Health Care Fraud and Abuse Enforcement

Georgia Hospital Association
Compliance Officer's Retreat
September 6, 2018

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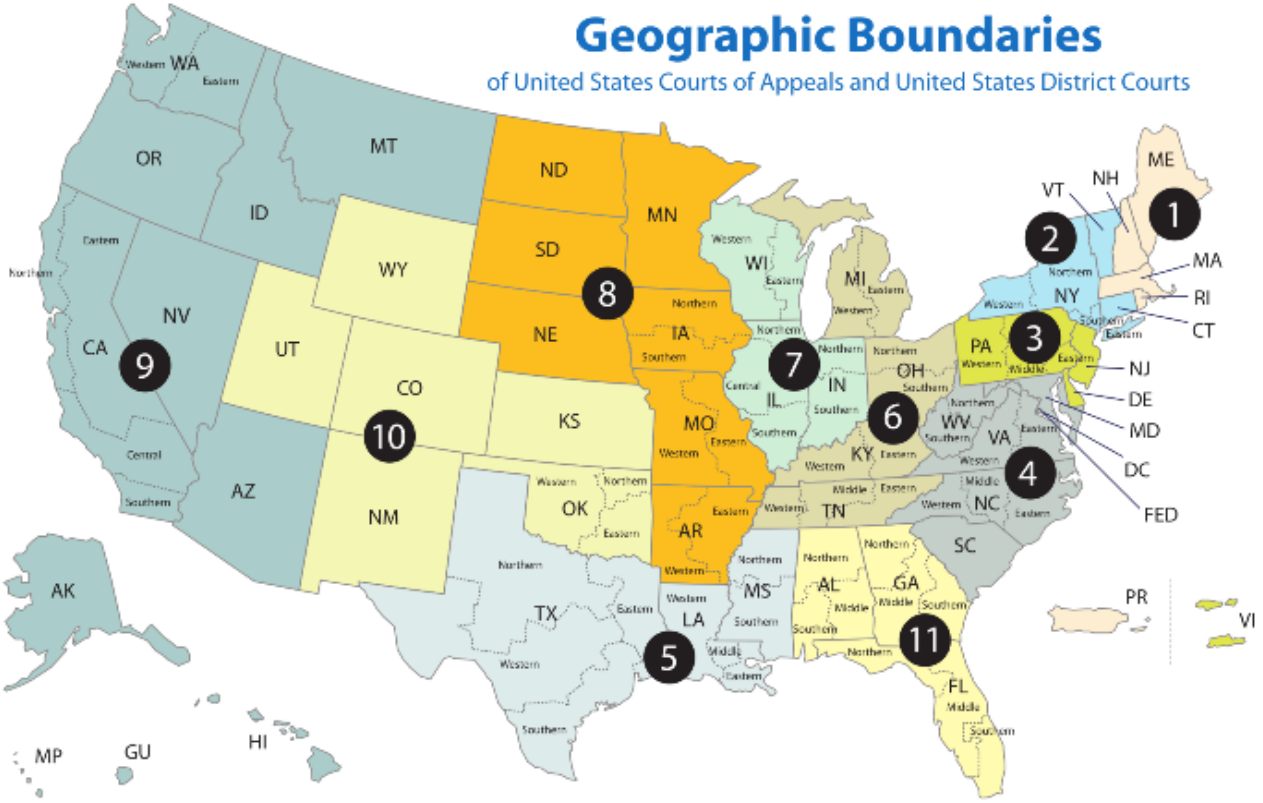
Introduction

What We Will Cover Today

- Overview of the Fraud and Abuse laws
- The current regulatory environment and latest trends in Fraud and Abuse (Stark, Anti-kickback Statute and False Claims Act) enforcement actions and associated litigation involving Health Care Providers;
- Notable legislative and administrative developments affecting the Fraud and Abuse laws' statutory framework and application;
- The latest developments in case law (particularly in the 11th Circuit) following the U.S. Supreme Court's *Escobar* decision;
- Tips for a working relationship between the Chief Compliance Officer and the General Counsel; and
- Best practices for effective compliance programs

Introduction

U.S. Federal Appellate Courts



Introduction

- **Federal Fraud and Abuse Laws**
  - Ethics in Patient Referrals Act ("Stark Law") (prohibits making certain types of referrals to an entity with which the provider has a financial relationship)
  - Anti-kickback Statute (prohibits paying for referrals)
  - False Claims Act (prohibits the filing of false or fraudulent claims)
- **Georgia's Fraud and Abuse Laws**
  - "Stark" Law equivalent (but applies to all payors)
  - Medicaid False Claims Act

