Evolving Landscapes: The FCA and Managed Care Fraud

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Main Learning Objectives

- Quick review of False Claims Act basics.
- Compare Medicare Advantage and Medicaid Managed Care: (1) design and growth; (2) problems and challenges; (3) financial incentives and legal hooks.
- Highlight FCA managed care case trends: (1) Number of complaints filed;
 (2) Number settled/resolved; (3) Key Defenses and Court responses.
- Implications for Compliance.

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Our Shared Perspective

- Foster effective collaboration between State and Federal Law Enforcement (and the Relator bar).
- Protect Government programs (and taxpayers).
- Conserve Government resources.
- Only pursue cases involving credible allegations of fraud.

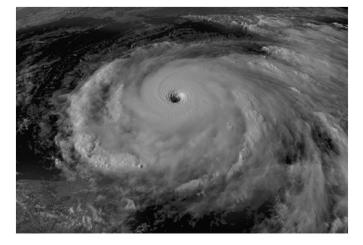
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Overall Theme: Eye of the Hurricane



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Overall Theme: Eye of the Hurricane

- Initial storm: First round of settlements (e.g., Janke \$22.6M; Swoben-SCAN \$320M; Sewell-Freedom Health \$32.5M)
- Current lull in the winds: Pending court decisions (e.g., Poehling-UHG, Ormsby-Sutter Health, Ross-Group Health)
- Storm still to come: Complaints not yet unsealed and/or resolved; new complaints to be filed.

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Overall Theme: Eye of the Hurricane

- **Cross-winds:** Administrative complaints (*e.g., UHG v Azar*) and dispositive motions filed by defendants. Government decisions not to intervene in some litigation.
- To be determined: What Category (I-V) is the storm?

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Review of FCA Basics:

- Federal False Claims Act, 31 U.S.C. 3729 et seq.
- State False Claims Acts (currently 31 FCAs [incl. D.C. and PR] with qui tam provisions).
- Whistleblower or "Relator" files initial complaint under seal and can pursue with or without government intervention.
- Threat of treble damages and penalties.

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Review of FCA Basics:

- Basic FCA Elements: (1) Claim; (2) Falsity; (3) Knowledge; (4) Materiality.
- "Claim" in managed care context: what is submitted to obtain payment to state or federal agencies and/or to MAO/MCO under contract with agencies. *E.g.*, (1) Encounter data; (2) Attestations.
- "Reverse False Claims" based on overpayments that provider is obligated to return.

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Review of FCA Basics:

- "Falsity" may be based on false records (e.g., upcoding, manipulation of charts), false statements (e.g., annual certifications), or violation of legal requirements (e.g., submission of accurate diagnosis data).
- "Knowledge" defined to include actual knowledge, deliberate ignorance, or reckless disregard. *Not* mere negligence.
- "Materiality" addressed by U.S. Supreme Court in *Escobar* decision. Requires holistic assessment of multiple factors.

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Review of FCA Basics:

■ FCA Liability can be Indirect: A defendant does not have to deal directly with the Government.

See, e.g., U.S. et al. ex rel. Kester v. Novartis, 23 F. Supp. 3d 242, 250 (S.D.N.Y. 2014)(citation omitted) ("...liability under section 3729(a) attaches whenever a person knowingly makes a false claim to obtain money or property, any part of which is provided by the Government without regard to whether the wrongdoer deals directly with the Federal Government; with an agent acting on the Government's behalf, or with a third party contractor, grantee, or other recipient of such money or property.")

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Comparison of MA and Medicaid Managed Care – Design & Growth:

	Medicare Advantage	Medicaid Managed Care
Created as alternative to traditional Fee for Service "pay and chase"?	Yes	Yes
Private health plans intended as gatekeepers to control costs?	Yes	Yes
Available nationwide?	Yes	Many but not all states
Govt contracts with health plans and pays a capitated monthly rate per enrolled bene for minimum level of care?	Yes	Yes
Govt makes risk adjustment payments for certain diagnoses?	Yes	Varies by State and RA provisions in contracts

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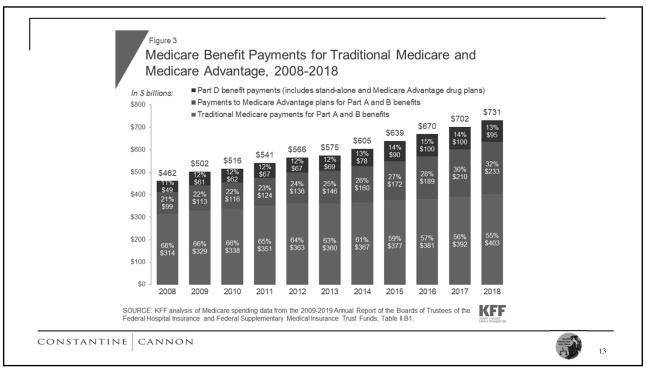


