The False Claims Act and Liability for Risk Adjustment

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Agenda

1. Medicare Risk Adjustment Background
2. Origins of Liability for Risk Adjustment
3. State of Settlements and Litigation
4. Recent Final RADV Rule and Audit Liability

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Medicare Risk Adjustment Background

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What is Risk Adjustment?

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

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Risk Adjustment in Government Programs

	Medicare Risk Adjustment	Medicaid Risk Adjustment	Affordable Care Act (ACA) Risk Adjustment
1	Diagnosis code-based model	All types of models	Diagnosis code-based model that is averaged at the plan level
2	Determines payments prospectively	Adjusts payments retrospectively	Redistributes a premium pool among participating plans
3	Accounts for demographic and health factors	Accounts for demographic and health factors	Accounts for demographic and health factors
4	Payment impact is not capped	Payment impact is capped	Payment impact is capped

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MA Risk Adjustment Process

1. Provider documents member visit in the medical record
2. Provider's office assigns diagnosis codes
3. Provider submits claim or encounter to MA plan

1. MA plan processes claims and encounter data from providers
2. MA plan may review provider charts for missed or unsupported diagnosis codes
3. MA plan submits risk adjustment data to CMS via EDPS files

1. CMS processes data for risk adjustment factor calculation and payment
2. CMS returns data to MA plans with accepted or error code status

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MA 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**

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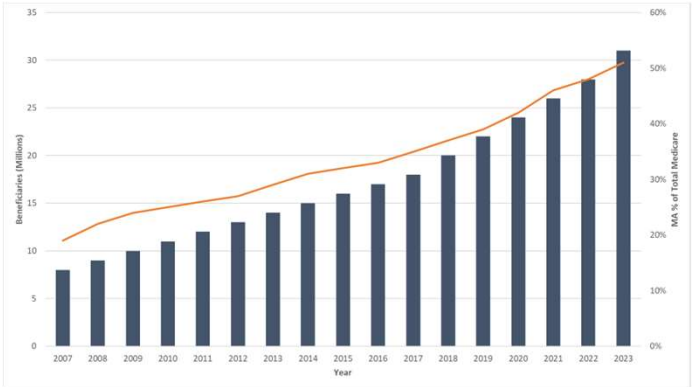
MA Growth

- MA enrollment continues to grow at a rapid rate
- The percentage of MA enrollees compared to all Medicare continues to increase and has surpassed 50%
- MA enrollment is forecasted to continue to grow over time
- MA will continue to be a focus of the government as more enrollees and more payments flow from CMS to MAOs

Medicare Advantage Enrollment and Percentage of Total Medicare Enrollment Over Time



Source: Kaiser Family Foundation - https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2023-enrollment-update-and-key-trends/

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Origins of False Claims Act Liability for Risk Adjustment

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Primary Legal Obligations Relating to Risk Adjustment

- To participate in the MA program, MAOs must execute a contract with CMS that require MA plans to operate ***"in compliance with the requirements of applicable Federal statutes, regulations, and policies."*** 42 U.S.C. § 1395w-27(a).
- As a condition of payment, the CEO, CFO, or delegated officer of MAOs must annually certify, based on "best knowledge, information, and belief," to the ***"accuracy, completeness, and truthfulness"*** of the diagnosis data it submits to CMS. Related entities that generate the diagnosis data must do likewise. 42 C.F.R. § 422.504(l).
- All diagnosis data submitted to CMS must ***conform with the ICD Guidelines***, which carry the force of law. 42 C.F.R. § 422.310(d)(1); 45 C.F.R. § 162.1002. See also U.S. ex rel. Osinek v. Kaiser, 2022 WL 16925963, *11-14 (N.D. Cal., Nov. 14, 2022).

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Primary Legal Obligations Relating to Risk Adjustment (cont.)

- Diagnosis codes submitted for payment are valid only if they are ***documented in the medical record*** as a result of a ***face-to-face encounter*** between a patient and a ***qualified provider; during the service year***. *See, e.g., CMS, Medicare Managed Care Manual*, Ch. 7 § 40 (Rev. 118, Sept. 19, 2014).
- Diagnosis codes must be based on documented conditions that exist at the patient visit and that ***"require or affect patient care treatment or management"*** for the visit. ICD-10 Guidelines § IV.J.
- After initial diagnosis, ***chronic diseases "treated on an ongoing basis*** may be coded and reported as many times as the patient ***receives treatment and care for the condition(s)."*** ICD-10 Guidelines § IV.I.

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State of settlements and litigation

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The Overall Landscape

- Massive privatization of Medicare.
- Collision between the practice of medicine, the business of medicine, and a complex reimbursement system.
- Necessarily limited government oversight and accountability.
- Powerful but uncertain new technologies and capabilities (e.g., generative AI).

