Managed Care Enforcement Trends and Compliance Risks

Health Ethics Trust – Certification Intensive Course

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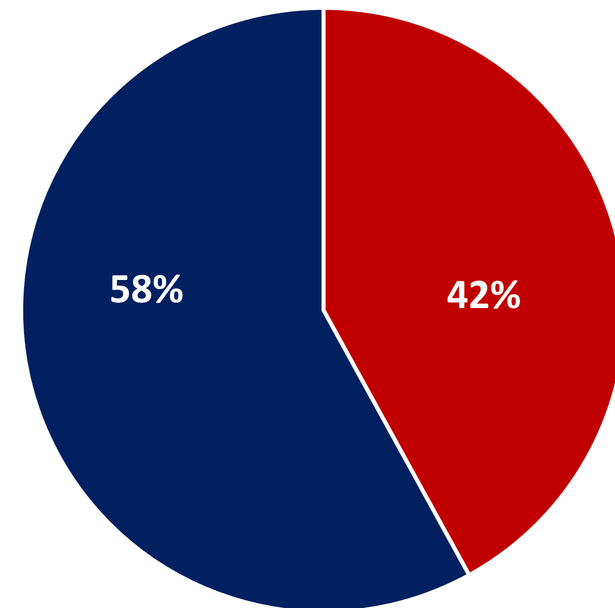
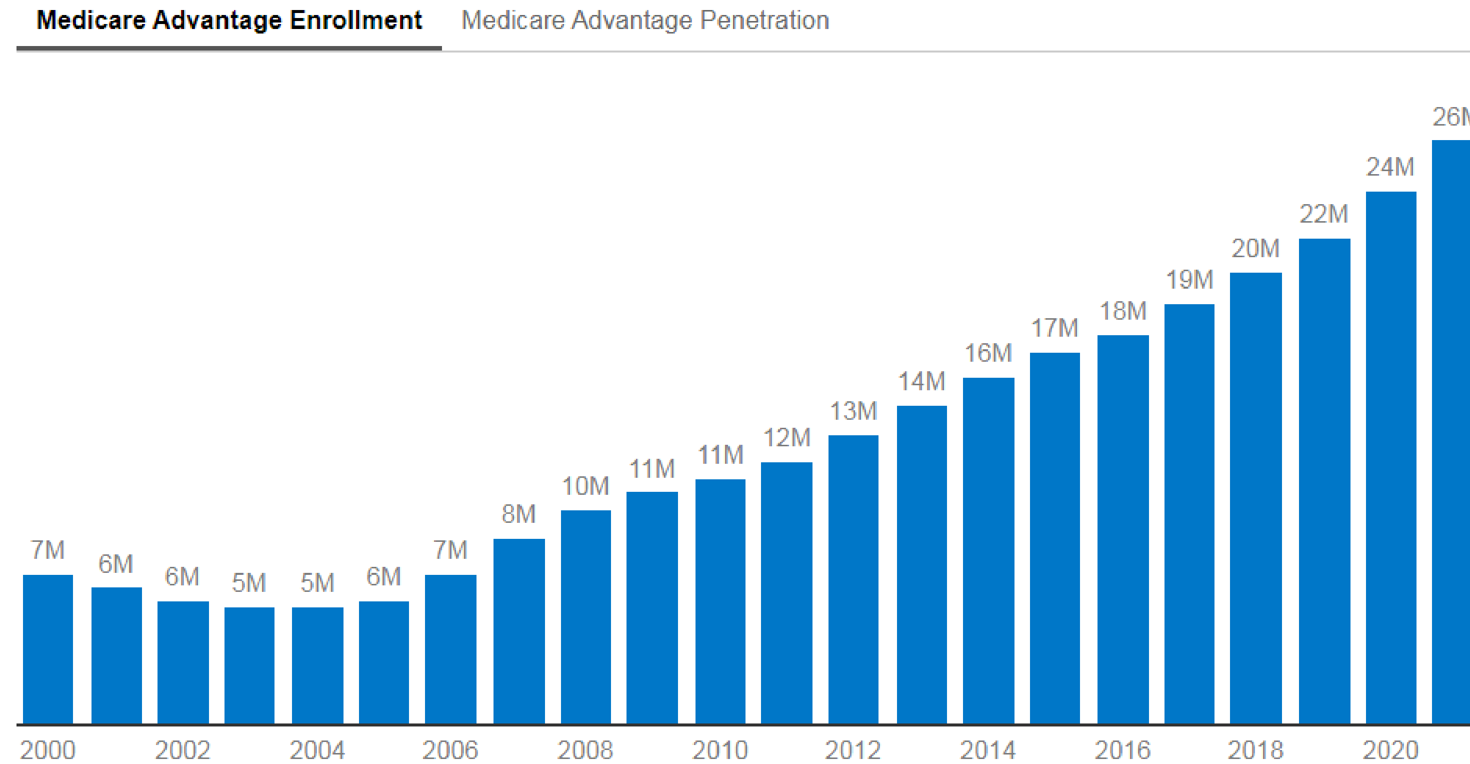
MEDICARE ADVANTAGE AND RISK ADJUSTMENT BACKGROUND

