Bridging the Divide

BUILDING COLLABORATIVE COMPLIANCE & MANAGED CARE STRATEGIES

Virtual Healthcare Enforcement Conference

Session: 201: *Managed Care Enforcement and Compliance*

Monday, November 16
11:45 AM - 12:45 PM CST

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Learning Objectives

- Locate applicable guidance on potential fraud, advisory opinions on what enforcement action would be for misconduct
- Recognize compliance risks in managed care strategies
- Design & Implement bi-directional education & training between Managed Care and Compliance

2

Creating "safe" connections.

Bridges are immensely important. Bridges allow safe passage where previously it was not possible or much more difficult.

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Industry experts leading the safe passage

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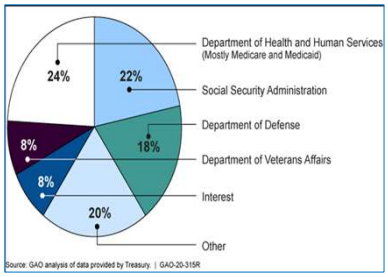
Rising healthcare costs continue to pressure test Health Systems across the Nation

- Next to national defense, the healthcare industry in the United States is one of the largest sectors of the economy. Currently reaching beyond 20 percent of the nation's gross domestic product, health care in the U.S. will be a significant factor in the national economy for the foreseeable future.
- In May of this year the AHA put out a report "**Hospitals and Health Systems Face Unprecedented Financial Pressures Due to COVID-19" that attempted to quantify the** impact of the COVID-19 Pandemic over a four-month period from March 1, 2020 to June 30, 2020. Based on these analyses, the AHA estimates a **total four-month financial impact of $202.6 billion** in losses for America's hospitals and health systems, or an average of **$50.7 billion per month**.

FY 2019 and FY 2018 Consolidated Financial Statements of the U.S. Government



FINANCIAL AUDIT:
FY 2019 and FY 2018 Consolidated Financial Statements of the U.S. Government
GAO-20-315R: Published: Feb 27, 2020. Publicly Released: Feb 27, 2020.

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Barbara Fonte, MHSA

Managed Care Trends and Compliance Risks

Shifting payment models and other industry trends are causing hospitals to consider nontraditional areas of compliance risk. Hospital finance leaders & Compliance Professionals meeting the paradigm collaboratively in an effort to best position their organizations to avoid risk.

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Reimbursement Trends in Managed Care

Understanding Value Equation:

It is defined as the quality of care—made up of outcomes, safety and service—divided by the total cost of patient care over time.

An ideal high-value health care system features six key components: a clear, shared vision with the patient at the center; leadership and professionalism of health care workers; a robust IT infrastructure; broad access to care; and payment models *that reward quality improvement over volume*. But the U.S. health care system was never deliberately designed to include these attributes.

- Global Payments
- Capitation
- Risk Sharing
- Fee for Service
- Medicare Advantage
- Negotiation: Interpreting Volume discounts

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Evolving areas of compliance concerns.

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Quality of Care

- Quality of care. Quality of care perhaps is the most pressing area of evolving risk. The OIG is intensifying its scrutiny of quality-of-care issues, as evidenced by the uptick in the number of corporate integrity agreements it has entered to resolve False Claims Act (FCA) allegations involving the quality of patient care. The OIG's action also includes the release of reports in 2018 on quality-of-care issues in long-term care hospitals and hospices.b

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Quality Reporting

- Quality reporting requirements continue to change and evolve, necessitating constant vigilance. The requirements also are playing a larger role in payment, through avenues such as the Medicare Access and CHIP Reauthorization Act of 2015 and CMS's Hospital Value-Based Purchasing Program, Hospital-Acquired Condition Reduction Program and Hospital Readmission Reduction Program. Thus, what may seem like minor reporting missteps could substantially affect revenues, whether through penalties or reduced incentives or through incentives to which the organization is not entitled.