Introduction

- **Federal Fraud and Abuse Laws**

	Anti-Kick Back Statute (AKS)	Stark Law	False Claims Act (FCA)
Prohibitions	• Prohibits offers of, solicitation of, or payment or receipt of remuneration intended to induce referrals for health care services covered by a government program • Covers provision of anything of value to a person who refers, orders/purchases or recommends	• Prohibits referrals of designated health services by a physician that if the physician (or an immediate family member) has a financial relationship with the entity performing the designated health service • Regulates financial relationships with physicians only (and physician's immediate family members)	• Prohibits the submission of false or fraudulent claims, false statements material to a false claim, and conspiracy to commit violation • Also prohibits concealing or avoiding obligation to repay money to government (failure to return overpayments) • Claims that violate AKS or Stark can also be considered false claims • Common false claims: lack of medical necessity; quality of care; billing/coding issues; off-label marketing; retention of overpayments
Exceptions	• Arrangements are not required to fit within a safe harbor; however voluntary safe harbors exist	• The arrangement must satisfy an exception or it violates the Stark law	N/a
Penalties	• Applies to either party involved in an arrangement that violates AKS • Criminal penalties ($25,000/offense, up to 5 years imprisonment) • Civil penalties (CMP 3x unlawful remuneration and $73,588/violation) • Exclusion from federal health programs • FCA liability	• No criminal enforcement • CMP enforcement for knowing violations: CMP $15,000/violation + 3x claims and/or $100,000 per circumvention scheme • Nonpayment of claims arising from prohibited arrangement • Recoupment of amounts received • Exclusion from federal health programs • FCA liability	• Treble damages • Per claim penalties between $10,781 and $21,562
Agency	Regulated by the OIG	Regulated by CMS	Regulated by DOJ

Introduction

Federal Fraud and Abuse Laws

- Important Reminders - No Intent Required for a Stark Law Violation
  - A strict liability statute
  - No such thing as "good faith" compliance
  - A violation occurs regardless of whether it is intentional or inadvertent
  - No materiality threshold (even minor violations are subject to severe penalties)
  - Stark is not a criminal statute

Introduction

Federal Fraud and Abuse Laws

- Establishing a Violation – Intent under the Anti-Kickback Statute
  - Major difference between Stark (no intent required) and Anti-kickback Statute
  - A criminal statute
  - Affordable Care Act: "With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section."
  - Legislatively overrules Hanlester (51 F.3d 1390, 9th Cir., 1995)
  - "One purpose test" - Anti-kickback Statute applies if one purpose of the remuneration is to induce referrals even if there are other legitimate purposes. (U.S. v. Greber, 760 F.2d 68 (3d Cir. 1985))

Introduction

Federal Fraud and Abuse Laws

Stark and Anti-kickback Statute Comparison

	THE ANTI-KICKBACK STATUTE (42 USC § 1320a-7b(b))	THE STARK LAW (42 USC § 1395nn)
Intent	Intent must be proven (knowing and willful)	No intent standard for overpayment (strict liability)
Penalties	Criminal and Administrative	Civil
Exceptions	Voluntary safe harbors	Mandatory exceptions
Federal Health Care Programs	All	Medicare/Medicaid

Introduction

Federal Fraud and Abuse Laws

- **False Claims Act (FCA)**
  - The FCA, 31 U.S.C. §§ 3729–3733, is the federal government's primary weapon to redress fraud against government agencies and programs
  - The FCA provides for recovery of civil penalties and treble damages from any person who knowingly submits or causes the submission of false or fraudulent claims to the United States for money or property
  - Under the FCA, the Attorney General, through DOJ attorneys, investigates and pursues FCA cases
  - DOJ is devoting more and more resources to pursuing FCA cases—and considering whether *qui tam* cases merit parallel criminal investigations

Introduction - Regulatory Bodies

Introduction

Why the Government Cares

- Kickbacks can lead to:
  - Corruption of medical decision making
  - Overutilization
  - Increased costs
  - Patient steering
  - Unfair competition
- Gov't estimates fraud and abuse costs taxpayers $30 billion to $100 billion each year.