Background on Managed Care Programs with Risk Adjustment

- The health care world is changing.
- FFS → Managed Care
- MA enrollment has more than doubled in the last decade
- 26M beneficiaries (42% of Medicare beneficiaries) enrolled in MA in 2021. Trend continues.
- MA enrollees accounted for $343 billion (46%) of total Medicare spending in 2021
- By 2023, expenditures by MAOs expected to reach ~ $250 billion



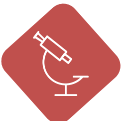
Medicare Advantage Enrollment Trends



Source: Kaiser Family Foundation

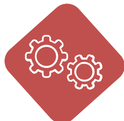
What is Risk Adjustment and how is it used?

1. Process of measuring the relative health status and health spending of a population of patients



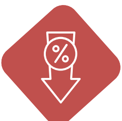
1. Diagnosis code based models

2. Prescription medicine based models

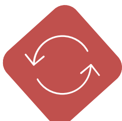


3. Combination based models

2. Used for a variety of purposes including:



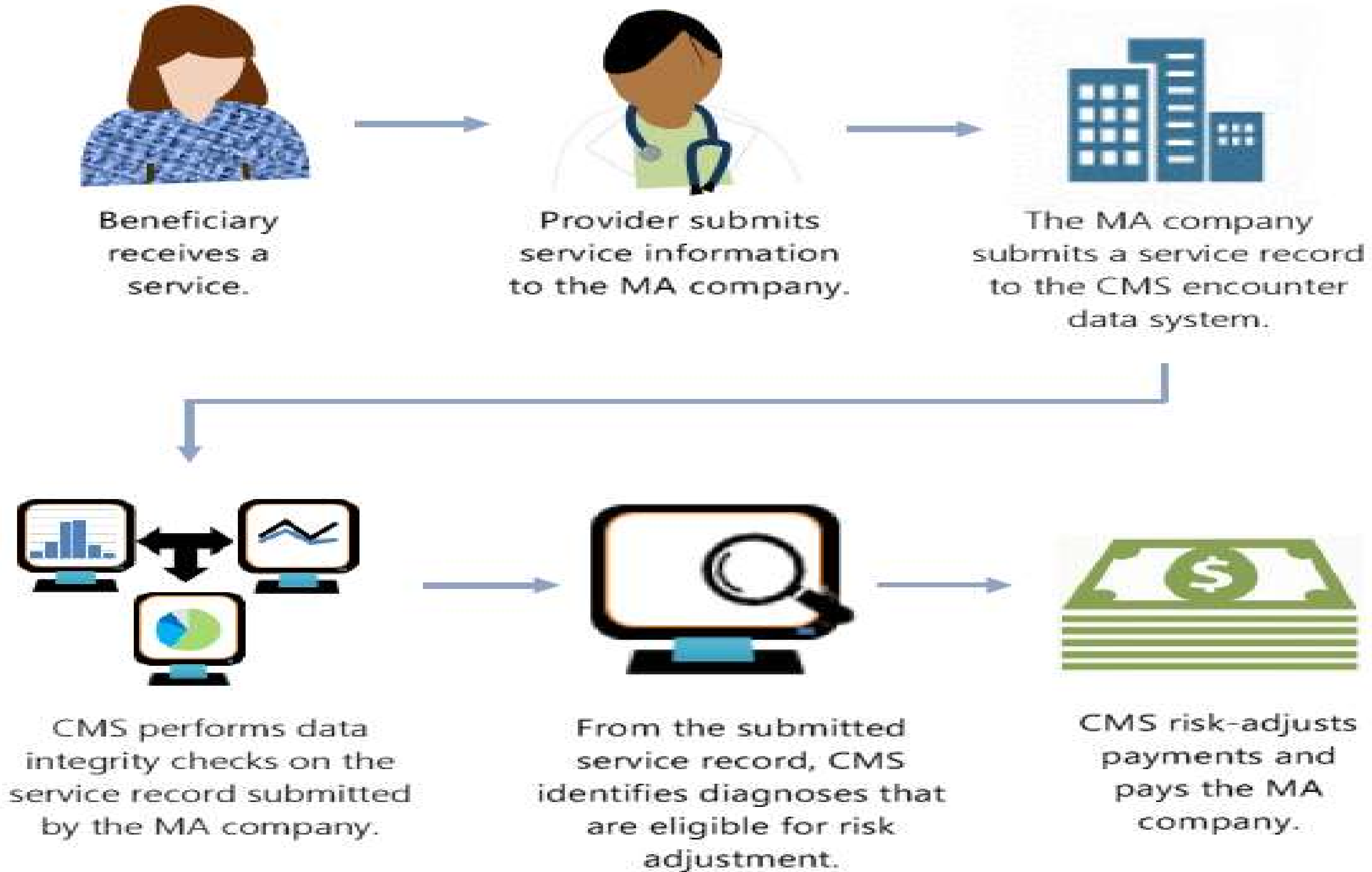
1. Minimize incentives that lead to adverse selection in beneficiary enrollment



2. Re-allocating premiums in a “zero-sum” model using equitable comparisons of underlying membership

3. Aligning premium payments with health risk and expected costs

Exhibit 1: MA risk-adjustment process



Source: OIG summary of CMS's guidance on the MA risk-adjustment process.[6]

Medicare Risk Adjustment: Risk Score Calculation

Risk Adjustment Impact Example (Community, NonDual, Aged Member: V24 Model)

Scenario 1: Comprehensively Coded			Scenario 2: Partially Coded			Scenario 3: No Coding		
