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Lessons Learned from OIG Investigations and the Critical Role of CFOs in Compliance Programs

May 2023

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Objectives

- Examine how Compliance Programs can help mitigate an OIG inquiry to prevent deeper investigation
- Gain insight into OIG audit and review activity
- Reconsider the criticality of CFO and Finance Team on ensuring an Effective Compliance Program
- Understand the importance of evidencing your Compliance Program
- Learn specific action items to help ensure you are minimizing regulatory risk
- Understand why you never underestimate the potential risk of whistleblowers


INCOME TAX
FLOWER AND PARTY SUPPLY
• Electronic File
• Personal - Business
• Sales Tax Forms
• Fictitious Business Names & License
• Income Tax - Todo El Ano
e-file

Office of Inspector General ("OIG")

- Established 1976
- Fight fraud, waste, and abuse ("FWA") and oversight of Medicare, Medicaid and other HHS programs
- *Dual reporting to HHS and to Congress*
- CMS - **$2.4 trillion** portfolio of programs– significant portion of Federal budget
- Mission:

  *"provide objective oversight to promote the economy, efficiency, effectiveness, and integrity of HHS programs, as well as the health and welfare of the people they serve"**
- Tax dollars

*About OIG | Office of Inspector General | Government Oversight | U.S. Department of Health and Human Services (hhs.gov)

Fraud

- Fraud - an *intentional* act of deception, misrepresentation or concealment in order to gain something of value

- Waste - over-utilization of services and misuse of resources

- Abuse - excessive or improper use of services or actions that are inconsistent with acceptable business or medical practice.
  - Refers to incidents that, although not fraudulent, may directly or indirectly cause financial loss to Medicare and Medicaid program

Why do we care?

- Resources
  - Approximately 1,650 auditors, investigators, and evaluators, supplemented by staff with expertise in law, technology, cybersecurity, data analytics, statistics, medicine, economics, health policy, and management and administration

  - Rigorously analyze data to detect concerning trends and outliers, issue compliance guidance for the health care industry, and make recommendations to HHS to improve program integrity

OIG Approach

- For every $1 dollar invested in the Health Care Fraud and Abuse Control Program, we [OIG] recovered more than $4 for taxpayers*
- Data-driven approach to detect, investigate, and prosecute fraud
- Coordinated, multi-pronged with:
  - Department of Justice (DOJ)
  - Medicaid Fraud Control Units (MFCUs)
  - Federal agencies
  - State, and local law enforcement agencies

*Semiannual Report to Congress (oversight.gov)

OIG Semi-annual Report to Congress

- Describes OIG's work identifying significant risks, problems, abuses, deficiencies, remedies, and investigative outcomes relating to the administration of HHS programs and operations

- June 2022
  - *“America’s taxpayers could recoup nearly $3 billion in misspent Medicare, Medicaid, and other HHS funds as a result of work by HHS-OIG”*

OIG Semi-Annual Report to Congress

In general:

- $3 billion in expected recoveries as a result of HHS-OIG audits and investigations
- 320 criminal enforcement actions against **individuals or entities** that engaged in crimes that affected HHS programs
- Reported 320 civil actions, which include false claims (FCA), civil monetary penalty (CMP) settlements, and administrative recoveries related to provider self-disclosure matters
- Excluded 1,043 individuals and entities from participation in Federal health care programs

OIG Semi-Annual Report to Congress

Specific issues:

- pursued bad actors who are exploiting the **public health emergency** (“PHE”)
- **COVID-19** tests drove a 4% increase in total Medicare Part B spending on laboratory tests in 2020 - concerns about potential impacts on beneficiary health
- March through December 2020, 84 percent of Medicare beneficiaries received **telehealth** services from providers with whom they had an established relationship
- Enforcement action targeting fraud schemes involving 5.1 million illegally prescribed controlled substance pills and roughly $7 million billed in **opioid-related** fraud loss
- more than half of **States** failed to meet performance measures for their **oversight of nursing homes** in three or four consecutive years during FYs 2015–2018

Department of Justice (DOJ)

- *"The mission of the Department of Justice (DOJ) is to uphold the rule of law, to keep our country safe, and to protect civil rights"*
- Enforcement of federal law and administration of justice in the United States
- Health Care Fraud Unit (HCFU) - 80 prosecutors focus solely on prosecuting complex health care fraud matters

Department of Justice – FYE 2021 (09/30/21)*

- $5.6 billion in settlements and judgments from civil cases involving fraud and false claims
- $5 billion = health care industry

- False Claims Act **(FCA)** primary tool used to combat fraud
- Whistleblower actions comprise a significant percent of FCA cases

*Justice Department's False Claims Act Settlements and Judgments Exceed $5.6 Billion in Fiscal Year 2021 | OPA | Department of Justice

Department of Justice – FYE 2021 (09/30/21)*

- 598 Qui Tam suits filed under FCA in FY2021 (whistleblowers)
  - Average of 11 new cases/week
- $237 million paid to Qui Tam Relators
- Of $5.6 billion, $1.6 billion result of whistleblower suits

- In 2019 recoveries of $3 billion – 75% result of whistleblower lawsuits

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Department of Justice

U.S. Attorney's Office

Northern District of Illinois

FOR IMMEDIATE RELEASE

Tuesday, July 12, 2022

Suburban Chicago Doctor Charged with Health Care Fraud in Connection with Alleged False Claims to Medicare and Private Insurer

CHICAGO — A suburban Chicago doctor who specialized in removing moles to screen for cancer was charged today in federal court with submitting fraudulent claims for reimbursement to Medicare and a private insurer.

