False Claims Act Risk and the RADV Final Rule

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Medicare Advantage Landscape

- Half of all eligible Medicare Beneficiaries are now enrolled in Private Medicare Advantage (MA) plans
- Growth in MA Enrollment explains half of the projected increase in MA spending through 2029
- Payments to MA plans for Part A and Part B benefit nearly tripled between 2011 and 2021
- MEDPAC: Medicare payments to MA plans for uncorrected coding intensity (in billions)

Medicare Part C and D Plans Have Become Targets for False Claims Act Allegations

- DOJ, OIG and CMS have prioritized fraud by Medicare Advantage (“MA”), Medicaid Managed Care (“MCO”) and Prescription Drug Plans (“PCP”) and at least two dozen unsealed False Claims Act cases alleging fraud by managed care plans have been identified
- Allegations include inappropriate manipulation of the risk adjustment process for increased reimbursement
- The first FCA MA case was filed in 2009 and many unsealed FCA cases have alleged MA fraud since that time
- Enforcement activity against MA, MCO and PCP organizations has primarily involved manipulation of risk scores thru the submission of alleged false and fraudulent diagnosis codes

MA and FCA Enforcement Trends: MA Risk Adjustment Main "buckets" of FCA Allegations

- Relator's and Government frequently contend that MA and MAO's improperly identify and submit diagnosis codes to CMS, including conducting "one way" retrospective reviews of patient charts to identify additional diagnosis codes
- Using coding enhancement data mining software to identify missed diagnosis codes
- Failure to correct unsupported or false diagnosis codes
- Upcoding w/o sufficient support in patient records
- Using vendors to identify diagnosis codes through in-home assessments
- Pressuring or incentivizing providers to upcode and add diagnosis codes without any basis
- Other compliance failures

False Claims Act

- 31 USC § 3719, the False Claims Act ("FCA" sets forth seven bases for liability. The most common ones are:

  1. Knowingly presenting, or causing to be presented, to the Government a false or fraudulent claim for payment

  2. Knowingly making, using, or causing to be made or used, a false record or statement material to get a false or fraudulent claim paid

False Claims Act (cont'd.)

3. Conspiring to commit a violation of the False Claims Act

4. Knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealing or avoiding or decreasing an obligation to pay or transmit money or property to the government

- Obligation defined as an established duty, whether or not fixed, arising… from retention of any overpayment

Elements of an FCA Offense

The Defendant must:

- Submit a claim (or cause a claim to be submitted)
- To the “Government”
- That is false or fraudulent
- Knowing of its falsity
- Seeking payment from the Federal treasury
- Damages (maybe)

Knowing & Knowingly

- No proof or specific intent to defraud is required
- The Government need only show person:
  - Had “actual knowledge of the information”; or
  - Person acted in “deliberate ignorance” of the truth or falsity of the information; or
  - Person acted in “reckless disregard” of the truth or falsity of the information

Penalties

- Three times the amount of damages which the Government sustained
- Civil penalty per false claim ($10,781.00 to $21,563.00) with annual increases

Qui Tam Actions & Government Intervention

- A private person ("Relator") may bring a False Claim Act action under the *qui tam* provisions of the FCA – The Whistleblower
- Government may intervene in a suit brought by Relator
- Relationship between Relator and Government
  - Collaborators in recovery of money
  - Rewards for whistleblowers

FCA Statistics

- If the government intervenes and obtains recovery, the Relator can receive between 15% and 25% of the proceeds
- Since 1986, of all the *qui tam* actions filed, the average yearly intervention rate has been about 22-25%
- Billions in health care FCA recoveries since 1986, with annual average recoveries in excess of $2 billion
- Recoveries have increased (higher penalties and more adverse publicity)
- Whistleblower protection is provided to those that take lawful actions in furtherance of the *qui tam* suit, including initiation, investigation, testimony for, or assistance in the action

United States ex rel. Cutler vs. Cigna Corp (M.D. Tenn.)

- Department of Justice intervened on October 14, 2022 and case pending
- Invalid patient diagnosis codes to inflate for risk adjustment payments
- Home visits resulted in inflated risk scores
- Payor pressure on network providers to maximize high value chronic condition diagnosis
- Motion to Dismiss is claiming that Defendant Cigna did not submit false claims or violated any other relevant obligations and had no reason to believe the clinicians were submitting improper diagnosis to support higher risk scores

United States ex rel. D'Cunha vs. University of Pittsburg Medical Center ("UPMC") (W.D. PA.)