Male: 90-94 Years		0.841	Male: 90-94 Years		0.841	Male: 90-94 Years		0.841
HCC 18: Diabetes with Chronic Complications		0.302	HCC 19: Diabetes without Complication		0.105	No Diabetes Coded		-
HCC 51: Dementia With Complications		0.346	HCC 52: Dementia Without Complication		0.346	No Dementia Coded		-
HCC 85: Congestive Heart Failure		0.331	HCC 85: Congestive Heart Failure		0.331	No CHF Coded		-
HCC 96: Specified Heart Arrhythmias		0.268	No Specified Heart Arrhythmias Coded		-	No Specified Heart Arrhythmias Coded		-
HCC 138: Chronic Kidney Disease, Moderate (Stage 3)		0.069	CKD 2 (Does Not Risk Adjust)		-	No CKD Coded		-
Interaction: Diabetes and CHF		0.121	Interaction: Diabetes and CHF		0.121	No Diabetes and CHF Interaction		-
Interaction: CHF and Renal		0.156	No CHF and Renal Interaction		-	No CHF and Renal Interaction		-
Interaction: CHF and Specified Heart Arrhythmias		0.085	No CHF and Specified Heart Arrhythmias Interaction		-	No CHF and Specified Heart Arrhythmias Interaction		-
HCC Count: 5		0.042	HCC Count: 3		-	HCC Count: 0		-
Subtotal		**2.561**	**Subtotal**		**1.744**	**Subtotal**		**0.841**
FFS Normalization Factor		1.069	FFS Normalization Factor		1.069	FFS Normalization Factor		1.069
Coding Intensity Factor		5.9%	Coding Intensity Factor		5.9%	Coding Intensity Factor		5.9%
Adjusted Risk Score		2.255	**Adjusted Risk Score**		1.535	**Adjusted Risk Score**		0.741
Base Premium	$	800	Base Premium	$	800	Base Premium	$	800
Monthly Premium	$	1,804	Monthly Premium	$	1,228	Monthly Premium	$	593
Annual Premium	**$**	**21,648**	**Annual Premium**	**$**	**14,736**	**Annual Premium**	**$**	**7,114**