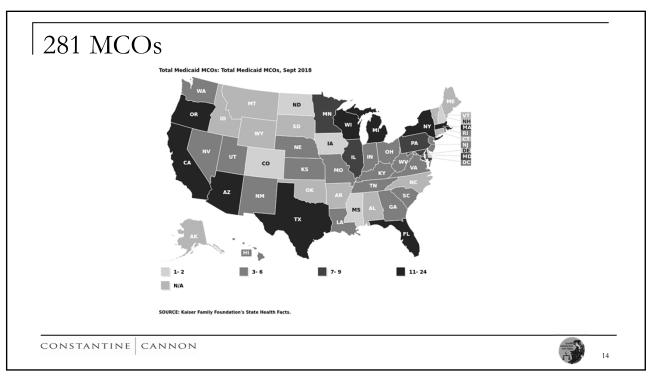
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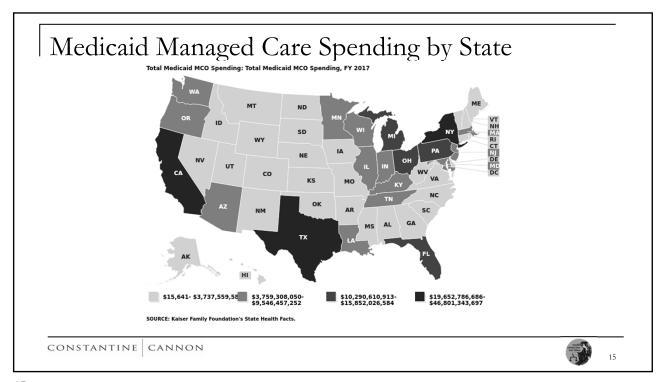
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Comparison of MA and Medicaid Managed Care – Design & Growth:

	Medicare Advantage	Medicaid Managed Care
Health plans required to meet certain program integrity standards	Yes	Yes
Delivery of care involves network of entities and individual providers	Yes	Yes
Dramatic growth in number of plans and enrolled benes	Yes (> 1/3 all Medicare benes; Est. 20 million)	Yes (281 MCOs as of Sept. 2018; As of 7/17, 54.1 million – 69% all Medicaid benes)
Dramatic growth in government spending	Yes (\$210B in FY2017 to MA plans for Part A and B bnfs)	Yes (\$281.7B in FY 2017)
Increased—but imperfect—government oversight and audits	Yes	Yes
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Comparison of MA and Medicaid Managed Care – Potential Problems and Challenges:

	Medicare Advantage	Medicaid Managed Care
Government makes significant overpayments to health care plans.	Yes	Varies by State
Enrolled benes not able to access providers within plan network.	Yes	Varies by State and MCO
Enrolled benes denied covered services – both initially and on appeal.	Yes	Varies by State and MCO
Government agencies not able to adequately audit.	Yes	Varies by State
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Government Reports and Letters:

- HHS OIG Report, July 2018 "Weaknesses Exist in Medicaid Managed Care Organization's Efforts to Identify and Address Fraud and Abuse"
- California State Auditor, April 2019 "Although [CA Medicaid Agency's] Oversight of Managed Care Health Plans is Generally Sufficient, It Needs to Ensure That Their Administrative Expenses Are Reasonable and Necessary"
- Letter from U.S. Senators to CMS Administrator, Sept. 13, 2019 Taxpayers have overpaid MA plans more than \$30B
- HHS OIG Report, December 2019 "Billions in Estimated Medicare Advantage Payments from Chart Reviews Raise Concerns"

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Comparison of MA and Medicaid Managed Care

- Possible Financial Incentives by MCOs:

	Medicare Advantage	Medicaid Managed Care
Make patients appear <i>sicker</i> than really are – to increase risk scores and RA payments.	Yes	Depends on state contracts
Make network appear <i>larger</i> than really is – to increase number of capitated payments.	Yes	Yes
Provide <i>fewer</i> services to benes than required – to decrease costs and increase profits.	Yes	Yes
Selectively <i>audit</i> providers – to increase submission of unsupported diagnosis data.	Yes	Depends on contract specifics
Reduce compliance efforts	Yes	Yes

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Comparison of MA and Medicaid Managed Care – Legal Hooks:

	Medicare Advantage	Medicaid Managed Care
Statutes	Yes	Yes
Regulations	Yes	Yes
Agency Guidance	Yes	Yes
Contracts and Agreements	Yes	Yes
Agency enforcement actions, investigations, reports	Yes	Yes

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Legal Hooks – Key MA Regulations:

- Diagnoses must be supported by **adequate medical record** documentation. 42 CFR 422.504(I)(1).
- Plans must expressly certify that info provided is "accurate, complete, and truthful." 42 CFR 422.504(I)(2).
- MAOs are required to "adopt and implement an **effective compliance program.**" 42 CFR 422.503(b)(4)(vi).