- DOJ intervened on September 3, 2021and case pending
- Whistleblower complaint alleges submission of false claims for non-compliant surgeries that caused complications, lengthy hospital stays and complex follow-up procedures resulting in additional diagnosis codes with increased risk scores and increased capitation payments to MAO's and ultimately UPMC
- DOJ allegation of patient harm and improper outcomes associated with non-compliant surgeries resulting in additional diagnosis codes with increased scores and artificially-inflated capitation payments

Private Investor Fraud

- FCA liability for investors knowledgeable of fraud through Board and Management activity or through due diligence process
- DOJ intervention in cases focusing on retrospective chart reviews against
  MA plans, providers and vendors conducting chart review services
- Pressure on health care providers to sign forms long after initial patient visit or encounter used to add risk adjustment diagnosis for increased reimbursement

MA and FCA Enforcement:
MA Risk Adjustment

"The Department of Justice is actively pursuing 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."

MA and FCA Enforcement Trends:
MA Risk Adjustment (continued)

- DOJ priority • Heavy reliance on and significant attention from Relator Bar
- Currently 29 public False Claims Act cases of which 27 are Qui Tam cases and 2 are Department of Justice initiated cases
- Defendants from all levels of the MA system • MAOs & Affils. • Group Providers • Vendors / Consultants• Individuals • MSOs • Private Investors • Focus appears to be shifting from MA plans to providers

Primary Legal Obligations Relating to Risk Adjustment

- To participate in the MA program, MA plans 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 MA plans 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. § 422.404(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)

Primary Legal Obligations Relating to Risk Adjustment (continued)

- 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

Primary Legal Obligations Relating to Risk Adjustment (continued)

- Diagnoses that are only probable, suspect, questionable, or otherwise uncertain or provisional may not be coded. See, e.g., ICD-10 Guidelines § IV.H.
- Prior conditions that no longer exist may be coded with "history codes," but only "if the historical condition . . . has an impact on current care or influences treatment." ICD-10 Guidelines § IV.J.
- MA participants must "adopt and implement an effective compliance program" to "prevent, detect, and correct non-compliance with CMS's program requirements." 42 C.F.R. § 422.503(b)(4).
- MAO must return any CMS overpayments (e.g., due to unsupported diagnosis codes) within 60-days of being identified. If not returned, a CMS overpayment becomes an "obligation" under the FCA. 42 U.S.C. § 1320a-7k(d)(3); 42 C.F.R. § 422.326.

Methods of Increasing Risk Scores that Have Received DOJ/OIG Scrutiny

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

MA Risk Adjustment and FCA Enforcement: 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.) ($1.5M)

MA Risk Adjustment and FCA Enforcement: Who are the Whistleblowers?

- They 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
  - 10 = Individual or Group Providers (Prime HC)
  - 7 = Executives / Managers
  - 4 = Vendors / Consultants
  - 32 = Total (some overlap in categories)
- Approx. 29% are physicians and 20% are coders

FCA Case Trends:
Whistleblowers in MA Risk Adjustment Cases

Physicians

- Physicians are the **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

- Coders are the **gate-keepers to payment**
- Certified coders are also subject to legal and ethical obligations

Risk Adjustment Overview and RADV Final Rule

Level Setting:
The MA Risk Adjustment Process and Coding Intensity

"Risk-adjusted payments are based on medical diagnoses submitted by the MA plans that, by long-standing regulations, must be supported in the Medicare enrollees' medical records to ensure accurate payment." – Centers for Medicare and Medicaid Services (January 30, 2023)

- Under the current approach, insurers receive higher payments for enrollees with greater health needs (measured as a "risk score") whose care is expected to cost more.
- The goal of this policy is to ensure that plans have sufficient resources to serve individuals with greater health needs and to discourage insurers from disproportionately enrolling healthy enrollees.
- It also creates a strong financial incentive to increase risk scores (by thoroughly identifying and submitting data for more health conditions), driving up payments to MA plans.
- Annual HHS OIG Work Plan has consistently cited improper payments made to MA plans

OIG Targeted MA Risk Adjustment Audits

- OIG conducted audits in 2012 on 2007 dates of service
  - Similar to historic CMS RADV audits
  - Appeals with limited, if any, recoveries
- Re-initiated auditing of MA plan risk adjustment data in last few years
- 7 audits since 2019 • No support for nearly 69% of diagnoses used for risk adjustment • $113 M in overpayments made by Medicare to plans

- Methodology
  - Primarily focused on targeted codes or traditional CMS RADV methodology
- Targeted Codes
  - Acute myocardial Infarction
  - Acute Cerebrovascular Accident
  - Major Depressive Order
  - Peripheral Vascular Disease
  - Embolism
  - Cancers – Lung, Breast, Prostate, Colon
  - Miskeyed Diagnoses

CMS RADV Audits: CMS Final Rule, Effective April 3, 2023

- Extrapolation
  - Extrapolates RADV sample results beginning with 2018 payment year
  - Declines to identify any specific extrapolation methodology
  - Reserves right to extrapolate or not depending on circumstances
- Audit methodology
  - No clear audit methodology approach
  - Can use targeted sampling of “high risk” conditions
- FFS Adjuster
  - No application of an FFS adjuster to overpayment determinations

