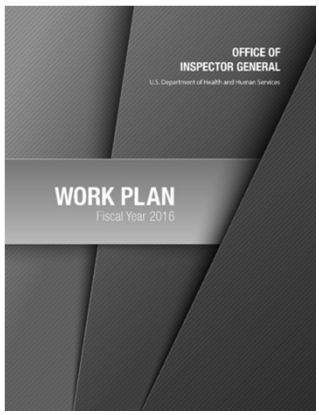
Work Plan Items: Providers

- State Compliance with MCO Provider Enrollment Requirements
- Risk Adjustment Data
- Medicaid MCO payments to providers for treating health-care acquired conditions
- Questionable billing by pharmacies, information provided by plans to CMS, and billing of compounded topical drugs



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Enforcement: Providers

- Billing Fraud
  - Coordination with MEDICS, MCOs, CMS, States, and other government partners
- Unlicensed NJ Dentist Agrees to Pay $1.1 Million and 50-year voluntary exclusion

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Enforcement: Providers

- Region 8 Mental Health Services: $6.93M settlement and CIA
  - allegations that it was paid for services that it either did not provide or that were not provided by qualified individuals as part of its preschool Day Treatment program.
- CIA with pediatric mental health provider includes claims review of managed care claims

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Risk Areas for Plans

- Stinting on care: improper denials of care/payment
- Risk adjustment fraud
- Data security vulnerabilities
- Improper cap payments
  - Per-bene rate
  - Deceased
  - No longer in the plan

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OIG Report: MA Appeal Outcomes Raise Concerns About Service Denials

- MAOs overturned 75% of their own denials during 2014-2016
- High volume of overturned denials raises concerns that that some beneficiaries were denied services and payments that should have been provided.
- Beneficiaries rarely use appeals process – only 1% of denials were appealed in 2014-2016
- OIG recommends CMS enhance oversight of MAO contracts, address inappropriate denials, provide beneficiaries with clear information about serious violations by MAOs.

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OIG Report: Data Security Vulnerabilities

- OIG identified data security vulnerabilities at two Arizona Medicaid MCOs
- Disparate treatment of data security at the state and MCOs
- Increased risk to Medicaid patient data
- OIG recommendations
  - CMS conduct documented risk assessment
  - Inform all State agencies of the cybersecurity vulnerabilities identified

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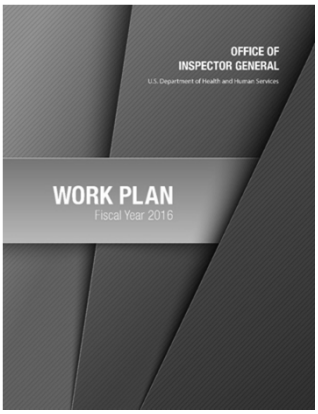
Work Plan Items: Plans

- Inappropriate Denial of Service and Payment in Medicare Advantage
- Review of MCO's use of Medicaid funds to provide services
- Managed care payments made for dead beneficiaries



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Work Plan Items: Plans

- Risk Adjustment Data – Part C
  - Audits of risk adjustment data
  - Study: Financial Impact of Health Risk Assessments and Chart Reviews on Risk Scores in Medicare Advantage
- Part D Sponsor compliance with remuneration reporting requirements

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Enforcement: Plans

- United Litigation
  - Risk adjustment fraud
- Freedom Health Settlement
  - Wide ranging Part C fraud
  - Resolved with CIA, Part C reviews
- Centers Plan for Healthy Living
  - improper enrollment of individuals into long term care plan who were not eligible for the plan.

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Risk Area: Quality of Care

- Access to providers, provider network adequacy
- Access to services
- Part D sponsors inclusion of drugs on formularies

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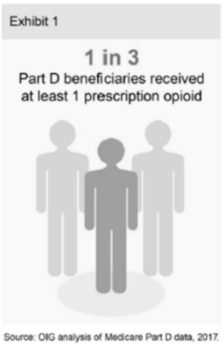
Risk Area: Quality of Care

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

- 90K beneficiaries at serious risk
- 400 prescribers had questionable opioid prescribing patterns.