Introduction

Why the government cares…and why you should, too

- Fighting Fraud = Good Investment
- Government continues to view fraud, waste, and abuse as a significant source of revenue
- The return-on-investment for Health Care Fraud and Abuse Control (HCFAC) program
  - For every $1 spent by the government on enforcement, it recovers $6.10.
- Government teams recovered $3.7 billion in FY 2017 for False Claims Act cases (of which $2.4 billion was for health care fraud)
- Since January 2009, USDOJ has recovered $24 billion in health care fraud cases

The Current Regulatory Environment

The Current Regulatory Environment

More Aggressive and Expanded Enforcement

- "*There is no shortage of FCA allegations that we can pursue, so we want to focus our attention on the most worthy of cases.*" - Deputy Associate Attorney General Stephen Cox, Feb. 2018
- "*The United States Department of Justice and the Department of Health and Human Services just announced the largest ever healthcare fraud enforcement action by the Medicare Fraud Strike Force, involving 601 charged defendants and more than $2 billion.*" - USDOJ Release July 7, 2018
- "*Weaknesses Exist in Medicaid Managed Care Organizations' Efforts To Identify and Address Fraud and Abuse*" – DHHS/OIG Report, July 2018
- "*We will make it a high priority of the [D]epartment [of Justice] to root out and prosecute fraud in federal programs and to recover any monies lost due to fraud or false claim[s].*" - U.S. Attorney General Jeff Sessions, January 2017

The Current Regulatory Environment

More Cooperation Between Agencies

DOJ

DOJ is devoting more and more resources to pursuing FCA cases—and considering whether *qui tam* cases merit criminal investigation

Support Agencies

Parent agencies (e.g., HUD, SBA) participate in financial sector FCA investigations

Cooperation

Inspectors General

Government

The Current Regulatory Environment

Enforcement Trends

- Government increasing use of data analysis…because it is there
- Increased focus on individual liability/responsibility (Yates Memo)
- Increased focus by DOJ criminal division
- Rise in state AG/Medicaid Fraud Control Unit actions
  - Including opioid-related suits against drug manufacturers, distributors, providers, and pharmacists

The Current Regulatory Environment

Medicare Fraud Strike Force

- FY 2017
  - Filed 253 indictments, informations and complaints involving charges filed against 478 defendants who allegedly billed federal health care programs more than **$2.3 billion**;
  - Obtained 290 guilty pleas negotiated and 33 jury trials litigated, with guilty verdicts against 40 defendants; and
  - Secured imprisonment for 305 defendants sentenced, averaging more than 50 months of incarceration.
- Since its inception, Strike Force prosecutors filed more than 1,660 cases charging more than 3,490 defendants who collectively billed the Medicare program approximately **$13 billion**