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The Overall Landscape (cont.)

"The department pursued cases alleging that organizations participating in the Medicare Advantage (or Medicare Part C) program **knowingly submitted or caused the submission of inaccurate information or knowingly failed to correct inaccurate information** about the health status of beneficiaries enrolled in their plans to increase reimbursement."

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False Claims Act Settlements and Judgments Exceed $2 Billion in Fiscal Year 2022

Second-Highest Number of Settlements in History

Settlements and judgments under the False Claims Act exceeded $2.2 billion in the fiscal year ending Sept. 30, 2022, Principal Deputy Assistant Attorney General Brian M. Boynton, head of the Justice Department's Civil Division, announced today. The government and whistleblowers were party to 351 settlements and judgments, the second-highest number of settlements and judgments in a single year. Recoveries since 1986, when Congress substantially strengthened the civil False Claims Act, now total more than $72 billion.

"Protecting taxpayer dollars by preventing fraud and abuse is a critical priority for the Department of Justice," said Principal Deputy Assistant Attorney General Boynton. "The large number of settlements and judgments this past year demonstrates

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MA Risk Adjustment Activities That Have Received DOJ/OIG Scrutiny

- One-way look retrospective chart reviews
- Health Risk Assessments and Annual Wellness Visits
- Medical record addenda
- Natural Language Processing (NLP)
- Physician incentives/pressure to diagnose for HCCs
- Use of EMR queries and physician prompts
- "Data-mining" medical records and problem lists
- Failure to audit and correct known deficiencies

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MA Risk Adjustment Cases

DOJ priority

- Heavy reliance on and significant attention from Relator Bar

First FCA risk adjustment complaint

- U.S. v. Janke (filed by DOJ in early 2009)

Recently unsealed complaints

- Wilbur v. Martin's Point (7/31/23 - Rel's Complaint Unsealed)
- Cutler v. Cigna (10/14/22 – DOJ Complaint-In-Intervention)
- Osinek v. Kaiser (10/12/22 – DOJ Amended Complaint-In-Intervention)

Currently, 30 *public* FCA cases

- 28 (qui tam); 2 (non-qui tam)

Defendants from all levels of the MA system

- MAOs & Affils. (22+)
- Group Providers (16+)
- Vendors / Consultants (9+)
- Individuals (9)
- MSOs (1)

Focus appears to be shifting from MA plans to providers and vendors

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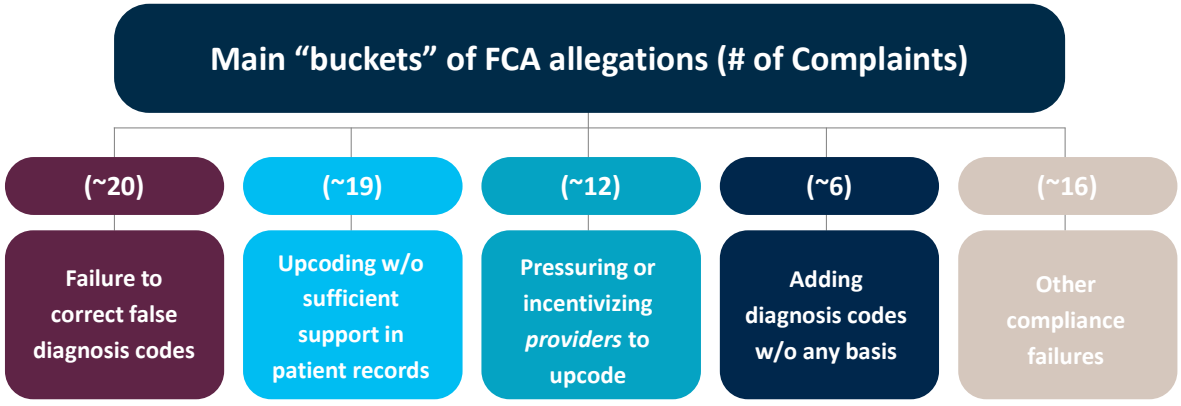
MA Risk Adjustment Cases (cont.)



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MA Risk Adjustment Case Trends

Intervention

DOJ partially intervened in 19 of 28 qui tam cases (68% intervention rate)

- Compare to ~22% in FCA cases generally
- DOJ filed Statements of Interest or Amicus brief in 3 cases in which it did not intervene

Investigation Period

From date of qui tam complaint to DOJ intervention decision:

- Longest = 95 mos.
- Shortest = 10 mos.
- Average = 42 mos.

Govt. investigations are getting shorter…

- Average period after *Kaiser* case = 26.4 mos.