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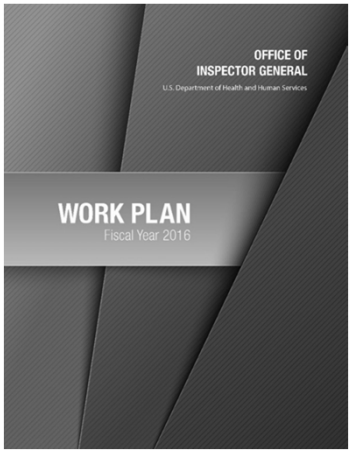
Work Plan Items: Quality of Care

- Availability of Behavioral Health Services in Medicaid MCOs
- Denials by Part C and D plans
- Health-Care-Acquired Conditions in Medicaid MCOs



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Program Integrity in Medicaid Managed Care Regulation

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Medicaid MCO Regulation

Program Integrity in the MCO contract

- 42 C.F.R. 438.608
- Robust, effective compliance program
- Applies to subcontractors

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Medicaid MCO Regulation

Provider Screening and Enrollment

- 42 C.F.R. 438.608(b)
- Network providers required to be enrolled in Medicaid
- Applies to subcontractors

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Medicaid MCO Regulation

Treatment of Overpayment Recoveries

- 42 C.F.R. 438.608
- Must be addressed in contract
- States have a lot of flexibility

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Medicaid MCO Regulation

Partnering with States

- Strong partnership between plans and states
- Payment suspension
- Coordination with law enforcement

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Maximizing Fraud Fighting Impact

- National Health Care Anti-Fraud Association
- Healthcare Fraud Prevention Partnership
- Managed care plan SIU

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Conclusion

- OIG is tackling fraud, waste and abuse in the managed care programs head on
- OIG's focus in two key areas:
  - Combatting fraud, waste, and abuse by health care providers billing managed care plans, and
  - Ensuring integrity and compliance by managed care plans and Part D sponsors

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Managed Care Developments

- Annual Attestation
- CMS RADV Audits
- HHS-OIG RADV Audits
- The Overpayment Rule (*Azar*)
- False Claims Act cases in Managed Care
- DOJ Theories of Liability
- Compliance

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Data Accuracy and Payment Accuracy Obligations: Annual Attestation

- Medicare regulations require MAOs to annually certify on "best, knowledge, information, and belief" the "accuracy, completeness, and truthfulness" of risk adjustment data they submit to CMS. 42 C.F.R. § 422.504(l).
- CMS/OIG regulatory guidance provides only general guardrails for what is expected under this standard, including instructing MAOs to make "good faith efforts" to certify the accuracy, completeness, and truthfulness of data, CMS, 65 Fed. Reg. 40,268 (June 29, 2000), and to conduct "sample audits and spot checks" to confirm that the information collection and reporting system is working correctly. OIG, 64 Fed. Reg. 61,900 (Nov. 15, 1999).

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Data Accuracy and Payment Accuracy Obligations: CMS RADV Audits

- CMS periodically conducts Risk Adjustment Data Validation ("RADV") audits of selected Medicare Advantage contracts "to ensure risk adjusted payment integrity and accuracy," 42 C.F.R. § 422.311(a), which involve a review of a sample of medical records to determine whether the diagnoses that the MAO submitted associated with those medical records are properly supported by the underlying record
- In 2012, CMS announced its intention to apply a Fee-For-Service Adjuster ("FFS Adjuster") amount to determine and calculate "overpayments" it would recover for future RADV audits, but never released the FFS Adjuster amount.
- Instead, on November 1, 2018, CMS issued a proposed rulemaking indicating an intention to eliminate the previously announced FFS Adjuster. CMS also indicated its intention to expand RADV auditing to include new methodology types. This proposed rule is currently open to industry comment until April 30, 2019, and industry stakeholders are preparing comments and expert reports challenging CMS's proposal.