Risk Adjustment Overview

- **What is Risk Adjustment?**
  - Risk mitigation tool
    - Purpose is to:
      - Offset high-risk (i.e., high-cost) enrollees
      - Guard against selecting healthy enrollees by adjusting for health status
  - Where is it used?
    - Medicare Advantage market
    - Medicaid Managed Care market - each state has its own RA program; must be “actuarially sound” (no UPL since 2002 – thus no more ceiling; capitation rates must cover projected costs)
    - Commercial market

Risk Adjustment Overview

- **How Does Risk Adjustment Work?**
  - Commercial market
    - Affordable Care Act (ACA) created risk adjustment program for individual and small group markets (non-grandfathered plans; Exchange plans included)
    - The temporary transitional reinsurance program (ACA Section 1341) and temporary risk corridors program (ACA Section 1342) were for years 2014 through 2016.
    - Age, sex, and diagnosis are used to produce a risk score for each enrollee. Risk scores are concurrent, meaning they are based on enrollee data from the applicable benefit year.
    - States may set up their own risk adjustment programs if they operate their own Exchange, or they may permit HHS to develop and manage the program in the state. HHS operates all 50 states

Risk Adjustment Overview

- **How Does Risk Adjustment Work?**
  - Commercial market (continued)
    - The risk adjustment methodology developed by HHS is based on the premise that premiums should reflect differences in plan benefits, quality, and efficiency rather than the health status of the enrolled population.
    - The HHS-operated risk adjustment methodology determines each plan's risk adjustment transfer amount under the state payment transfer formula based on the actuarial risk of enrollees, the actuarial value of coverage, utilization, the cost of doing business in local rating areas, and the effect of different cost-sharing levels on utilization.
    - Thus, plans that have healthier people with lower risk scores pay into a pool in each state, and plans with sicker members get to take money, which gives the program a zero-sum outcome.

Risk Adjustment Overview

- **How Does Risk Adjustment Work?**
  - Medicare Advantage
    - The MA risk adjustment program is prospective, i.e., plans use prior data to predict future risk
    - Plans evaluate the health of their own members and build risk scores based on medical coding
    - Unlike ACA approach, the Medicare trust fund covers the cost (i.e., no zero-sum game)
    - Thus, there have been concerns with “upcoding”, improper diagnoses and risk scores to obtain greater payment

Risk Adjustment Overview

- **Capitation and Risk Adjustment**
  - CMS makes capitation payments to the MA Organizations with whom it contracts who then enter into participation agreements with providers to deliver services to beneficiaries.
  - CMS sets the payment rate based on local area benchmarks that represent the maximum amount CMS will pay health plans for benefits for beneficiaries in that locale. Higher payments made in rural areas and lower payments in urban areas.
  - The benchmarks for each area are based on a statutory formula using average traditional Medicare spending per beneficiary.
  - The CMS annual Advance Notice and Rate Announcement are used to update the factors that impact the annual benchmark. These factors include the growth rate in the Traditional FFS Medicare, the Medicare Advantage growth rate, and changes to the Star Ratings System.

Risk Adjustment Overview

- **Capitation and Risk Adjustment**
  - Health plan payment is also modified by the risk scores of enrollees and quality performance payments to reflect the health status and demographic characteristics of the members
  - Health conditions and diseases are assigned diagnosis codes - ICD-10-CM codes
  - CMS groups individual diagnosis codes into broader diagnosis groups, which are then filtered into HCCs.
  - HCC's help to predict costs of care and are considered as part of the adjustment process for payments, i.e., "risk adjustment".
  - Risk-adjusted payments are based on medical diagnoses submitted by the MA Organizations that need to be supported in the patients' medical records to ensure accuracy in payment.
  - The Risk Adjustment Factor Score (RAF) measures patient complexity; each HCC assigned a RAF

Risk Adjustment Overview

- **RADV Final Rule**
  - Issued in January 2023
  - Addresses instances where MA Organizations received more than they otherwise should have received because the medical diagnoses submitted for risk adjustment payment were not supported in the enrollee's medical record.
  - Codifies in regulation that, as part of the RADV audit methodology, CMS will extrapolate RADV audit findings beginning with payment year 2018.
  - Confirms that CMS will not apply a fee-for-service adjuster in the audits to account for any effect of erroneous diagnosis codes in the data from Medicare Parts A and B that are used to calibrate the MA risk adjustment model.
    - The fee-for-service adjuster was previously utilized to calculate a permissible level of payment error and limit RADV audit recovery to payment errors above that level