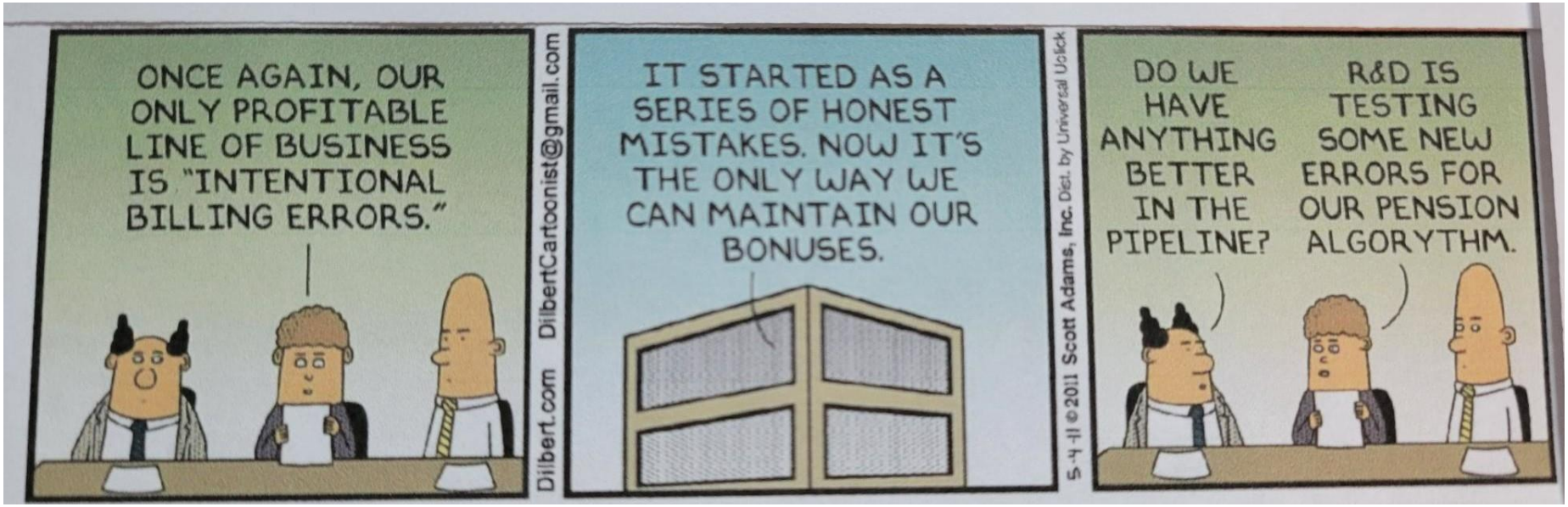
JOHN A. GREAGER II owned and operated Cancer Therapy Associates S.C., in Lombard, Ill. From 2015 to 2021, Greager fraudulently obtained approximately $4.1 million from Medicare and Blue Cross Blue Shield of Illinois by submitting fraudulent claims that falsely represented that certain health care services, including mole removal procedures, had been provided to patients, according to a criminal information filed in U.S. District Court in Chicago. Greager knew that those services were not provided as represented on the claims and, at times, were medically unnecessary, the information states. The information also alleges that Greager removed more moles from patients than was medically necessary, and then dictated notes and provided paperwork to employees to submit fraudulent claims for reimbursement for those medical procedures.

The information charges Greager, 74, of Hinsdale, Ill., with one count of health care fraud. Arraignment in federal court has not yet been scheduled.

The charge was announced by John R. Lausch, Jr., United States Attorney for the Northern District of Illinois; Emmerson Buie, Jr., Special Agent-in-Charge of the Chicago Field Office of the FBI; Mario Pinto, Special Agent-in-Charge of the U.S. Department of Health and Human Services, Office of the Inspector General; Irene Lindow, Special Agent-in-Charge of the U.S. Department of Labor's Office of Inspector General in Chicago; and Amy K. Parker, Special Agent-in-Charge of the U.S. Office of Personnel Management Office of the Inspector General. The government is represented by Assistant U.S. Attorneys Jared Hasten and Virginia Hancock.