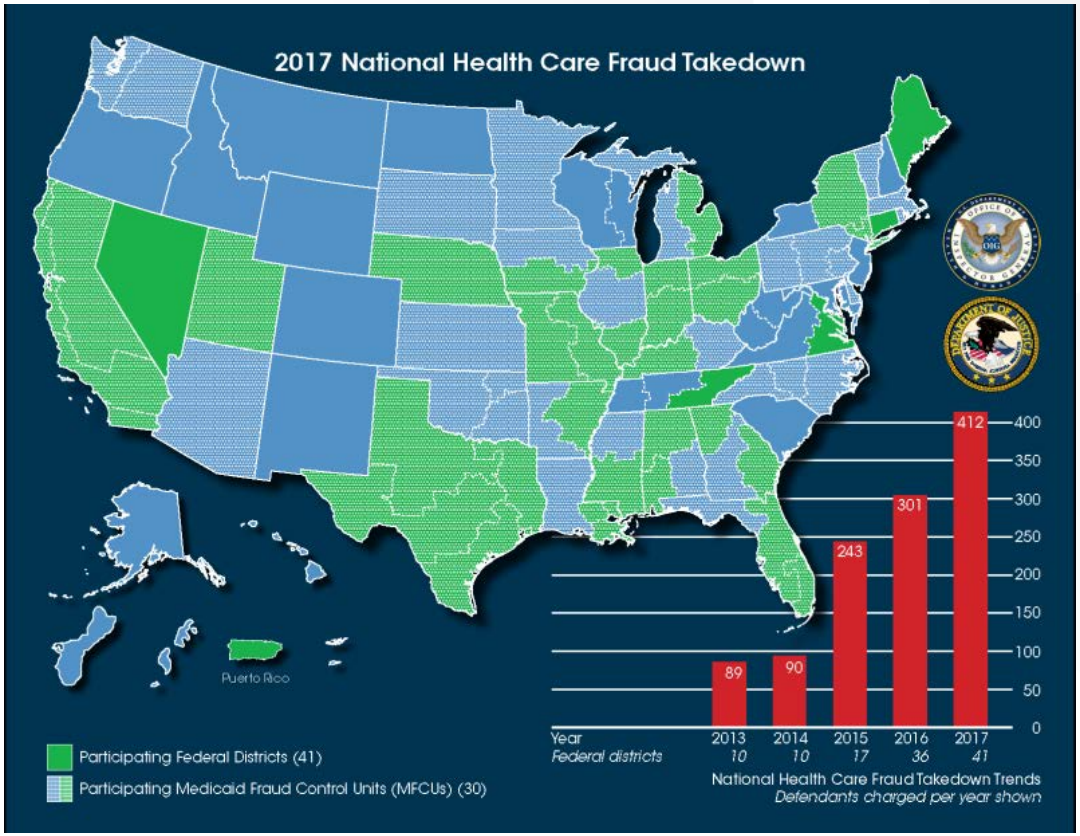
The Current Regulatory Environment

Federal and State Joint Enforcement Activities in Georgia – 2018 National Health Care Fraud Takedown

- U.S. v. Frank H. Bynes, Jr.
  - Savannah physician indicted June 2018
- U.S. v. Rosa Fitzhugh
  - Atlanta LPN agency indicted June 2018
- State of Georgia v. Paula Houston and Otis Nettles
  - Cobb County false claims indictment May 2018
- U.S. v. Douglas Moss and Shawn Tywon
  - Valdosta physician indicted May 2018
- U.S. and State of Georgia v. Miracle Home Care, Inc., et al.
  - Savannah adult transportation service indictment June 2018
- Settlement with Antioch Medical Associates, P.C. and Dr. J. Alphonso Dandy
  - Savannah false claims settlement June 2018

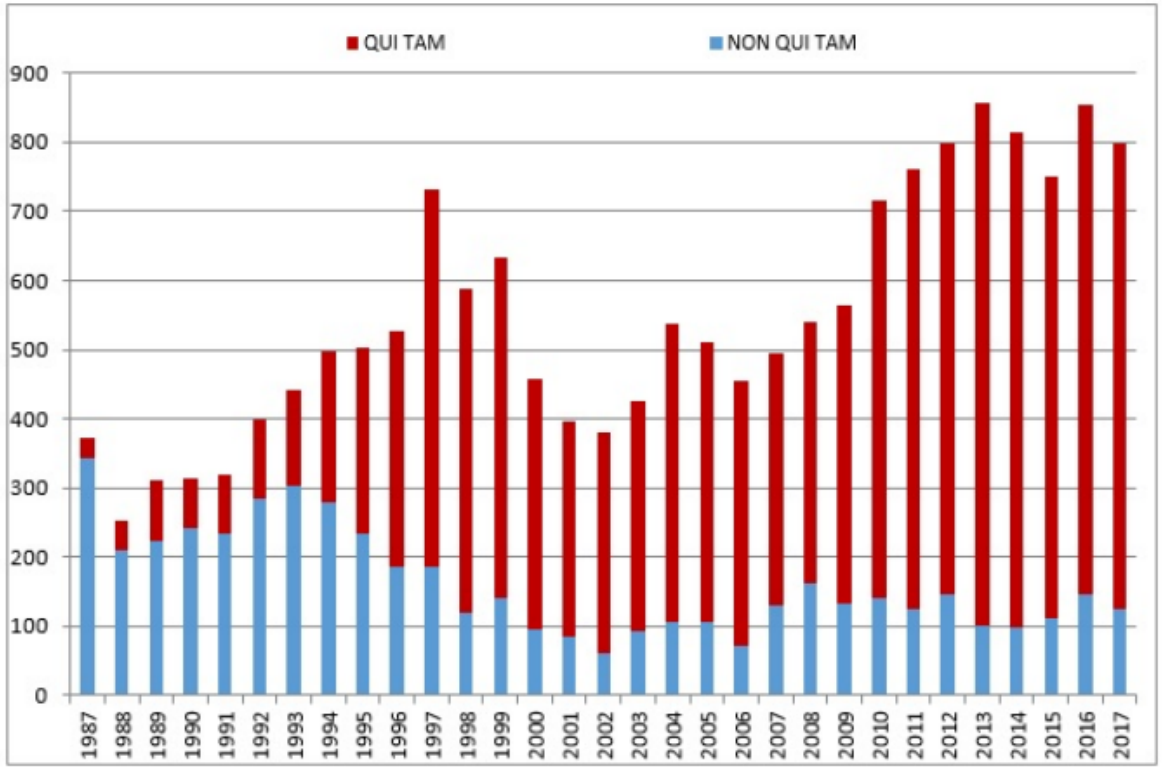
The Current Regulatory Environment

Medicare Fraud Strike Force - 2017



The Current Regulatory Environment

Number of FCA New Matters, Including Qui Tam Actions (1987-2017)