GOVERNMENT FOCUS

Government Focus

- HHS-OIG is focused on MA reimbursement
  - Recent reports on topics such as MA chart reviews, MA health risk assessments, and MA encounter data
  - Ongoing audits of particular MAO contracts
- DOJ is focused on MA reimbursement
  - In February 2022, the DOJ Civil Division noted in a press release that MA remained an "important priority"
  - Ongoing enforcement activity

Data Accuracy & Payment Accuracy Obligations

- CMS RADV Audits
  - Conducted "to ensure risk adjusted payment integrity and accuracy" (42 C.F.R. § 422.311(a))
  - Review medical records to determine whether diagnoses are properly supported
- HHS-OIG RADV Audits
  - In October 2017, HHS-OIG updated its work plan to include a review of "Risk Adjustment Data – Sufficiency of Documentation Supporting Diagnoses."
  - 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."
  - Reports can be an excellent resource for understanding RA compliance and audit risk areas.

MA Risk Areas OIG Focused on in 2021

Risk-Adjusted Payments

- Targeted Diagnoses
- RADV-like audits

Health Risk Assessments and Chart Reviews

- Only source for diagnosis
- No indication of follow-up care

Provider Data

- NPIs for ordering providers missing
- DMEPOS, clinical laboratory services, imaging, and home health

OIG Audits of Medicare Advantage

Compliance Audit of Diagnoses Submitted by MAOs (RADV-like)	Compliance Audit of Specific Diagnosis Codes (Targeted)
• Sample across plan and review all diagnoses for selected beneficiaries • 200 enrollees selected per plan; over 1,500 HCCs	• Target high-risk diagnoses with a greater probability for error; specific scenarios or mis-keyed • 200+ enrollee years sampled per plan

OIG Targeted Audits

MAO	Percent of HCCs Not Validated	Percent Disagreement with HCC Determination	Questioned Costs (Overpayments Identified)
Essence	34%	0%	$160,000
BCBS Michigan	76%	0%	$14,540,000
Anthem	61%	2%	$3,470,000
Coventry	82%	4%	$550,000
UPMC	69%	8%	$6,400,000
Healthfirst	65%	0%	$5,220,000
Total	66%		$30,340,000

FALSE CLAIMS ACT AND REGULATORY BACKGROUND

False Claims Act (31 U.S.C. §3729)

- Prohibits knowingly presenting a false claim or knowingly making a false record or statement material to a false claim
- Reverse false claims
- Damages, penalties and whistleblowers:
  - Government may recover treble damages
  - Civil penalties of $11,803 to $23,607 per claim
  - *Qui tam* provisions allow individuals to sue and share in recovery

Regulatory and Enforcement Landscape

- **Medicare Part C Overpayment Rule (42 C.F.R. §422.326)**
  - MAOs must report and return "overpayments" to CMS within 60 days of identification (42 U.S.C. §1320a-7k(d)(1)-(2))
  - CMS promulgated a Final Rule implementing the ACA's requirement for Part C overpayments (42 C.F.R. §422.326)
- ***UnitedHealthcare Ins. Co. v. Azar (Sept. 2018)***
  - D.C. District Court Judge Rosemary Collyer vacated the Overpayment Rule because it was "arbitrary and capricious" and "violate[d] the statutory mandate of 'actuarial equivalence.'"
  - However, the Court of Appeals reversed in August 2021, holding that the statutory mandate of "actuarial equivalence" does not apply to the Overpayment Rule
  - But . . . UnitedHealthcare filed a petition at the Supreme Court on February 16, 2022

Regulatory and Enforcement Landscape (cont.)