The public is reminded that an information is not evidence of guilt. The defendant is presumed innocent and entitled to a fair trial at which the government has the burden of proving guilt beyond a reasonable doubt.

Health care fraud is punishable by a maximum sentence of ten years in federal prison. If convicted, the Court must impose a reasonable sentence under federal statutes and the advisory U.S. Sentencing Guidelines.


ONCE AGAIN, OUR ONLY PROFITABLE LINE OF BUSINESS IS "INTENTIONAL BILLING ERRORS."
Dilbert.com DilbertCartoonist@gmail.com
IT STARTED AS A SERIES OF HONEST MISTAKES. NOW IT'S THE ONLY WAY WE CAN MAINTAIN OUR BONUSES.
5-4-11 ©2011 Scott Adams, Inc. Dist. by Universal Uclick
DO WE HAVE ANYTHING BETTER IN THE PIPELINE?
R&D IS TESTING SOME NEW ERRORS FOR OUR PENSION ALGORYTHM.

OIG Evaluation of Risk

- Pursue or dismiss a Qui Tam action
- No interest in meritless cases
- OIG makes recommendations to DOJ

- If found guilty of fraud, potential for **exclusion from participation in Federal and state health care programs** – Medicare/caid, Tricare, etc.
- OIG's formal protocol for prioritizing cases for exclusion
- Fraud Risk Indicator – how assess future risk posed by persons who have allegedly engaged in civil healthcare fraud

OIG Exclusion

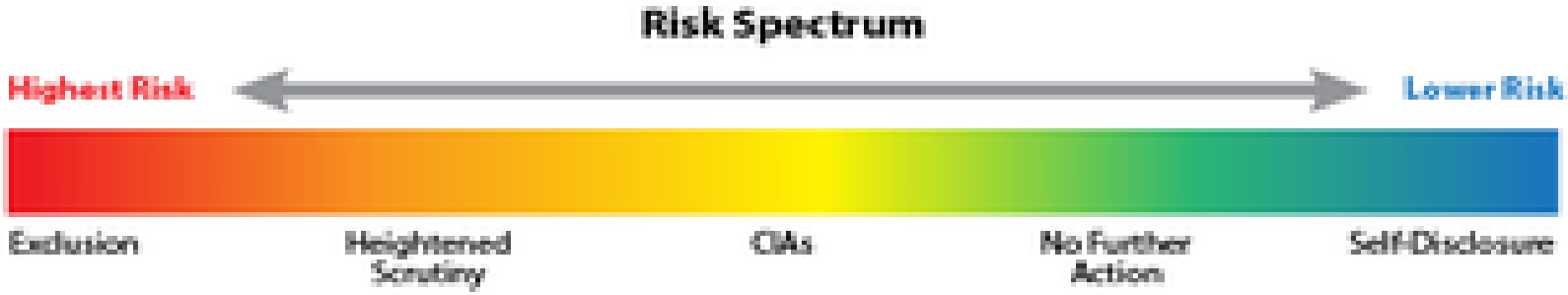
- OIG Exclusions Program*
- Final administrative action by OIG that prohibits participation in any Federal Health care Program
- Imposed because the individual or entity is found to pose an unacceptable risk to patient safety and/or program fraud
- Medicare/caid, Tricare will not pay for any service provided, directly or indirectly, by an excluded person or ent

Death sentence - Leverage

- *Exclusions | Office of Inspector General | U.S. Department of Health and Human Services (hhs.gov)

Fraud Risk Indicator

- Primary civil tool for addressing healthcare fraud is the FCA
- False Claims Act settlements on the Risk Spectrum
- OIG assessment of future risk posed by persons who have allegedly engaged in civil healthcare fraud



OIG Risk Categories

- Highest Risk/Exclusion – Parties OIG determines highest risk of fraud excluded from Federal health care programs
- High Risk/Heightened Scrutiny – posts a significant risk to Federal health care programs and require additional oversight but refused to enter into CIA
- Medium Risk/CIA – signed CIA to settle investigation and party promises to fulfill obligations in exchange for participation in programs
- Lower Risk/No Further Action – exclusion or CIA not sought, and cases closed without further eval of effectiveness of compliance efforts
- Low Risk/Self-Disclosure – good faith effort and cooperation with review and resolution process **demonstrates an effective Compliance Program**

What happens if investigated?