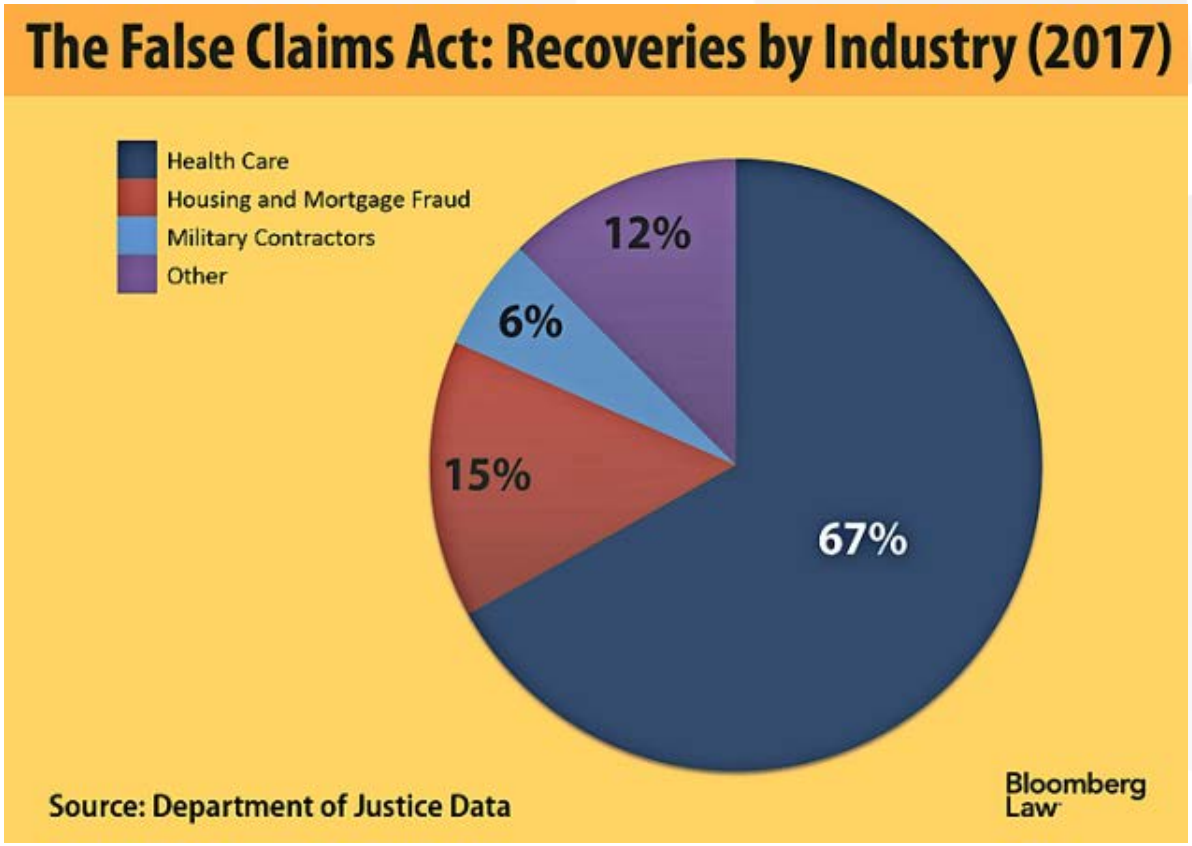


799 new cases in 2017 FFY:

- 674 *qui tam* cases
- 125 non-*qui tam* cases

The Current Regulatory Environment

Settlements or Judgments by Industry in 2017- $3.7B



The Current Regulatory Enviroment

Settlements or Judgments Mid-Year 2018

>$600 million

FCA settlement recoveries

$114 million

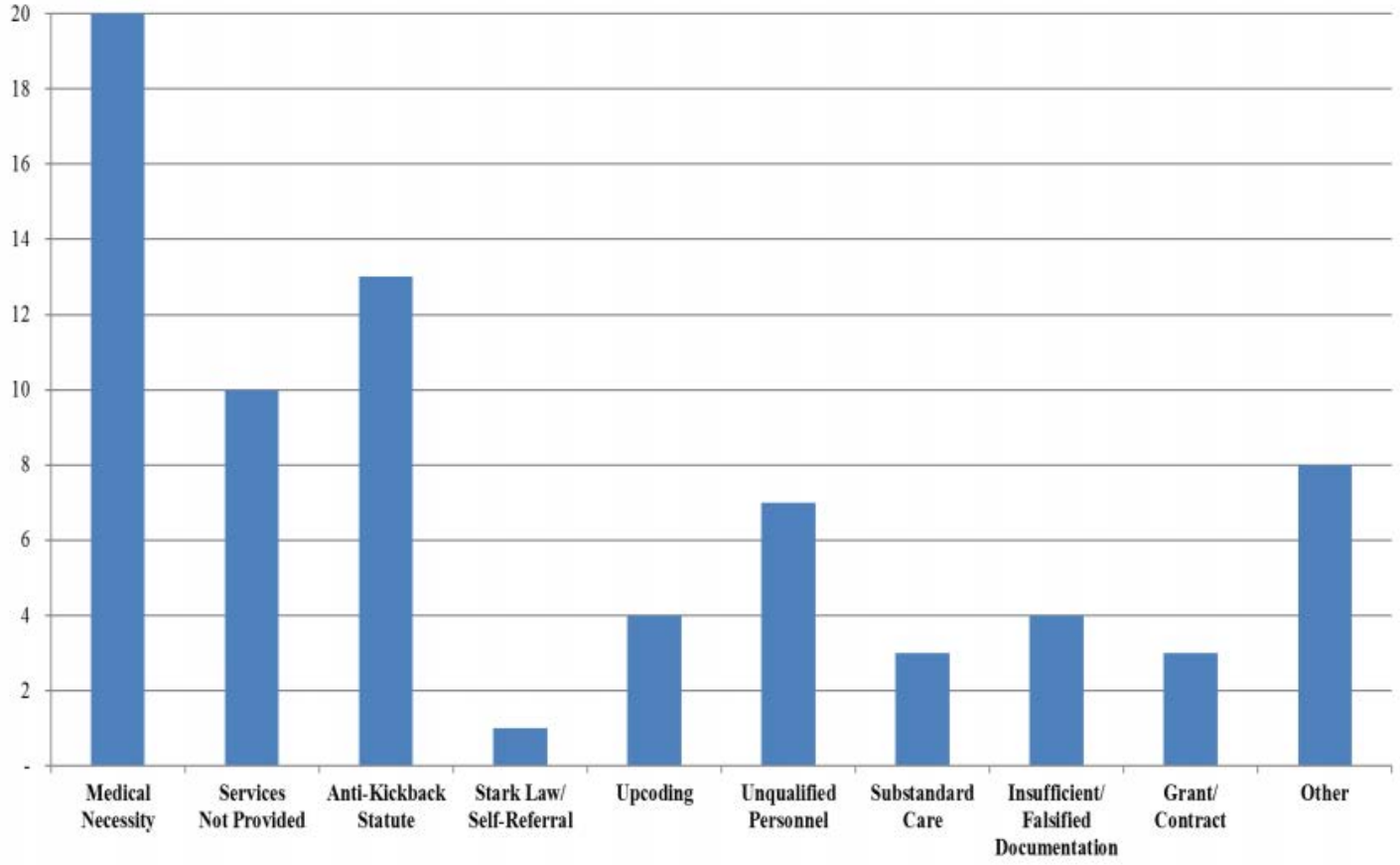
Judgments from FCA cases

9th?

After 8 consecutive years exceeding $3 billion in FCA recoveries, the streak is in jeopardy this year

The Current Regulatory Enviroment

2017 FCA Settlements with Providers, by Allegation Type



The Current Regulatory Environment

Georgia Medicaid Fraud

- "*Enforcement of the Georgia False Medicaid Claims Act is a top priority for our office…Fraud perpetrated against the Medicaid program harms every citizen of Georgia.*" Georgia Attorney General Chris Carr
- Cobb dental company to pay out **$24 million** after Medicaid fraud accusations (2018)
- Navicent Health pays **$2.5 million** for Federal and State false claims act violations relating to ambulance billings with were either inflated or medically unnecessary (2017)
- Since 2011 Georgia Medicaid Fraud Unit has recovered more than **$190 million**