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Case Management

- Case management. Because case management is intended to promote cost-effective, high-quality outcomes, it has both clinical and financial aspects. A patient who lingers too long in a hospital, for example, presents both financial problems (because payment often is based on a case rate for the patient's condition, not length of stay [LOS]) and an increased risk of additional health problems (such as infection and complications).

  Strong controls are necessary for:
  - Discharge planning
  - Utilization management
  - LOS and avoidable days
  - Readmissions
  - Throughput and logistics
  - Transitions of care

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Avoiding pitfalls: What does success look like?

- Finance leaders can support compliance efforts by connecting key compliance and clinical leaders and educating all parties on the financial and revenue cycle implications of evolving risks, such as:
  - Payment effects of value-based purchasing penalties and incentives
  - Billing requirements for hospital-acquired conditions and adverse safety events
  - The financial cost of medical necessity issues in terms of denials, reduced payment and unreimbursed costs

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Critical components requiring strong controls

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Collaborating for Safe Passage

Hospitals & Providers need to bridge "the bedside and the business side" to communicate and collaborate on compliance. Collaboration improves patient lives, the organization's financial performance and diminishes risk.

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Pamela Coyle Brecht, Esq.

Relators' View of The Divide (FCA Bridges Where Compliance Falls Short)

- The Magnitude of Potential Overpayments by Medicare Advantage Plans is an indicator of the potential for FCA filings involving Managed care organizations (MCOs)
- FCA Liability Issues for Managed Care Participants (MCOs and Providers)
- Emerging Trends in Managed Care
- Avoiding converting dedicated employees to whistleblowers

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What's at stake?

- Magnitude of Potential MA Overpayments drives potential for FCA filings involving MCOs
- 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"
- Recent FCA Settlements in Managed Care
  - Feb. 2019: *Sutter Health* (non-FCA) (NDCA) - $30M, fraud against the MA program by submitting false patient information via "risk adjustment data [the defendants] knew to b inaccurate, incomplete or false
  - 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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Qui Tam & FCA Cases

- Who are the whistleblowers in managed care FCA cases?
- Current and former employees of MCOs), network providers, contractors: nurses, physicians, data analysts, coders, auditors, compliance staff
- Retaliation after efforts to identify and correct issues internally
- FCA Liability for Managed Care Participants (MCOs and Providers) is not limited to whistleblower-driven cases. The US has brought its own cases (i.e. Janke and Anthem)
  - *Janke*: Nov. 2010 $22 M settlement against owners of MAO for falsifying diagnosis codes
  - *Anthem*: March 2020 suit based on MA's use of third-party vendor to conduct retrospective chart review after risk adjustment data submitted to CMS for payment, which the MA knew could be flawed. Risk area: when chart reviews are conducted only to submit additional Dx codes to CMS, but not to identify overpayments where the chart reviews showed the submitted Dx co

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FCA Liability Issues for Managed Care Participants (MCOs and Providers):

- How Managed Care Compliance could have bridged the gap Applicable Cases
  - *US ex rel Valdez v Aveta Inc*: $1B Medicare Advantage FCA suit resolved in June 2020
  - *Sutter Health LLC*: $30 M settlement (not QT claim)in April 2019 (included hospitals and medical foundations) submitted unsupported diagnoses codes to MA plans to inflate risk adjustment scores, causing overpayments to the MA plans
    - AKS settlement in Dec. 2019: $5.6 M
    - Whistleblower awarded: $5.9 M
  - *US ex rel Swoben v Scan Health Plan*: $270 M settlement in Oct. 2018 based on knowing submission of unsupported and undocumented diagnoses codes
  - *US ex rel Graves v Plaza Med Cen*ter:2017 $3 M FCA settlement in 2017 against Humana, the healthcare provide, and its owner. $4 M attorney fees awarded in 2018

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Avoiding converting dedicate employees to whistleblowers

- Set up data analysis to catch over and under on diagnoses and risk adjustment scores
- Audit, audit, audit
- Collect and Respond to Employees'/ Contractors' Compliance Concerns
  - Hotline – usually delegated
  - Verbal report to supervisor
  - Email communications
- Communicate the Outcome of the Investigation to the Employee/Contractor
- Document the Outcome of the Investigation
- Conduct and Document Exit Interviews
  - Get Compliance Officer/ Designee Involved

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Sarah Kessler, Esq.