- In the end, results may be positive – finding of no wrong-doing
- Serious distraction from operations and strategic goals
- Investigations drain resources
- Repayments
- Fines/Penalties
- Corporate Integrity Agreement (“CIA”)
- Jail time for individuals

OIG Investigations

- OIG doesn't have a lack of cases to investigate
- When they are initially assessing an organization to determine whether or not to open an investigation, they can tell, in very short order, whether there is evidence the Compliance Program is designed to do anything - or nothing.
- Intent and Evidence

Scenario #1

- Employed CCO at small health system
- OIG review request of Medicare payments to providers for selected drugs – objective is to determine whether the payments made to providers for outpatient services for selected drugs were correct
- Data mining, data analytics identify drug claim line items
- HCPCS Code **J1745 -** *Injection, infliximab, excludes biosimilar, 10 mg Remicaid*
- Rheumatoid/psoriatic arthritis, ankylosing spondylitis, ulcerative colitis
- $5-10,000/dose

Scenario #1

- OIG Report – *Medicare Part B Overpaid Millions for Selected Outpatient Drugs* – July 2015
- Medicare contractors in 13 jurisdictions overpaid $35.8 million for selected outpatient drugs during audit period
- 88% of providers billed incorrect units or HCPCS codes
- Medically Unlikely Edits (MUE)/prepayment edits not in place
- Overpayments - FWA

Lessons Learned - Takeaways

- **Low Risk/Good Faith Effort**

- Do your own audits – Auditing and Monitoring Plan, internal controls, Compliance Workplan

- Report out at Compliance Committee meetings

- Engage all operational departments re: claim submission

- Do you have an Overpayment P&P?
  - How do you proactively identify Overpayments?
  - What is your process for returning Overpayments?

- Stay informed on regulatory issues - Special Fraud Alerts, Bulletins, OIG Workplan, MLN Connects, NGS Medicare, Medicare Quarterly Provider Compliance Newsletter, other guidance, etc.

Scenario #2

- Consultant to manage Corporate Integrity Agreement (CIA)
  - Very large organization
  - Overpayments not returned – FCA violations/fines
  - Clinic/Outpatient claims
  - Weak Compliance Program – resulted in CIA
  - Whistleblower – was former CCO
  - Culture
    - Apathetic
    - CFO disinterested
    - Finger-pointing
  - Resource intensive

Leadership is solving problems. The day soldiers stop bringing you their problems is the day you have stopped leading them. They have either lost confidence that you can help or concluded you do not care. Either case is a failure of leadership.

(Colin Powell)

izquotes.com

Lessons Learned - Takeaways

- Assessment of future risk – resulted in **CIA/Medium Risk**
- Listen to your employees (Hotline) (and Chief Compliance Officer)
- Conduct meaningful Compliance Education – specific examples, scenarios, etc.
- Need a CEO/CFO that take compliance seriously
- General lack of respect for regulatory compliance
- Don’t pretend – you’re not fooling anyone

Scenario #3

- Chief Compliance Officer – Interim
- Small health system with 4 small hospitals and LTAC
- Anti-kickback Statute (AKB) violations
- NO Compliance Program
- FBI and OIG Investigation

Scenario #3

- Federal and state investigations
- Whistleblower (Hotline) – pending CIA

- Culture
  - NO accountability (Enforcement of Disciplinary Standards)
  - CFO fired – new CFO over-whelmed
  - Complete failure to abide by state and federal rules – systemic failure
  - 1 hospital was **Excluded/Highest Risk**

Lessons Learned - Takeaways

- Requires a drastic change in culture – accountability
- Need a Compliance Program – how identify risk (Risk Assessment)?
- If you take your eye off the ball for too long, it's very difficult to fully recover
- Needed additional senior leadership support/failure to take responsibility – specifically CFO and Financial Team
- **Highest Risk/Exclusion**

Scenario #4

- Clinical Compliance Officer – Interim
- Very large academic medical center

- *OIG Medicare Compliance Review* – inpatient and outpatient services through data mining and analysis
- Specific Medicare billing rules – 10 business days to respond to OIG

Scenario #4

- Questionnaire, audit reports, policies and procedures
- Processes in place to ensure if problem occurs – will find it and correct it
- Culture
  - Siloed departments
  - CFO unwilling to accept responsibility for review/audit
  - Lack of accountability

Lessons Learned - Takeaways

- High Risk/Heightened Scrutiny – onsite investigators
- Discord with Management Team - Need an engaged CFO
- Lots of conflict!
- Lack of a culture of accountability

- Need internal audits and reviews – Auditing and Monitoring
- Support for the Compliance Department – Staff and budget

Scenario #5

- Senior VP Compliance – Interim
- Management Company providing support services for small hospitals - hospitals maintain licensure through state and contract for services with Management Company
- Pressure on CEO to hire CCO by HR and CFO
- Reported had a Compliance Program
  - Purchased electronic education module
  - External Compliance Hotline never called - answered by HR

Scenario #5

- Build program from ground up
  - Board resolution
  - Compliance Committee
  - Code of Conduct

- *Go in your office and do compliance – and don't bother anyone*
- Establish a Culture of Compliance – need to change
- Great hospital leadership
- Remarkable management and employee dedication