Enforcement Trends and Priorities

Enforcement Trends and Priorities

The Opioid Crisis

- More than 300,000 Americans have died from overdoses involving opioids since 2000.
- U.S. v. Godfrey Ilonzo (N.D. Ga. June 26, 2017) - Opioid-dispensing pharmacist convicted and pays **$5 million** penalty to community. The clinic owner, office manager and two physicians were convicted.
- Council of Economic Advisers estimates that in 2015, the economic cost of the opioid crisis was **$504 billion**, or 2.8 percent of GDP that year.
- The "Pill Mill" – The most widely prescribed opioid is hydrocodone. 6.2 billion hydrocodone (Vicodine) and 5 billion oxycodone (Percocet) pills distributed in the U.S. in 2016.
- In Georgia from June of 2016 to May of 2017, the total number of opioid doses prescribed to Georgia patients surpassed 541 million. To put that in perspective, that is approximately 54 doses for every man, woman and child in Georgia.

Enforcement Trends and Priorities

The Opioid Crisis, continued

- June 28, 2018 - Southern District of Florida Charges 124 Individuals Responsible for **$337 million** in False Billing as Part of National Healthcare Fraud Takedown.
- March 21, 2017 - A new 64-page report from the Healthcare Fraud Prevention Partnership (HFPP), a public-private partnership which includes CMS, gives payers resources that treat, educate, and develop improvements for combating opioid harm to patients. https://downloads.cms.gov/files/hfpp/hfpp-opioid-white-paper.pdf
- In August FY 2017, the U.S. Attorney General announced the formation of the Opioid Fraud and Abuse Detection Unit.

Enforcement Trends and Priorities

Individual Accountability

- 2015 "Yates Memo" issued by Sally Q. Yates (Deputy Attorney General) to emphasize *individual* accountability for corporate misconduct (including owners, executives, etc.)
- May 2017 – DOJ reaches a **$155 million** EMR settlement *and* holds the executives jointly liable
- FY 2017 - HHS-OIG excluded a total of 3,244 individuals and entities. Among these were exclusions based on criminal convictions for crimes related to Medicare and Medicaid (1,281) or to other health care programs (309); for patient abuse or neglect (266); or as a result of licensure revocations (973).
- 2010 – Archbold Memorial Hospital's CEO and CFO found guilty of healthcare fraud **($13.9 million)**.

Legislative and Judicial Updates

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Legislative and Judicial Updates

Recent Healthcare Fraud/FCA Verdicts, Recoveries and Settlements within Georgia, Florida and South Carolina

- Meadows Regional - **$12.875 million** (2017 - Georgia)
- Tenet Healthcare - **$513 million** (2016 - Georgia)
  - Whistleblower received $84.43 million
- Memorial Health - **$9.9 million** (2016 – Georgia)
- Lexington Medical Center - **$17 million** (2016 – South Carolina)
  - Whistleblower received $4.5 million
- Tuomey Healthcare - **$237 million** (2015 – South Carolina)
  - Settled for $72.4 million and whistleblower received $18.1 million
- Columbus Regional Healthcare - **$35 million** (2015 – Georgia)
- Navicent Health/MCCG - **$20 million** (2015 – Georgia)
- North Broward Hospital - **$69.5 million** (2015 – Florida)
- Adventist Health - **$118.7 million** (2015 – Florida)
- Halifax Hospital – **$85 million** (2014 – Florida)
  - Whistleblower received $20.8 million

Legislative and Judicial Updates

Georgia Statutes

- Patient Self-referral Act of 1993 – Georgia's "Stark Law" equivalent *except for the fact that the Georgia law an all payor statute*.
- Georgia Medicaid False Claims Act (2007)
- Georgia Taxpayer Protection False Claims Act (2012)
  - Expands the Georgia Medicaid False Claims Act (2007) to apply to any person or business who knowingly or recklessly submits a false claim to a government body of Georgia (not just for Medicaid fraud), including lesser political divisions like school boards and MARTA, regardless of whether the person or business actually intended to defraud the government.
- SB352 (2018) – This bill, designed to address the opioid crisis, would have also created a state anti-kickback statute but without the Federal safe harbor protections. It did not pass.