- **Use of Agency Guidance Documents in FCA Enforcement**
  - **Brand Memo** (Jan. 2018) – former AAG Rachel Brand issued a Memorandum limiting the use of agency guidance documents in litigation, stating that DOJ "may not use its enforcement authority to effectively convert agency guidance documents into binding rules"
  - ***Azar v. Allina Health Services*** (June 2019) – Supreme Court reinforced the Brand memo's principals and invalidated an informal policy posted by a government agency
    - The policy altered a "substantive legal standard" affecting Medicare payments without going through the Medicare Act's required notice-and-comment process
  - **CMS Memo** (October 2019) – CMS acknowledged that its informal guidance may inform an existing statutory or regulatory requirement, but it "may not be used as the sole basis for an enforcement action."
  - **Garland Memo** (July 2021) – Rescinded Brand Memo and criticized it as "overly restrictive" and a "substantial departure" from DOJ's "traditional approach" to guidance documents

FCA CASE TRENDS & ENFORCEMENT ACTIVITY

Key Matters that are Public

- Approximately 24 public MA-related Qui Tams since 2009
- 13 settlements totaling ~ $790M to date.
- Over $370M in settlements since 2018 including the two largest:
  - $270M Health Care Partners (2018)
  - $90M Sutter (2021)
- Other settlements include providers and MAOs:
  - $5M Beaver Medical (2019)
  - $6.3M GHC (2020)
  - $2.25M Keystone (2020)

FCA Risk Adjustment Case Trends
General Observations

- **Whistleblowers include**:
  - Providers/clinicians (physicians, nurses, hospitals)
  - Coders, auditors, billers, records managers
  - Executives/managers for MAOs/affiliates
  - Vendors/consultants
  - (In some cases, whistleblower first raised concerns internally)
- **Defendants include:**
  - MAOs / Plans / Group and Individual Providers
  - Vendors / MSOs
  - Consultants / Subcontractors
- **DOJ Intervention**
  - DOJ partially intervened in 14 of 22 qui tam cases filed (64%). Higher rate than usual.

FCA Risk Adjustment Case Trends

Common Allegations

1. **Adding DX Codes to Increase Risk Scores**
   - Physicians may be innocent bystanders – or participants.
2. **Upcoding without Sufficient Support in Patient Records**
   - Data mining, home health assessments, and EMR.
   - Addenda
   - Outside vendors sometimes involved (MSOs, auditors, consultants).

FCA Risk Adjustment Case Trends
Common Allegations

3. **Failure to Correct Inaccurate or Unsupported DX Codes**
   - Chart Reviews
     - one way only ("adds" not "deletes")
     - retrospective
   - Failure to delete codes after audits.
   - Failure to expand audits once inaccurate coding found.
4. **Provider Incentives/Pressure to Submit False DXs**
   - Bonuses, queries, problem lists, etc.
5. **Patient Incentives**
   - Free gift cards, eye exams.

FCA Risk Adjustment Case Trends
Common Allegations

6. **Kickbacks**
    - Payments to beneficiaries *(e.g.*, $50 gift cards)
    - Payments to physicians

7. **Other Alleged Compliance Failures**
    - Lack of compliance training
    - Failure to satisfy compliance obligations
    - Failure to check accuracy of codes sent to CMS

Enforcement Activity

Provider Submissions

- Janke settlement
- *Baez/Thompson*
- *Graves*
- *Nutter*
- DaVita settlement
- Sutter settlement

Chart Review

- *Swoben*
- *Poehling*
- *Sewell*
- *Ross*
- Anthem

In-Home Assessments

- *Silingo*
- *Ramsey-Ledesma*
- *Gray*
- *Cutler*

Provider Assessments

- *Ormsby*
- *Rasmussen*
- *Zafirov*
- *Mansour*

Select Enforcement Activity

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

Silingo, No. 13-01348 (C.D. Cal.) (unsealed *qui tam*, DOJ declined, dismissal reversed on appeal, case settled)

- In-home assessment vendor allegedly submitted false diagnoses to health plan defendants
- Plan defendants allegedly submitted those diagnoses to CMS without adequate vendor oversight

Select Enforcement Activity (cont.)