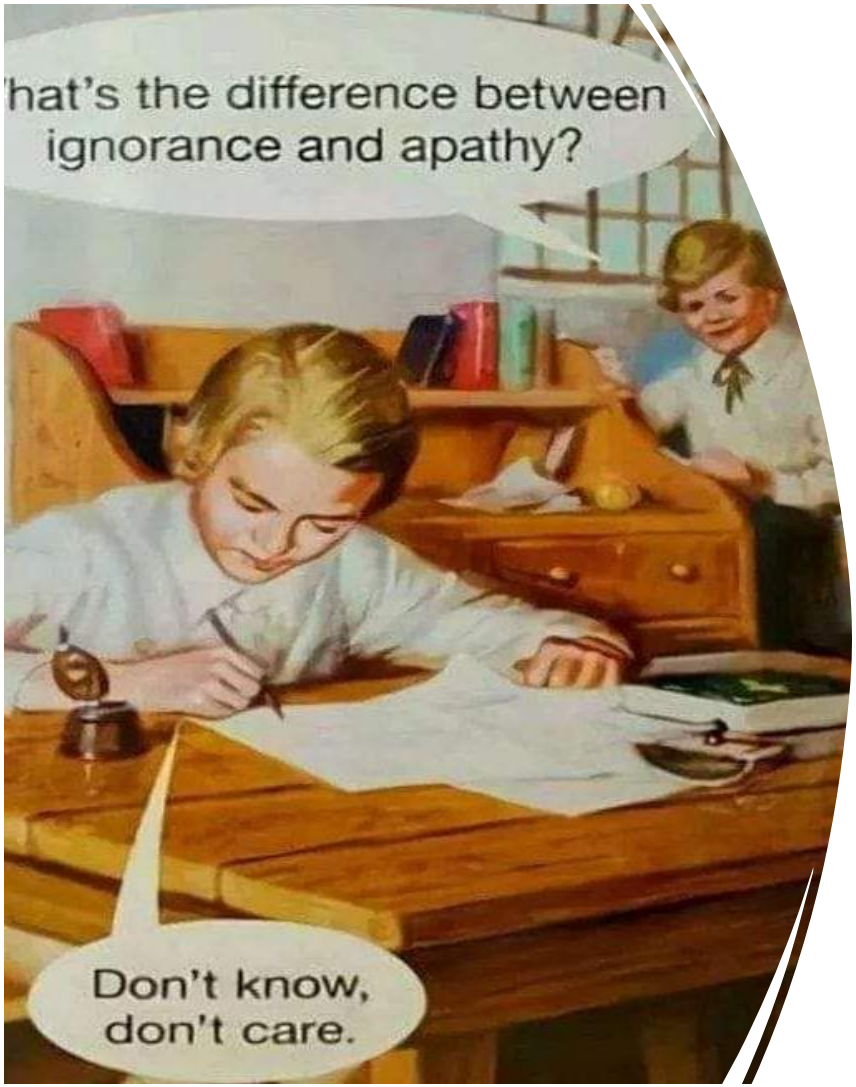
Scenario #5

- CFO abruptly fired
- Controller fired the next day
- No CFO for 4-5 months - Interim
- New CFO
- New CFO fired after 6-8 weeks
- Left few weeks later
- Culture:
  - Apathy towards regulatory compliance
  - Egotism
  - Well paid
- 6 months later subpoena/call from OIG investigator

- Whistleblowers

Lessons Learned - Takeaways

- Fraud Risk Indicator?
- Don’t discount employees as whistleblowers – listen! (Hotline)
- Resources for Compliance Department
- Code of Conduct to present and support a Culture of Compliance
- Educate employees
- Don’t wait too long to ensure you have a really good Compliance Program