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Data Accuracy and Payment Accuracy Obligations: HHS-OIG RADV Audits

- HHS-OIG also conducts RADV audits, having first conducted a series of RADV audits for CY 2006 data and releasing a report for each audit in 2012 and 2013.
- In these early RADV audits, HHS-OIG appeared to apply a more stringent coding standard than CMS applies in its RADV audits.
- A regulatory change to 42 C.F.R. § 422.311(a) in 2014 confirmed that both CMS and HHS have authority to conduct RADV audits.
- In October 2017, HHS-OIG updated its work plan to include a review of "Risk Adjustment Data – Sufficiency of Documentation Supporting Diagnoses," with expected reports to be issued in 2018 and 2019.
- In January 2018, HHS-OIG also indicated its plan to report on "Financial Impact of Health Risk Assessments and Chart Reviews on Risk Scores in Medicare Advantage."
- Since 2017, HHS-OIG has initiated a number of new RADV audits; however, no results have been published to date.

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The Overpayment Rule

- The Affordable Care Act enacted a requirement that MAOs report and return "overpayments" to CMS within 60 days of identification. 42 U.S.C. § 1320a-7k(d)(1)-(2).
- In 2014, CMS promulgated a Final Rule implementing the ACA's statutory requirement for Part C overpayments. The language of the regulation largely tracks the ACA. 42 C.F.R. § 422.326.
- ***UnitedHealthcare Ins. Co. v. Azar***. On September 7, 2018, D.C. District Court Judge Rosemary Collyer issued a decision vacating the Overpayment Rule because it was "arbitrary and capricious" and "violate[d] the statutory mandate of 'actuarial equivalence.'"
- Part D Overpayment Rule, 42 C.F.R. § 422.360, still in effect following *Azar* ruling.

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The False Claims Act

False Claims Act Elements

- Prohibits knowingly presenting a false claim or knowingly making a false record or statement material to a false claim
- Reverse FCA imposes liability on a person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government"
- "Knowingly" includes acting in reckless disregard or deliberate ignorance of the truth or falsity of the information
- "Obligation" is defined as "an established duty, whether or not fixed, arising from an express or implied contractual … relationship … , or from the retention of any overpayment."

Damages, Penalties and Whistleblowers

- Government may recover treble damages
- Civil penalties of $21,000+ per claim
- *Qui tam* provisions allow individuals (e.g., employees, contractors, providers) to sue and share in ultimate recovery

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Recent Qui Tam Cases: Risk Adjustment

<u>Provider Submissions</u>

- *Janke*, No. 09-14044 (S.D. Fla.) (FCA settlement)
  - Defendants allegedly submitted codes for MA reimbursement that were not supported and failed to look for erroneous diagnoses or delete codes upon learning that they were inaccurate
  - $22.6M settlement in November 2010
- *Thompson*, Nos. 12-81110, 15-80012 (S.D. Fla.) (criminal; civil *qui tam*, not pursued by relator)
  - Network provider allegedly submitted false diagnoses to health plan
  - Guilty plea by provider in criminal matter on March 4, 2016
  - DOJ intervened in civil matter as to provider
- *Graves*, No. 10-23382 (S.D. Fla.) (unsealed *qui tam*, DOJ non-intervention, case settled)
  - Network provider allegedly submitted inaccurate diagnoses, and health plan submitted data with allegedly inadequate compliance oversight
  - 2018 settlement with provider and plan for $3 million.

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Recent Qui Tam Cases: Risk Adjustment

Provider Submissions

- *Swoben* / DaVita Disclosure, 09-5013 (C.D. Cal.) (civil *qui tam*, voluntary disclosure, case settled)
  - DaVita acquired HealthCare Partners ("HCP"), a large independent physician association, in 2012. DaVita voluntarily disclosed practices instituted by HCP (also a defendant in the *Swoben qui tam* alleging unlawful one-way chart reviews) that caused MAOs to submit incorrect diagnosis codes to CMS and obtain inflated payments in which DaVita and HCP shared.
  - In October 2018, DaVita entered into a $270M settlement with DOJ to resolve both the *Swoben* allegations and the diagnosis coding practices at the center of DaVita's voluntary disclosure.
- *Sutter*, 15-CV-01062-JD (N.D. Cal.) (civil *qui tam*, DOJ intervened)
  - Defendants, Sutter Health and Palo Alto Medical Foundation, allegedly knowingly submitted unsupported diagnosis codes to the MAOs with which they contracted (unnamed in the complaint)
  - DOJ intervention in December 2018