Risk Adjustment Overview

- **MA 2024 Final Rate Announcement**
  - Opted to phase in the finalized risk adjustment program over three years.
  - Removed 2,000 codes from its HCC model, including major depressive disorder, diabetes with chronic conditions, vascular disease, rheumatoid arthritis, and inflammatory connective tissue disease.
  - It is important for MA plans to continue submitting v24-applicable codes to CMS for risk score calculation through 2025. This is due to the phase-in approach CMS will use for v28:
    - 2023: 100% v24
    - 2024: 67% v24 + 33% v28
    - 2025: 33% v24 + 67% v28
    - 2026: 100% v28

Risk Adjustment Overview

- **21st Century Cures Act**
  - As part of the goal to phase out using CMS' Risk Adjustment Processing System (RAPS), the Cures Act paved the way for CMS to begin using the Encounter Data System (EDS)
  - In 2021, 75 percent of diagnosis data used for risk score calculation came from EDS, while 25 percent came from RAPS.
  - In 2022 and beyond, EDS will be used entirely as the source of MA plan diagnoses.
  - **The biggest difference between these systems is the data source:**
    - (RAPS): MA plans submit data in five fields of the reporting system: date of service from, date of service to, provider type, diagnosis code, and patient identifier. Data is abstracted from claims submitted by providers, but also includes diagnoses captured during internal or vendor-contracted audits of medical records ("Chart Reviews").
    - (EDS): A claim is sent from the provider to the MA plan. The insurance company forwards the claim to CMS.

Risk Adjustment Overview

- **So Where Is the Risk?**
  - Providers need to submit "complete and accurate" claims; language in the MA network agreement likely provides this standard
    - However, while a claim may be complete and accurate for purposes of the 837P, it may not contain all ICD-10 codes
  - So then what is "complete and accurate"?
    - Especially important now that codes need to appear on Encounter Data Submissions or EDS (i.e., claims)
  - Opportunity to review contract templates to see if language updates are needed re capturing additional diagnoses codes via an updated claim, for example
    - This would factor into negotiations with network providers
    - Concerns with operationalizing this process (e.g., resources)

Risk Adjustment Overview

- **So Where Is the Risk?**
  - Coding must be updated annually for HCCs; thus, providers need to capture historical codes that are still applicable; remove inapplicable codes
  - Providers aren't coders; some may have policies/procedures for coding initiatives including a manual review before each claim is submitted
    - Providers have policies and procedures regarding clinical documentation and internal audits thereof – may focus on a fee-for service environment (e.g., no HCC)
    - Contractual/collaboration opportunities to improve processes – but need to take holistic view
  - False Claims risk will still be an ongoing issue with switch to EDS
  - RADV audits will need to consider risk adjustment and provider recoupment

Risk Adjustment Overview

- **Additional Thoughts**
  - Other factors that impact a patient's health and well-being, such as health related social needs, are important
  - Z codes are not widely utilized at present – A subset of Z codes (Z55-Z65) is designed to capture health risks related to socioeconomic and psychosocial factors.
  - Z codes' interaction with risk adjustment models is yet to be determined
    - Z codes do not currently have HCC values associated with them.
    - Policies can address use
  - Z Codes can inform supplemental benefits (housing, utilities)
  - ACO REACH has health equity plan requirement
  - Home checks to identify diagnoses to check at next annual wellness visit

Key Medicare Advantage Compliance Guidance

- Social Security Act § 1851 et seq. and 42 C.F.R. Part 422 – Medicare Advantage statutes and regulations
  - 42 C.F.R. § 422.504(i) – MA Organization Relationship with First Tier, Downstream and Released Entities
  - Proposed and final rules for commentary on MA regulations
- Medicare Managed Care Manual, including Chapter 21 – Compliance Program Guidelines
- Medicare Program Integrity Manual and CMS program integrity guidance
- OIG compliance program guidance, work plans, advisory opinions
- Medicare Advantage and Part D HPMS memos
- National and local coverage determinations as applied to Medicare Advantage
- Requirements governing specific delegated activities, e.g. utilization review, marketing and communications
- Code of Conduct and Ethics, including, if available, a Vendor Code of Conduct and Ethics
- Other compliance policies, standard operating procedures and training materials
- Provider manuals, reimbursement guides and other policies and procedures
- Pre-delegation audits and questionnaires, compliance attestations

Compliance Best Practices

- Assess what may be a key regulatory requirement versus guidance versus best practice and see where the proposed activity falls based on your organization's risk tolerance
- Ensure the appropriate rigor and structure to guide business requests through the approval process, even for activities and materials that do not require CMS review. Documents the concrete steps taken to evaluate and establish a defensible position for your decisions
- Do not ignore reports of non-compliant activity
- Monitor Compliance Program Effectiveness; Reporting, Response, Resolution and Remediation Processes
- Establish an infrastructure to monitor for any CMS guidance updates as well as OIG advisory opinions, DOJ settlements and other relevant news

Questions?

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Thank You