Success Rate

DOJ/Relators, Defendants

- 15 US /13 Def split on MTD
- 3/3 split on SJ

Appeals

- DOJ/Relators have won all 3 appeals

No S.Ct. decisions; No trials

- Cert denied in *UHG v. Becerra*

Settlements

16 settlements in 14 cases

- ~$970 M govt. recovery
- DOJ has obtained a settlement or is still litigating all cases in which it intervened (100% success rate)
- ~6 cases ongoing
- More filed, not public

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MA Risk Adjustment Major Settlements

2010

U.S. v. Janke (S.D. Fla.) ($22.6 M)

2012 & 2018

U.S. ex rel. Swoben v. SCAN Health Plan (C.D. Cal.) ($319 M) and U.S. ex rel. Swoben v. Secure Horizons (C.D. Cal.) ($270 M)

2017

U.S. & State of Florida ex rel. Sewell v. Freedom Health, Inc. (M.D. Fla.) ($32.5 M **& CIA**)

2019

U.S. ex rel. Nutter v. Beaver Medical Group LP (C.D. Cal.) ($5 M **& CIA**)

2020

- ***U.S. ex rel. Ross v. Group Health Cooperative*** (W.D.N.Y) ($6.4 M with GHC; ongoing as to other defendants)

2021

- ***U.S. ex rel. Ormsby v. Sutter Health*** (N.D. Cal.) ($90 M **& CIA**)

2023

- ***U.S. ex rel. Helzner v. Complete Physician Services*** (E.D. Pa.) ($1.5 M)
- ***U.S. ex rel. Wilbur v. Martin's Point Health Care, Inc.*** (D. Me.) ($22.5 M)
- ***United States ex rel. Cutler v. Cigna Corp., et al.*** (M.D. Tenn.) ($172.3 M **& CIA**)

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Cigna Settlement (9/29/23) - $172.5M

History of the FCA *qui tam* Litigation:

- **10/2/17:** Relator files FCA Complaint under seal in SDNY. Relator is a former officer and owner of a vendor to Cigna b/w 2012-2017.
- **6/11/19:** Relator files an Amended Complaint.
- **2/25/20:** DOJ files notice *declining to intervene in part*, but continuing to investigate Relator's other allegations.
- **8/3/20:** The Court unseals the case.
- **12/4/20:** Cigna moves to transfer the case from SDNY to MDTN.
- **9/29/21:** Judge grants Cigna's motion to transfer.
- **1/11/22:** DOJ files motion to partially intervene.
- **8/2/22:** Court grants DOJ's motion to partially intervene.
- **10/14/22:** DOJ files Complaint-in-Intervention
- **12/16/22:** Cigna files Motion to Dismiss DOJ Complaint
- **2/15/23:** DOJ files Opposition to Cigna's Motion to Dismiss
- **3/17/23:** Cigna files Reply to DOJ's Opposition to the Motion to Dismiss

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Cigna Settlement (9/29/23) - $172.5M (cont'd)

History of the FCA *qui tam* Litigation:

- **6/5/23:** DOJ files Notice of Supplemental Authority re: Supreme Court's *SuperValu* decision.
- **6/19/23:** Relator files Second Amended Complaint.
- **6/20/23:** Cigna files Response to DOJ's Notice of Supplemental Authority (and Joint Request for Additional Briefing).
- **8/3/23:** Relator files Third Amended Complaint.
- **9/1/23:** Joint Status Report on Discovery.
- **9/11/23:** Cigna files a new Motion to Dismiss.
- **9/29/23:** **The parties file a Notice of Settlement.**
- **9/30/23:** **DOJ issued press release announcing three part settlement, including the Relator's claims in above litigation.**

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Cigna Settlement (9/29/23) - $172.5M (cont'd)

The Three-Part Settlement:	**Settlement Amount**
A. The FCA Qui Tam (SDNY & MDTN): "Invalid Diagnoses" Based on Home Visits (2012 – 2019)	$37M (including $18.5M restitution)
B. DOJ's Own Investigation I (EDPA): One-Way Look Chart Review Program (2014-2019)	$116M (including $58M restitution)
C. DOJ's Own Investigation II (EDPA): Inaccurate and untruthful Morbid Obesity diagnoses (2016-2021)	$19.5M (including $9.8M restitution)

Plus 5 year CIA!

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Cigna Settlement (9/29/23) - $172.5M (cont'd)

The "Covered Conduct" in the FCA Qui Tam Settlement:

"Cigna violated the FCA by knowingly submitting to CMS for risk adjustment purposes false and invalid diagnoses of serious, complex medical conditions that:

(a) were based only on the home visits to Medicare Part C beneficiaries conducted by contracted health care providers;

(b) required specific testing or imaging to be reliably diagnosed, which was not performed; and

(c) were not reported to Cigna by any other healthcare provider who saw the beneficiary during the year in which the home visit occurred (the "Invalid Diagnoses").