Enforcement Guidelines & Fundamental Elements of Compliance in Managed Care

HHS/OIG: FRAMEWORK

- Provide applicable guidance on potential fraud, advisory opinions on what enforcement action would be for misconduct
- Innovative solutions- Government supportive: Innovation going on through department, [PCB ask re OIG guidance, opinion letter, outcomes-based issues]
- Examples of innovative models in managed care, part C [outcomes-based?]
- OIG high-level innovation, payment models and demonstration projects, rather than us versus them
- Where boundaries pushed too far, misconduct in past then partnership moving forward through integrity agreement – partnership versus punishment
- CMS shift in reimbursement for outcomes based Risk areas identified through litigation that has settled
- Audits/evaluations OIG has issued with managed care risk areas
- CIAs with managed care organizations
- OIG audit and evaluations

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Intersecting Domains; Six dimensions of quality health care

(effective, efficient, safe, timely, patient centered and equitable)

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OFFICE OF INSPECTOR GENERAL

A Focus on Medicare Advantage & Medicaid Managed Care Fraud and Enforcement

Sarah Kessler
Senior Counsel
Office of Counsel to the Inspector General

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Who we are:

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What we do:

Audit Evaluate Investigate Counsel

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Identifying Risk Areas

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Managed Care Risk Areas

- Inappropriate denial of services
- Provider network issues
- MA Risk Adjustment
- Data quality and security problems
- Integrity of bids
- Payments to ineligible providers
- Provider and supplier fraud (e.g., DME)

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OIG's Focus

- Beneficiary Harm
- Increased Costs
- **Fraud in Managed Care**
- Across Payors
- Coordination Needed

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Quality

Federal $

Data

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Quality

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OIG Report: Provider Shortages and Limited Availability of Behavioral Health Services in New Mexico's Medicaid Managed Care

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Federal Funds

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OIG Report: Essence Healthcare, Inc. – Targeted RADV

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OIG Report: MA Payments from Chart Reviews

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OIG Report: MA Payments Solely from Health Risk Assessments

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Data

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- OIG Report: MAO Encounter Data Lack Essential Information

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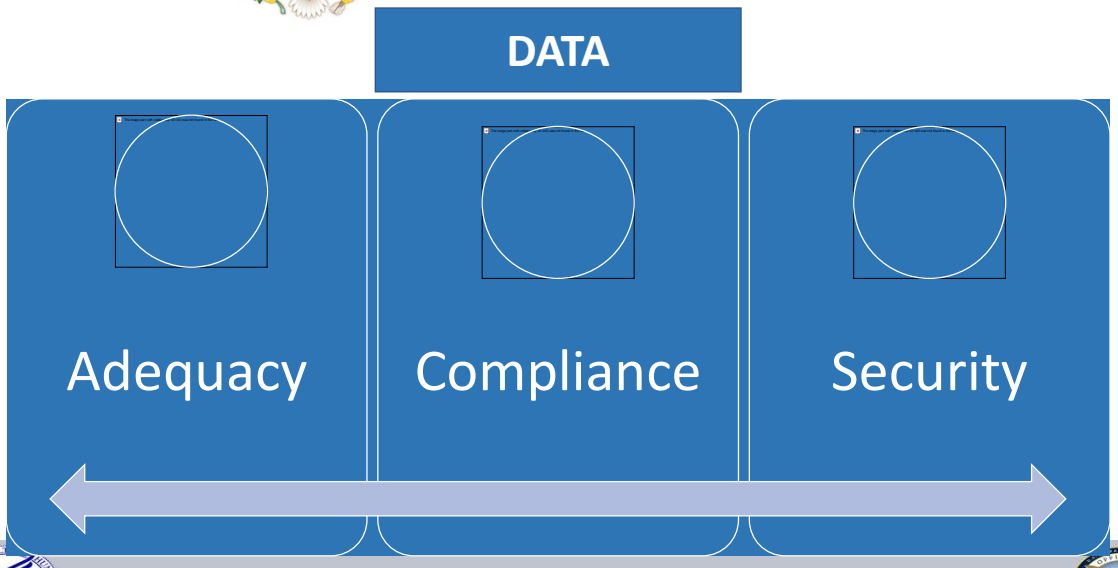