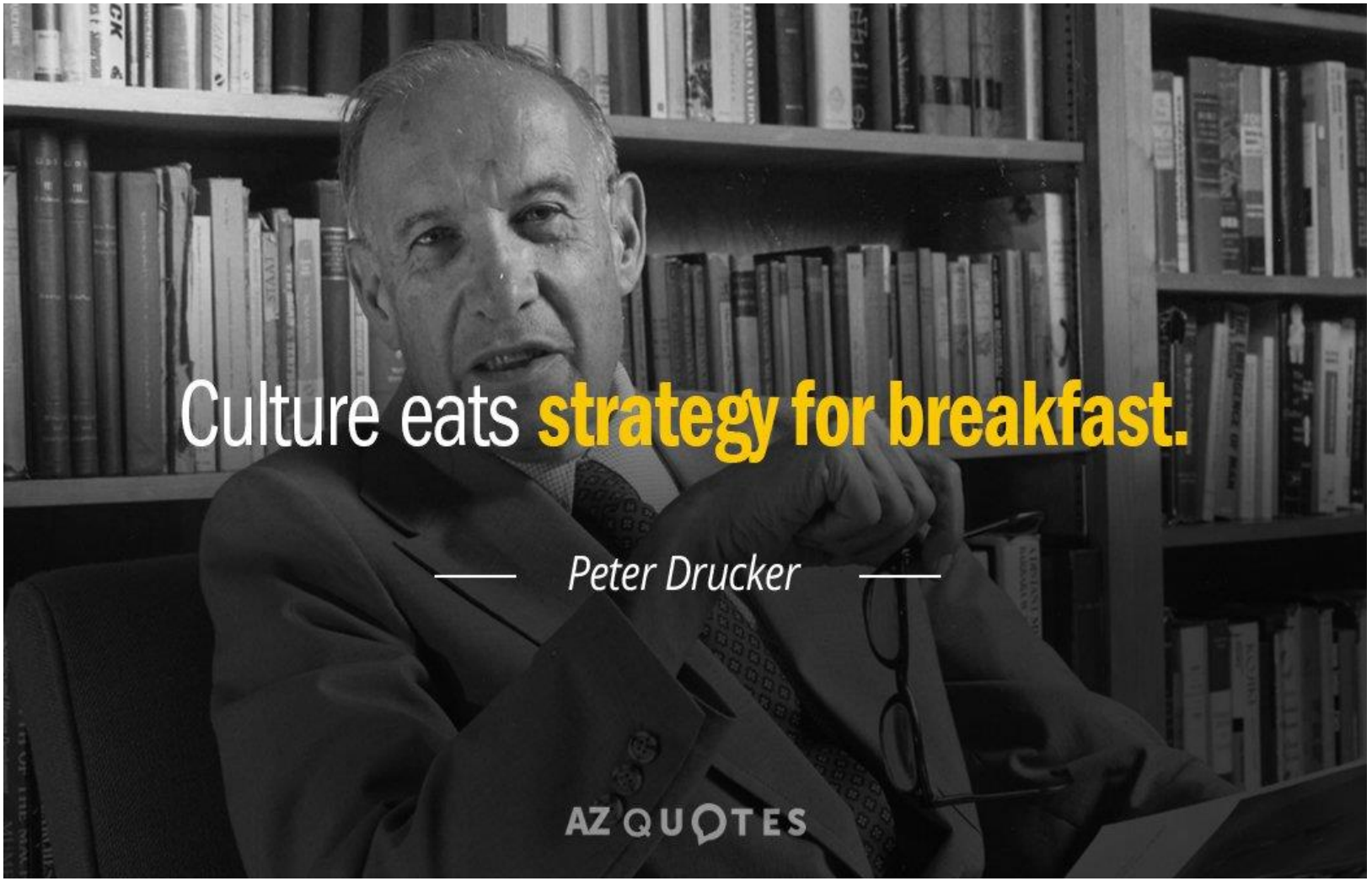


What do they have in common?

- Problematic Cultures – Enterprise Risk
- OIG Fraud Risk Indicator – how assess future risk posed by individual or entity
- What is needed?
  - Sufficient resources
  - CFO and Financial Team support

Overall Take-aways

- Extremely difficult, if not impossible, to have an Effective Compliance Program without the pro-active, affirmative support of Finance/CFO
- Systematic or process failures – what does evidence show?
- Don't think your organization is too small to be investigated
- Don't underestimate a potential whistleblower
- Consider your organizational culture


Culture eats strategy for breakfast.
Peter Drucker
AZ QUOTES

Organizational Culture

- Collection of beliefs, values and methods of interaction that create the environment of an organization
- Foundational values, collective consciousness
- Reflects shared experiences of employees and leaders
- Behaviors, words, “the way things are done”, climate (feeling)
- How make decisions, how approaches problems
- How information is conveyed

OIG and Culture

*"Hospitals with an organizational culture that values compliance are more likely to have effective compliance programs and, thus, are better able to prevent, detect, and correct problems."**

*Supplemental CPG for Hospitals (hhs.gov)

OIG and Culture

- *"In short, the hospital should endeavor to develop a culture that values compliance from the top down and fosters compliance from the bottom up.* ***Such an organizational culture is the foundation of an effective compliance program."****

- Compliance programs are intended to keep an organization aligned with their mission, vision and values

*Supplemental CPG for Hospitals (hhs.gov)

Compliance and Culture

What words would your employees use to describe your organization's culture?

On Sunday evening, how do your employees feel about coming to work on Monday?

OIG Compliance Program Guidance (CPG)

- CPG for **Hospitals**
  - Supplemental CPG for Hospitals
- CPG for Individual and Small Group **Physician Practices**
- CPG for **Nursing Facilities (SNF)**
  - Supplemental CPG for Nursing Facilities
- CPG for **Hospices**
- CPG for **Home Health** Agencies
- CPG for **DME-POS**
- CPG for **Clinical Labs**
- CPG for **Third-Party Medical Billing** Companies
- CPG for **Ambulance** Suppliers
- CPG for **Medicare+Choice** Organizations
- CPG for **Pharmaceutical** Manufacturers
- CPG for Recipients of **PHS Research** Awards