Poehling, No. 11-0258 (C.D. Cal.) (unsealed *qui tam*, DOJ intervention, case proceeding, trial scheduled for 2/21/2023)

- 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; DOJ’s partial summary judgment motion was denied in March 2019

Ormsby, 15-CV-01062-JD (N.D. Cal.) (civil *qui tam*, DOJ intervened, MTD denied, case proceeding)

- Defendants, Sutter Health and Palo Alto Medical Foundation, allegedly knowingly submitted unsupported diagnosis codes to the MAOs with which they contracted
- DOJ intervention in December 2018
- Court denied defendants’ motions to dismiss, rejecting defenses regarding actuarial equivalence and knowledge
- $90M Settlement announced in August

2020: Enforcement Activity

2020 Settlements:

- **Kaiser Foundation Health Plan of Washington** $6.3 million settlement with DOJ to resolve allegations that it submitted inflated and invalid diagnoses codes for MA beneficiaries, by knowingly allowing a third-party vendor to routinely "upcode" claims (Nov. 2020)
- **Independence Blue Cross (IBC**) agreed to pay $2.25 million to resolve allegations that it incorrectly calculated actual prior costs in the financial bids it submitted, resulting in inflated reimbursement to IBC (Sept. 2020)

2020: Enforcement Activity

<u>Pending Litigation</u>:

- ***U.S. v. Anthem, Inc***. March 2020 FCA action related to Anthem's alleged failure to delete inaccurate diagnosis codes submitted to CMS for risk adjustment purposes, effectuated in part through one-way chart review. Anthem's motion to dismiss is pending
- ***U.S. ex rel. Cutler v. Cigna Corp.*** Unsealed FCA *qui tam* in which relator alleges Cigna-HealthSpring inappropriately captured diagnoses not supported in the underlying medical record by encouraging nurses to diagnose beneficiaries with exaggerated medical problems, promoted falsification of diagnoses, and reported health conditions not supported by medical documentation or reliable clinical information.
- DOJ declined in part to intervene. Case recently reassigned to SDNY. Case proceeding.

2021: Notable New Cases

- ***U.S. v. Kaiser Permanente***
  - On July 30, 2021, the government intervened on six separate *qui tam* complaints against Kaiser, which were originally filed between 2013 – 2021. One complaint remains unsealed.
  - The government intends to intervene only on those allegations relating to the submission of false claims for "risk-adjustment payments based on diagnoses improperly added via addenda under Medicare Part C from the years 2009 until present."
  - Allegations include, among other things, that Kaiser failed to audit potential coding concerns, remediate as required and appropriately submit data corrections. Failure to look back at past data submissions.
  - The government's consolidated complaint in intervention was filed on October 25, 2021.
  - Motion to dismiss on first-to-file bar is currently pending. Hearing held on April 21, 2022.

- ***UnitedHealthcare Insurance Co. et al. v. Becerra et al. ("UnitedHealthcare"), case number 18-5326 (D.C. Circuit 2021)***

HHS-OIG REPORTS & CORPORATE INTEGRITY AGREEMENTS

SCAN Health Plan

- HHS-OIG performed an RADV-like audit of 200 enrollees, with 1,577 HCCs from 2015
  - Identified 164 unvalidated HCCs, 20 of which had other appropriate HCCs for more/less severe manifestations of the diseases
  - Identified 21 additional HCCs that should have been billed
  - Estimated that SCAN received $54.3 million in <u>net</u> overpayment
- HHS-OIG recommended that SCAN refund the government the overpayment and improve its policies and procedures