The Government further alleges that the Invalid Diagnoses were not supported by the information documented on forms completed by the contracted providers and did not conform with the [ICD Guidelines], as required by applicable federal regulations.

The Government further alleges that Cigna falsely certified on an annual basis that the diagnosis data it submitted to CMS was 'accurate, complete, and truthful.'"

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Cigna Settlement (9/29/23) - $172.5M (cont'd)

To what portion of the "covered conduct" in the FCA Qui Tam settlement did Cigna admit?

Mostly conduct that is perfectly legal, but also . . .

Paragraph 2.g.

"According to diagnostic criteria disseminated by Cigna to the vendors, the clinical assessment of some of these diagnoses relies on laboratory evaluation, diagnostic imaging, or other diagnostic testing when making a particular diagnosis for the first time.

In many cases, Cigna did not require 360 Program vendors conducting in-home assessments to have the equipment available to conduct such laboratory testing, imaging, or other diagnostic testing when diagnosing these conditions."

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Cigna Settlement (9/29/23) - $172.5M (cont'd)

Cigna also admitted to the following …

Paragraph 2.h.

"In thousands of instances, the in-home assessments conducted by 360 Program vendors resulted in diagnoses of Cigna members, and the submission to CMS of resulting risk-adjusting diagnosis codes, that had not been previously reported to CMS by Cigna from any other encounter with a healthcare provider during the year in which the home visit occurred."

Paragraph 2.i.

"Based on the in-home assessments of members completed by vendors pursuant to the 360 Program, in many instances Cigna reported to CMS diagnoses for Medicare Advantage Plan members where the 360 forms did not include clinical information that corroborated the diagnoses and did not reflect that the diagnostic testing necessary to make the diagnosis for the first time had been performed."

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Who Are the Whistleblowers?

The MA Risk Adjustment whistleblowers to date come from *all types of private entities* that participate in the MA Risk Adjustment system.

They have diverse backgrounds, expertise, and levels of responsibility:

- **11 = Auditors, Coders, Billers, Records**
- **9 = Individual Providers**
- **1 = Group Providers (Prime HC)**
- **7 = Executives / Managers**
- **4 = Vendors / Consultants**

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Who Are the Whistleblowers? (cont.)

Of the 31 known MA Risk Adjustment whistleblowers to date, approximately 29% are physicians and 20% are coders.

Physicians

Gate-keepers to Medical Treatment

Due to their training, ethical and legal obligations, and acutely felt desire to help patients, some physicians speak up and respond when the practice of medicine meaningfully suffers from the business of medicine.

Coders & Auditors

Gate-keepers to Payment

If certified, may also be subject to legal and ethical obligations.

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Recent final RADV rule and audit liability

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RADV Final Rule

RADV Audit Background

- Risk Adjustment Data Validation (RADV) audits are CMS's main enforcement tool for evaluating and confirming accuracy of risk adjustment payments made to MAOs
- CMS selects a sample from a MAO contract's member population to determine if the associated HCCs that drove incremental payment are supported in the medical record
- For those HCCs without the appropriate supporting documentation, CMS calculates what the revised payment would have been had the HCC not been included in the risk score

Historical RADV Audit Methodology (2011-2013 Payment Years)

- Plan selection methodology is not defined by CMS (30 contracts selected by year)
- RADV eligible population (e.g., members with at least one HCC, continuously enrolled throughout the data collection year, non-ESRD/hospice)
- 201 members selected from 3 strata defined by risk score
- FFS adjuster considered in extrapolation calculation
- https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/recovery-audit-program-parts-c-and-d/other-content-types/radv-docs/radv-methodology.pdf

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RADV Final Rule (cont.)

Final Rule (CMS-4185-F2)

- CMS modifies its approach to RADV audits
- Utilizes sub-cohorts / CMS Enrollee-level model to predict overpayments
- Extrapolation considered starting with 2018 payment years with no Fee-For-Service (FFS) adjuster
  - "CMS is not adopting any specific sampling or extrapolation audit methodology but will rely on any statistically-valid method for sampling and extrapolation that is determined to be well-suited to a particular audit."

2014 PY RADV Audits

- 188 plans selected with the most members in the top 10% based on predicted overpayments
- 32 members selected from plan
- Members had to have diabetes

Implications for the Industry

- Large potential liability for repayments under RADV audits starting with 2018 payment years going forward due to extrapolation without an FFS adjuster
- MAOs can focus on preparing for RADV audits by evaluating medical records collection and retention processes as well as examining coding accuracy to estimate liability
- Potential for increased enforcement activity

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Questions & Answers

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Thank you!

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