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Freedom Health CIA (May 2017)

- Provider Network Review
- Diagnosis Coding Review

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Beaver Medical Group CIA (Dec. 2019)

- Annual Chart Review
- Review of diagnoses data and medical records

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Conclusion

- Harnessing Data
- Financial Integrity
- Growing Program → Growing Risks

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Benjamin Singer, Esq.

Rising above the complexities of risk

The most relevant compliance program is one that is both multidimensional and adaptable, with a goal of getting in front of evolving risks via full collaboration with functional areas focused on improving clinical outcomes, such as care delivery, case management, quality and patient safety.

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Managed Care Enforcement: Risk Adjustment Updates

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UnitedHealthcare Ins. Co. v. Azar II (D.C. Cir.)

CMS's Overpayment Rule was vacated by a district court in a case currently on appeal.

- Under the CMS Overpayment Rule, MA plans receive an "overpayment" whenever they submit to CMS a diagnosis code that lacks adequate support in the underlying medical record.
- UnitedHealth challenged legality of Overpayment Rule, and on September 7, 2018, D.C. district court vacated the Rule, holding:
  - It violates the Medicare Act's actuarial equivalence and same methodology provisions by holding MA data to a higher accuracy standard than traditional Medicare data.
  - It is arbitrary and capricious under APA because CMS failed to explain how its decision not to include an Fee-For-Service Adjuster ("FFS Adjuster") is consistent with its 2012 policy to include a FFS Adjuster in its RADV audit methodology.
- The D.C. Circuit (Pillard, Roger, Walker, JJ) is scheduled to hear argument on the government's appeal on November 3.

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UnitedHealthcare Ins. Co. v. Azar II (D.C. Cir.)

On appeal, the government's goal is to avoid enforcement challenges created by district court's statutory interpretation of "actuarial equivalence" by implicitly conceding the Rule is procedurally defective and inviting D.C. Circuit to reverse on that limited basis.

- The government argues that, if the D.C. Circuit affirms the district court, it should rule on narrow arbitrary and capricious grounds, leaving CMS the discretion to issue further regulations interpreting actuarial equivalence.
  - Such a ruling would afford CMS more room to maneuver in both the forthcoming RADV Audit Rule as well as pending FCA cases against MA plans.
- The government also argues against the district court's ruling on the merits.
  - *Statutory Holding* – DOJ argues that the Overpayment Rule requires MAOs to undertake the same "limited error correction" performed on traditional Medicare diagnosis data, and so there is no actuarial equivalence problem.
  - *Arbitrary and Capricious Holding* – The Overpayment Rule requires no "comprehensive" audit of MA risk adjustment data and payments, and so the rationale for adopting an FFS Adjuster in RADV audits is inapplicable to that Rule

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Proposed RADV Audit Rule to Eliminate FFS Adjuster

- On November 1, 2018, following the district court's decision in *Azar II*, CMS issued a proposed rule reversing 2012 notice on RADV Audits and announced that results of sample RADV audits would be extrapolated *without* applying a FFS Adjuster.
  - CMS relied on a FFS Adjuster Study (the "Study") which purported to show that auditing diagnosis codes in traditional Medicare prior to generating MA payment model would not result in underpayments to MA plans.
- MA industry participants submitted comments to CMS, arguing that omission of FFS Adjuster violated the Medicare Act's actuarial equivalence requirement, and that the Study was actuarially flawed.
- Rumors that CMS may finalize the RADV Audit Rule by end of year.
- MA plans will almost certainly challenge a final RADV Audit Rule that refuses to apply a FFS Adjuster to audit recoveries.