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Legal Hooks – The MA Gold Standard:

Diagnosis codes submitted to CMS must meet specific standards, including:

- The diagnosis code must result from a face-to-face encounter with a clinician and a patient;
- This encounter must be during the relevant year;
- The diagnosis code must be appropriately documented in the patient's medical record at the encounter, and
- The diagnosis code must be based on documented conditions that require or affect patient care treatment or management.

See, e.g., 42 C.F.R. § 422.504(I)(3); CMS, Medicare Managed Care Manual Chapter 7, § 111.8 (Rev. 57, Aug. 13, 2004)

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Legal Hooks - Medicaid Managed Care Regulations MAY 6, 2016 Modernized managed Aligns Medicaid rules with Medicaid regulations; first Directs procedures overhaul since 2002 those of other plans, such & regulations on as Medicare Advantage recovery of (MA) overpayments & Qualified Health Plans (QHPs) Increases data reporting Strengthened requirements regulations regarding · Design of capitation fraud referrals from managed care plans to state Medicaid Medical loss ratio (MLR) Fraud Control Units · Risk adjustment (MFCUs) · Encounter data Network adequacy Standardized requirements requirements across states · Provider directories CONSTANTINE CANNON

Legal Hooks – Medicaid Managed Care Regulations

- ACA gave CMS authority to withhold Federal matching funds
- 42 CFR 438.604- Contract Requirements. For contracts starting on or after July 1, 2017, States must require that MCOs:
 - Collect and submit encounter data sufficient to identify the provider rendering the service
 - Submit all encounter data necessary for the State to meet its reporting obligation to CMS
 - Submit encounter data in appropriate industry standard formats

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Legal Hooks – Medicaid Managed Care Regulations

 Industry standard formats: submit encounter data to CMS through Transformed Medicaid Statistical Information System (T-MSIS).

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Legal Hooks – MCO Program Integrity Requirements

- 42 CFR 438.608 Detect & Prevent Fraud, Waste & Abuse
- Prompt referral of fraud, waste or abuse directly to state & MFCU
 - Designate a compliance officer who reports to the CEO
 - · Establish a regulatory compliance committee
 - · Train employees on federal & state standard & requirements
 - Establish Effective lines of communication from compliance officer & employees
 - · Publish disciplinary guidelines
 - · Dedicate staff for routine monitoring & auditing of compliance risks

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FCA Managed Care Case Trends – Number of FCA Complaints Filed:

- Between 2008 and 2019, at least 26 FCA complaints have been filed specifically targeting fraud in the Medicaid and/or MA managed care programs.
- The most unsealed FCA complaints were filed in 2015 (5).
- Not included is the number of sealed FCA complaints.

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FCA Managed Care Case Trends – Liability Theories:

	Medicare Advantage	Medicaid Managed Care
Network Fraud	Yes	Yes
Risk Adjustment Fraud	Yes	Not yet
Kickbacks	Yes	yes
False Billing	Yes	yes

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FCA Managed Care Case Trends – Types of Defendants:

	Medicare Advantage	Medicaid Managed Care
Health Plans & Affiliates	Yes	Yes
Group Providers	Yes	Yes
Individual Providers	Yes	Yes
MSOs	Yes	Yes
Vendors	Yes	Yes

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FCA Managed Care Case Trends – Types of Whistleblowers/Relators:

	Medicare Advantage	Medicaid Managed Care
Health Plan Employee (e.g., Compliance Officer, Auditor)	Yes	Yes
Provider Employee (e.g., Nurse, Physician)	Yes	Yes
Vendor Employee (e.g., Auditor)	Yes	Yes
Beneficiary	No	Yes

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FCA Managed Care Case Trends –

Settlements/Resolutions

- Between 2008 and 2019, there have been at least 16 settlements of FCA complaints specifically targeting fraud in the Medicaid and/or MA managed care programs.
- The most settlements were in 2018 (6).
- At least two settlements are now pending.