7 Elements of a (Voluntary) Compliance Program

I. Written Policies and Procedures and Standards of Conduct

II. Designation of a Compliance Officer and a Compliance Committee /Oversight

III. Training and Education

IV. Effective Lines of Communication/Hotline

V. Auditing and Monitoring

VI. Response to Detected Offenses and Developing Corrective Action

VII. Enforcement of Disciplinary Standards

7 Elements of a Compliance Program

ACA Requirement for Compliance Program

- March 2010 - Affordable Care Act (Section 6401)* provides that:

  *a "provider of medical, or other items or services, or supplier within a particular industry sector or category," shall establish a compliance program as a condition of enrollment in Medicare, Medicaid, or the Children's Health Insurance Program (CHIP) – Mandatory for all providers**

*ppacacon.pdf (house.gov)

ACA Requirement for Compliance Program

- HHS and OIG to establish core elements for Compliance Programs
- Determine timeline for implementation of core elements and the requirement to have a program
- No regulations or enforcement date – yet!
  (except for Skilled Nursing Facilities)

- Still relying on OIG Compliance Program Guidance (“CPG”) – Stay tuned!

Federal Sentencing Guidelines (“FSG”)

- Compliance Program Guidance is based on the FSG
  - Chapter 8, Part B

- Uniform sentencing policy for defendants convicted in the United States federal court system – effective 1987

- In determining level of penalty/sentence, judges utilize a **Culpability Score**, a consideration is ***whether or not organization had an effective Compliance and Ethics Program***

Federal Sentencing Guidelines ("FSG")

- "Due Diligence" and "organizational culture" minimally require 7 elements

- To have an Effective Compliance and Ethics Program, must:
  - "Exercise due diligence to prevent and detect criminal conduct, and
  - Otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law." * [Emphasis added]

*USSC Guidelines| United States Sentencing Commission (ussc.gov)

Recent DOJ guidance – June 2020

- In conducting an investigation, determination of whether to bring charges or negotiate plea or other agreements

  is based on the status

  of the Compliance Program

  <u>at the time of the misconduct</u>

- “investments and improvements to its corporate compliance program and internal controls systems…..would prevent or detect similar misconduct in the future”

Recent DOJ guidance – June 2020*
(undated March 2023)

3 questions:

1. Is the Compliance Program well-designed?
   - Risk Assessment, P&Ps, training and communications, confidential reporting, investigation processes, 3rd-party management

2. Is the program being applied earnestly and in good faith? Effectively?
   - "adequately resourced and empowered to function" – more concrete measures that evidence implementation
     - Culture of ethics, management involvement and commitment, discipline

3. Does the Compliance Program work in practice?
   - Emphasis on continual data-driven (subjective) improvement; data analytics
   - Address potential gaps or weaknesses in compliance function
   - *Culture of Compliance*

**www.justice.gov/criminal-fraud/page/file/937501/download*

Compliance Programs

- Compliance Program requirements are very well-established
- Based on FSG Chapter 8 and OIG/CMS guidance for >20 years
- Is further guidance
  likely to change requirements?

- Conditions of Participation – condition of enrollment in Medicare/caid

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How do you feel about your Compliance Program?

- You should feel GREAT!
- Compliance is a positive
- Compliance is an asset
- Compliance is a strength for your organization

- Provides confidence in a highly regulated environment
- Reassurance to your board/governing body
- Demonstrates your overall commitment to ethical and responsible business practices to your workforce

Evidence and Outcomes

- Evidence of meaningful progress of the Compliance Program

- Compliance Program outcomes that evidence effectiveness
  - Auditing and Monitoring reports – Overpayments management
  - Code of Ethical Conduct
  - Financial Resources for Compliance Program
  - Education programs
  - Compliance Committee minutes
  - Evaluation of actual Hotline calls
  - Documentation of Investigations
  - Disciplinary Action (Accountability)
  - Policies and Procedures
  - Etc.

Effectiveness Review and Outcome Evidence

- Compliance Program Effectiveness Review
  - Evaluation of implementation of CP and
  - Action Plan to address deficiencies
  - Annual
- Regulatory compliance should be a part of overall business strategy
- **Need a plan**/strategy and sustainable processes

HOPE
IS
NOT
A
STRATEGY

Govering Body

- With the volume of new/revised laws and regulations, and incredible detail in operations required to comply, how to you assure your governing body that its all under control?
- What does the Board of Directors know and understand?
- *"Compliance Programs provide a central coordinating mechanism for furnishing and disseminating information and guidance on applicable Federal and State statutes, regulations and other requirements."**
- Efficient utilization of resources – good business

*Compliance Program Guidance for Hospitals (hhs.gov)

Further Thoughts

- If your organization is queried, are the right pieces in place?
- Are you sure you know how your organization will respond to an inquiry or investigation?
- Don't think you'll never be investigated!

- Are you sure you understand how your employees will respond if they encounter non-compliance? Or are interviewed?