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Recent Qui Tam Cases: Risk Adjustment

Chart Reviews

- *Swoben*, No. 09-05013 (C.D. Cal.) (unsealed *qui* tam, 9th Circuit revived on appeal, dismissal of DOJ complaint-in-intervention)
  - Network provider of SCAN and other health plans allegedly inflated risk scores through retrospective chart reviews
  - $320M settlement with SCAN in August 2012 (with $4M related to MA allegations)
  - DOJ Complaint-in-Intervention dismissed; DOJ elected not to amend
  - $270M settlement with DaVita HCP related partially to *Swoben* allegations announced October 1, 2018
- *Poehling*, No. 11-0258 (C.D. Cal.) (unsealed *qui tam*, DOJ intervention, case proceeding)
  - Health plan allegedly manipulated risk scores, by, among other things, performing "one-way" chart reviews and failing to delete specific codes determined to be inaccurate via temporary "two-way" chart review process
  - Attestation-based claims dismissed; MTD reverse FCA-based claims denied

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Recent Qui Tam Cases: Risk Adjustment

In-Home Assessments

- *Silingo*, No. 13-01348 (C.D. Cal.) (unsealed *qui* tam, DOJ declined, dismissal reversed on appeal, case proceeding)
  - In-home assessment vendor allegedly submitted false diagnoses to health plan defendants
  - Plan defendants allegedly submitted those diagnoses to CMS without adequate vendor oversight
- *Ramsey-Ledesma*, No. 14-00118 (N.D. Tex.) (unsealed *qui tam*, DOJ declined, case settled)
  - Similar to *Silingo*, but related to a different vendor
  - Health plans dismissed from case

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DOJ's Primary Theories of FCA Liability: Risk Adjustment

- False attestations (as it had originally asserted in both *Swoben* and *Poehling* but has been rejected by both courts)
- Failure to comply with contractual and regulatory requirements that health plan correct inaccurate diagnosis codes (as it is currently asserting in *Poehling*)
- Retained overpayments under the reverse FCA (a theory that has been pled but not advanced in recent briefing in *Poehling*)

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Compliance Guidance for Managed Care

- 2012 – HHS-OIG issued guidance for Medicare Advantage Organizations
- February 8, 2017 – DOJ's Fraud Section issued "Evaluation of Corporate Compliance Programs"

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Compliance Guidance for Managed Care

DOJ will evaluate adequacy of compliance program and oversight

HHS-OIG Guidance (Civil)

- "Employees, managers and the Government will focus on the **words and actions (including decisions made on resources devoted to compliance)** of an organization's leadership as a measure of the organization's commitment to compliance."
- "The use of **audits or other risk evaluation techniques** to monitor compliance and assist in the reduction of identified problem areas."

DOJ Criminal Division Guidance

- "How have senior leaders, through their **words and actions**, encouraged or discouraged the type of misconduct in question? What concrete actions have they taken to **demonstrate leadership in the company's compliance and remediation efforts**?"
- "What types of **audits** would have identified issues relevant to the misconduct? Did those audits occur and what were the findings? …. How often has the company updated its **risk assessments** and reviewed its compliance policies, procedures, and practices?"

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Compliance Resources

- Board of Directors Compliance Guidance
- Compliance Resource Guide
- TMC, Work Plan, and other media
- OIG CIAs

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Compliance Program Basics

<u>Seven Fundamental Elements</u>

1. Written policies and procedures
2. Compliance professionals
3. Effective training
4. Effective communication
5. Internal monitoring
6. Enforcement of standards
7. Prompt response

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Freedom Health (May 2017): Notable Elements of the CIA

- Provider Network Review:
  - Network Adequacy
  - New contract
  - Expanded Service Area Contracts
- Diagnosis Coding Review
  - Filtering logic
  - 100 member sample

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Advisory Opinion

- Requestor is a Medicaid MCO, wants to provide network providers with incentive payments for providing EPSDT services to existing enrollees
- This arrangement is protected under the eligible managed care organizations safe harbor, 42 C.F.R. 1001.952(t)
- Incentive payments are payments to provide or arrange for health care services

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