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FCA Managed Care Case Trends –

Settlements/Resolutions

- Nov. 2010: U.S. v. Janke, No. 2:09-cv-14044 (S.D. Fla.) (non-QT) -\$22.6M
- □ **Aug. 2012:** *U.S. ex rel. Swoben v. Scan Health Plan*,No. 09-5013 (CDCA) \$320M (\$3.8M for RA claims)
- May 2017: U.S. ex rel. Sewell v. Freedom Health, Inc., No. 8:09-cv-1625
 (M.D. Fla.) \$32.5M
- □ May 2017 U.S. et al. ex rel. Miller v. CareCore National LLC et al., No. 1:13-CV-1177 (SDNY) \$45M feds; \$9M states
- Oct. 2017: U.S. ex rel. Graves v. Plaza Medical Centers Corp., 1:10-cv-23382 (SDFL) - \$3M

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FCA Managed Care Case Trends –

Settlements/Resolutions

- □ **Jan. 2018:** *U.S. ex rel Ramsey-Ledesman v. Censeo Health, LLC,* (N.D. Tex. 2014) undisclosed
- □ **Feb. 2019:** Sutter Health (non-FCA) (NDCA) \$30M
- □ **June 2019:** U.S. ex rel. David Nutter MD v. Beaver Medical Group LP et al, (CDCA) \$5M
- □ Nov. 2019: U.S. ex rel. Silingo v. Mobile Med. Examination Svcs., Inc. et al. (CDCA) \$ TBD
- □ **Dec. 2019:** U.S. ex rel. Valdez v. Aveta, Inc. (D.P.R.) \$ TBD

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FCA Managed Care Case Trends – On-Going MA Litigation (Unsealed):

- Poehling-UHG: U.S. ex rel. Poehling v. UnitedHealth Group Inc., No. 16-08697 (CDCA) (originally filed in WDNY)
- Ormsby-Sutter Health: U.S. ex rel. Ormsby v. Sutter Health et al, 15-cv-01062 (NDCA)
- Ross-Group Health: U.S. ex rel. Ross v. Group Health Cooperative, et al., 12-CV-0299 (WDNY)

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FCA Managed Care Case Trends – On-Going Medicaid Managed Care Litigation (Unsealed):

 Generally, seeing cases involving allegations of MLR fraud, and providers defrauding MCOs under contract to Medicaid through inflating medical device invoices (specifics barred by seal)

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FCA Managed Care Case Trends – Defense Arguments and Court Response:

Defense Argument	Case Examples	Court Response
No FCA Liability because managed care involves capitated payments.	Silingo-Anthem	Generally rejected.
No Falsity because defendants had objectively reasonable interpretation of regulations.	Swoben-UHG	Generally rejected.
No Falsity because defendants did not violate binding legal obligation.	Ross-Group Health; Swoben- UHG.	Sometimes successful. See, e.g., Poehling-UHG. But see Swoben-UHG.

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FCA Managed Care Case Trends – Defense Arguments and Court Response:

Defense Argument	Case Examples	Court Response
No Falsity because overall rate of unsupported diagnosis codes does not exceed CMS's overall rate of unsupported codes	Ormsby-Sutter (citing UHG-Azar)	Not usually persuasive. See, e.g., Ormsby-Sutter (oral argument). But see Poehling-UHG.
No Knowledge because defendants had a compliance program that generally met CMS requirements.	Graves-Humana	Generally rejected.
No Knowledge because individual who signed certification didn't know was false.	Swoben-UHG	Sometimes successful. See, e.g., Swoben-UHG.

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FCA Managed Care Case Trends – Defense Arguments and Court Response:

Defense Argument	Case Examples	Court Response
No Knowledge because Health Plan doesn't control what diagnoses providers submit.	Swoben-UHG	Generally rejected.
No Materiality because Government continued to pay claims.	Ross-Group Health; Swoben- UHG	Generally rejected, unless allegations conclusory.
Allegations lack sufficient particularity (Rule 9(b)) or are not plausible (Rule 8)	Ross-Group Health; Silingo- Anthem; Swoben-UHG	Sometimes successful.
Public Disclosure/not original source		Sometimes successful.

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Implications for Compliance:

- A written compliance plan does not by itself shield a health plan or provider group from FCA liability.
- A compliance plan is only as good as the investigatory and enforcement tools with which it is equipped and the degree of seriousness with which it is taken by the organization.
- "Red flags" found in audits and other compliance activities must be addressed, not swept under the rug.
- Failure to follow internal policies may be evidence of FCA knowledge.

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| Conclusions – Main Learning Points

- Managed care health plans and affiliated entities and individuals are increasingly attractive targets for FCA whistleblower lawsuits.
- Health plans and affiliates should avail themselves of opportunities to participate in ongoing discussions with government agencies.
- Government enforcers face many challenges, but are gaining traction against managed care fraud, including risk adjustment and network compliance fraud.

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| Conclusions – Main Learning Points

- Having a written compliance plan is not enough. MCOs, MAOs, and Group Providers must develop and implement compliance systems that steer clear of FCA liability.
- Don't underestimate the merits and advantages of self-disclosure.

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Questions?

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