Tufts Health Plan

- HHS-OIG performed a targeted audit of 212 enrollee-years from 2015-16 with certain high risk diagnosis codes
  - 154 of the 212 sampled enrollee-years had diagnosis codes that were not supported in the medical records
  - Estimated that Tufts received $3.7 million in net overpayment
- HHS-OIG recommended that Tufts
  - Refund the net overpayment
  - Identify similar instances of noncompliance occurring before/after the audit period for the high-risk diagnoses examined and make corresponding refund
  - Improve compliance procedures to identify improvements to ensure diagnosis codes are not being miscoded

Essence Healthcare, Inc.
Targeted RADV

- Some of the diagnoses codes that Essence submitted for use in CMS's risk adjustment program did not comply with Federal requirements
  - Diagnoses codes submitted to CMS either were not supported in the medical records or
  - Diagnoses codes could not be supported because Essence could not locate the medical records
  - 75 of 218 had unsupported codes
  - $158,904 in identified overpayments
  - Cause: Policies and procedures to detect and correct noncompliance were ineffective

MA Payments From Chart Reviews

- Review of 2016 diagnoses data that resulted from chart reviews
  - Diagnoses that MAOs reported only on chart reviews (and not on any service records) resulted in an estimated $6.7 billion in risk adjusted payments for 2017
  - Almost half of MAOs reviewed had payments from unlinked chart reviews
    - OIG could not identify the specific service or encounter associated with the diagnosis.
    - $2.6 billion of the chart review payments did not link to specific services
  - MAOs often used chart reviews to add, rather than to delete, diagnoses
  - Raised concerns about:
    - completeness of payment data
    - validity of diagnoses on chart reviews
    - quality of care provided to beneficiaries

Billions in Estimated MA Payments from Diagnoses Supported Solely through HRAs

- Diagnoses that MAOs reported only on HRAs -- and on no other service records -- resulted in an estimated $2.6 billion in risk-adjusted payments for 2017
  - in-home HRAs generated 80 percent of these estimated payments
- Most in-home HRAs were conducted by companies that partner with or are hired by MAOs to conduct these assessments
  - not likely conducted by the beneficiary's own primary care provider\
- Raises concerns about:
  - completeness of data
  - validity of diagnoses
  - quality of care coordination

MAO Encounter Data Lack Essential Information

- Almost all MAOs have data systems that receive and store NPIs when providers submit them to MAOs on claims or encounter records
- MAOs reported that providers are already submitting the ordering provider NPIs on claims or encounter records for DMEPOS, laboratory services, and imaging services
- MAOs require NPIs to be submitted for their other lines of business (such as commercial and private health insurance, Medicaid, and the Children's Health Insurance Program)
- MAOs believe that NPIs for ordering providers are critical for combating fraud

Corporate Integrity Agreements

- Freedom Health (May 2017)
  - Provider Network Review
    - Network Adequacy / New Contract/ Expanded Service Area Contracts
  - Diagnosis Coding Review
    - Filtering logic / 100 member sample
- Beaver Medical Group (December 2019)
  - Annual chart review / Sample of 100 members enrolled in MA plans
  - Review of diagnosis data and medical records
- Sutter Health (August 2021)
  - Centralized risk assessment program
  - Review of diagnoses data and medical records

COMPLIANCE BASICS

Compliance Program Basics

Seven Fundamental Elements

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

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"

Compliance Guidelines

- Medicare Managed Care Manual. Chapter 21 – Compliance Program Guidelines and Prescription Drug Benefit Manual. Chapter 9 - Compliance Program (2012).
  - Monthly checks for excluded individuals among employees and first-tier, downstream, and related entities.
  - Processes to identify, deny, prevent payment of claims from excluded providers at point of sale.
  - Requires disclosure by employees and first tier, downstream or related entities of new exclusions.
  - Establish SIU unit or perform SIU functions through compliance.

Plan Duty to Investigate Providers

Medicare Advantage

- Sponsors are required to investigate potential FWA [Fraud, Waste, Abuse] activity to make a determination whether potential FWA has occurred.
- Sponsors must conclude investigations of potential FWA within a reasonable time period after the activity is discovered."
  - CMS Medicare Managed Care Manual
- OIG Work Plan

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?"

Questions?