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FCA Litigation: Medicare Risk Adjustment Practices

***U.S. ex. rel. Poehling v. UnitedHealth* (C.D. Cal.)**

- DOJ's FCA challenge to UnitedHealth's retrospective chart review practices
- DOJ alleges that:
  - United had a legal obligation to delete identified unsupported diagnosis codes, and retention of payments for those codes violates FCA.
  - United's so-called, "one-way" chart review program rendered knowingly false United's certifications to CMS that risk adjustment data was accurate and truthful.
- DOJ recently disclosed its contention that United failed to delete *millions* of unsupported diagnosis codes, including 1.9 million codes from 2013 alone, which will likely result in a multi-billion dollar damages claim *before* trebling.
- Discovery has been underway for two years and trial is set for 2022.

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FCA Litigation: Medicare Risk Adjustment Practices

***United States v. Sutter* (N.D. Cal.)**

- DOJ alleges that Sutter Health:
  - Pressured physicians to addend records to add diagnoses for MA members that were not "clinically accurate or relevant" to the addended patient encounter.
  - "Pre-populated" diagnosis coding lists with lucrative diagnoses and used a "pushpin icon" next to certain conditions to prompt physicians to document them.
  - Did not adequately follow up on internal audit findings showing inaccurate diagnosis codes submitted to MA plans.
- Federal magistrate judge rejected Sutter's motion to dismiss:
  - Rejected a defense based on the Medicare Act's "actuarial equivalence" requirement.
    - The order rejects MA plans' reading of *Azar II* in the FCA context.
    - Magistrate held every diagnosis code submitted to CMS is a "claim" and the submission of any inaccurate data, or the failure to submit any data correction, violates the FCA even if the error rate in traditional Medicare is higher.

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FCA Litigation: Medicare Risk Adjustment Practices

Recent FCA Cases:

- FCA *qui tam* unsealed against CIGNA (SDNY)
  - DOJ declined to intervene on certain claims and is still evaluating intervention as to other claims while case is proceeding in active litigation.
  - CIGNA allegedly submitted false diagnoses from a comprehensive "360 exam" program, usually performed in a home setting (i.e., in-home assessments).
- DOJ filed an FCA complaint against Anthem (SDNY)
  - DOJ alleges FCA theory about chart reviews similar to the claims asserted against UnitedHealth in *Poehling*.

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DOJ's Primary Theories of FCA Liability: Risk Adjustment

1. False attestations (as it had originally asserted in both *Swoben* and *Poehling* but has been rejected by both courts)
2. Failure to comply with contractual and regulatory requirements that health plan correct inaccurate diagnosis codes (as it is currently asserting in *Poehling*)
3. Retained overpayments under the reverse FCA (a theory that has been pled but not advanced in recent briefing in *Poehling*)

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Managed Care: Compliance Guidance

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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

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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." Revised version issued June 1, 2020.
  - Applies to all companies, including those in health care industry.

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HHS-OIG 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.

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DOJ Compliance Guidance

- **Narrowed to 3 Themes**

❑ Is the compliance program well-designed?

❑ Is the program being implemented effectively?

❑ Does the program work in practice?

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Similarities between HHS-OIG and DOJ Guidance

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?"

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Panel Discussion Questions

1. What trends are you watching for in evolving compliance areas?
2. Share your perspective on the role of data driven controls and monitoring for the mitigation of compliance risks.
3. The COVID-19 Pandemic has underscored the value of the Emergency Preparedness & the intersect with Medicare and Medicaid-How do you see the rule evolving in the wake of this most recent test?
4. In November of 2019, the Trump Administration announced the Transparency in Coverage Rule, what key factors should we be aware of as implementation begins?
5. CMS continues to develop, implement, and test new value-based payment structures, these models are complex and difficult to administer. What advice can you offer compliance professionals to best mitigate risk without limiting competitive strategies?

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