Managed Care Enforcement Trends and Compliance Risks

HCCA Virtual Compliance Institute

March 31, 2020

John E. Kelly, Esq.
Member
Bass Berry & Sims
Washington, DC

Benjamin D. Singer, Esq.
Partner
O'Melveny & Myers
Washington, DC

O'Melveny

BASS BERRY + SIMS PLC

1

Contents

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

O'Melveny

BASS BERRY + SIMS PLC

2

2

Managed Care Overview

- The health care world is changing.
- FFS environment ⟹ Managed Care
  - By 2019, 1/3 of all Medicare beneficiaries were enrolled in a Medicare Advantage Plan
  - In FY 2018, 45% of Medicaid spending was attributable to payments to MCOs, up from 28% in FY 2013.
  - ACA has approximately 11.5m marketplace enrollees (approximately 5% of 214m beneficiaries enrolled in commercial insurance)
  - By 2023, expenditures by Medicare Advantage Organizations (MAOs) expected to reach ~ $250 billion

3

Managed Care Overview

- Medicare and Medicaid contract with commercial entities to provide covered benefits for a Per Member, Per Month fee
- The PMPM varies depending upon the expected health status of the member (i.e., the higher the expected disease burden of the patient, the larger the payment)
  - Incorporates demographic and disease factors
  - Promotes access and reduces adverse selection
- More diagnoses that impact payment for a member will generally result in a higher member risk score and PMPM payment to the plan
- Diagnosis codes must stem from an encounter between a provider and the patient
- Plans required to submit encounter data
  - Services and items furnished to enrollees
  - Used to determine risk score calculation for payment
  - More comprehensive and additional data elements than diagnosis data

4

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).

Enforcement

Who conducts investigations?

- Federal & State Governmental Investigations:
  - A. Criminal or civil
    - i. DOJ/USAO (incl. DEA, FBI)
    - ii. OIG
    - iii. FDA, Postal Inspectors, Labor, IRS, DOD, VA, OPM
    - iv. MFCU/AG
  - B. Administrative
    - i. OIG (OI, OCIG)
    - ii. MAC/ZPIC/UPIC/MEDIC
  - C. Insurer
    - i. SIUs

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. Many industry stakeholders submitted comments strongly objecting to the proposed rule, with plans arguing that omission of FFS Adjuster violated statutory requirements and that CMS' underlying study supporting the rule was flawed.
  - CMS has not yet issued a final rule but is continuing to conduct RADV audits in the meantime

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, only one audit report has been published to date. The audit targeted "high-risk" diagnoses, finding roughly $150k in "overpayments" and several deficiencies with the plan's compliance and auditing programs.

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.'" DOJ has appealed the ruling and briefing to D.C. Circuit is set to begin later this spring.
- Part D Overpayment Rule, 42 C.F.R. § 422.360, still in effect following *Azar* ruling.

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

Brand Memo and *Azar v. Allina Health Services*

- In January 2018, then-Associate Attorney General Rachel Brand issued a memorandum noting that under the APA, informal government agency guidance documents "cannot create binding requirements that do not already exist by statute or regulation" and that DOJ "may not use its enforcement authority to effectively convert agency guidance documents into binding rules."
- ***Azar v. Allina Health Services***: In June 2019, the Supreme Court reinforced Brand memo principals. The Court invalidated an informal policy posted by a government agency to its website because the policy altered a "substantive legal standard" affecting Medicare payments without going through the Medicare Act's required notice-and-comment process.
- Following *Allina*, in October 2019, CMS acknowledged in a memorandum that while its informal guidance may inform an existing statutory or regulatory requirement, informal guidance "may not be used as the sole basis for an enforcement action," because to do so would violate *Allina*.

Recent Qui Tam Cases: Risk Adjustment

Provider Submissions

- *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, with plan paying under $1.5M; relator initially sought damages of $32M

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.
  - Court recently denied defendants' motions to dismiss, rejecting defenses regarding actuarial equivalence and knowledge under *Safeco/Purcell/Donegon* line of FCA cases

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, but DOJ's partial summary judgment motion was denied in May 2019

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, settlement in progress)
  - 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

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

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?"

O'Melveny BASS BERRY + SIMS PLC 21

21

Questions?

O'Melveny BASS BERRY + SIMS PLC

22