CFO/Finance Critical Authority in Risk Areas

- Finance/Cost Reports
- Audit Committee of Board
- Patient Financial Services/Business Office/CBO - FCA
- Contracting – Stark and Anti-KickBack (AKB)
- HIPAA Business Associate Agreements (BAA)
- Vendor Management Program
- Criminal Background Checks/Exclusions – Vendors

"Who holds the purse holds the power"

"He/She who pays the piper calls the tune"

Support Your Compliance Program

- Ask about Audits – what do you and your departments recommend?
  - Where are your risks? Your leadership knows – ask them!
- Ensure you are Monitoring – Every operational department should have monitoring activity on your Compliance Workplan
- Provide meaningful input on Policies & Procedures for Risk Areas
- Be active on the Compliance Committee
- Compliance should have a dedicated Budget*
- Support obtaining an external Effectiveness Review/Gap Analysis
- Support obtaining a Regulatory Risk Assessment

*Supplemental CPG for Hospitals (hhs.gov)

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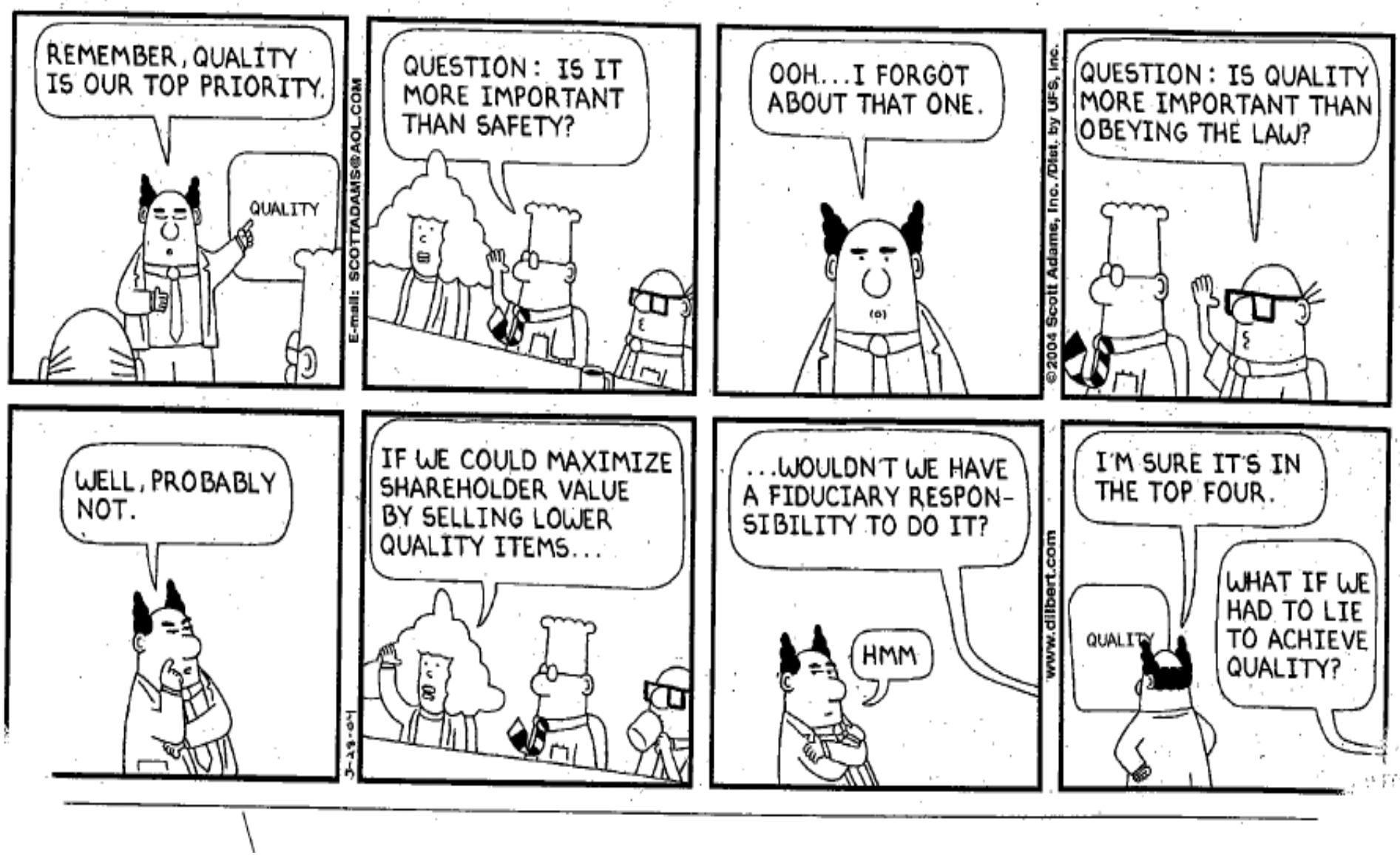

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