Legislative and Judicial Updates

Federal Laws

- U.S. intervenes in 25% of FCA *qui tam* actions. In such cases, 90% of the time there is a monetary recovery. However, only about 10% of non-intervened cases generate a recovery.
- January 10, 2018 (The Granston Memo) – DOJ issued a memorandum outlining factors for evaluating dismissal of *qui tam* FCA cases in which the government has declined to intervene.
  - Curbing Meritless Qui Tams
  - Preventing Opportunistic Qui Tam Actions
  - Preventing Interference with Agency Policies and Programs
  - Controlling Litigation Brought on Behalf of the United States
  - Preserving Government Resources
  - Addressing Egregious Procedural Errors

Legislative and Judicial Updates

Federal Laws, continued

- **The Brand Memo (January 25, 2018)**
  - Agencies commonly issue guidance documents interpreting legislation and regulations, and the government has sometimes employed evidence that a defendant violated such guidance to prove a violation of the underlying statute or regulation.
  - A January 25, 2018 DOJ internal memo prohibits DOJ from: (1) using noncompliance with other agencies' "guidance documents as a basis for proving violations of applicable law in" affirmative civil enforcement cases, and (2) using "its enforcement authority to effectively convert agency guidance documents into binding rules."
  - Under the Brand Memo, DOJ will be more limited in its ability to wield guidance affirmatively.

Legislative and Judicial Updates

Federal Laws, continued

- Patient Protection and Affordable Care Act ("PPACA") (2010)
  - IRC Sect. 501(r) – Community Needs Assessments
  - Revised/lowered the "intent" standard for Anti-kickback Statute violation: "a person need not have actual knowledge of [the Anti-Kickback Statute] or specific intent to commit a violation of [the Anti-Kickback Statute]." Prior to the PPACA, some courts required knowledge of the statute and specific intent to violate it.
  - Overpayments must be reported and repaid within 60 days after being discovered.
  - A violation of the Anti-Kickback Statute now constitutes a false or fraudulent claim for purposes of the False Claims Act.
  - New Disclosure Requirements for In-Office Ancillary Services Exception (specifically for "radiology services).

Legislative and Judicial Updates

Federal Laws, continued

- Stark Law – On June 25, 2018, CMS requests public comment on "how to address any undue regulatory impact and burden of the physician self-referral law." (https://www.federalregister.gov/documents/2018/06/25/2018-13529/medicare-program-request-for-information-regarding-the-physician-self-referral-law)
  - Focus is on "value-based medicine"
- Anti-Kickback Statute – On August 27, 2018, OIG publishes a request for information inviting comments regarding the Anti-Kickback Statute and Beneficiary Inducements Civil Monetary Penalty, in an effort to address regulatory provisions that may act as barriers to coordinated care or value-based care. Comments due by October 26, 2018.
  - Specifically, OIG solicits comments regarding: promoting care coordination and value-based care, beneficiary engagement, fraud and abuse waivers, cybersecurity, the ACO beneficiary incentive program, telehealth, and the intersection of the Stark Law and Anti-Kickback Statute. https://www.federalregister.gov/documents/2018/08/27/2018-18519/medicare-and-state-health-care-programs-fraud-and-abuse-request-for-information-regarding-the

Legislative and Judicial Updates

Federal Laws, continued

- *Escobar* (U.S. Supreme Court, 2016) - Key Points:
  - Validates the "implied certification theory" (i.e., a failure to disclose noncompliance can render a claim false or fraudulent and the misrepresentation must be material to the government's payment decision)
  - Determining materiality is a rigorous and fact-based inquiry (thereby requiring a higher burden on the qui tam relator)
  - Cited in over 300 cases
  - May make it easier to dismiss an FCA lawsuit at the summary judgment stage

Legislative and Judicial Updates

Federal Laws, continued

- 11th Circuit and District Court Decisions
  - Implied Certification
    - U.S. *ex rel.* Marsteller, 880 F.3d 1302 (11th Cir. 2018)
    - U.S. *ex rel.* Headen (N.D. Ala. Dec. 5, 2017)
    - U.S. *ex rel.* Payton (S.D. Ga. Sept. 6, 2017)
    - U.S. *ex rel.* Florida Society of Anesthesiologists (M.D. Fla. June 14, 2017)
    - U.S. *ex rel.* Doe (M.D. Fla. July 22, 2016)
  - Materiality (applying *Escobar*)
    - U.S. and State of Florida *ex rel.* Angela Ruckh (M.D. Fla. Jan. 11, 2018) Reversal of **$350 million** jury FCA verdict. The court found that the proof at trial failed to satisfy the FCA's heightened materiality and "scienter" requirement based on *Escobar*.
    - U.S. *ex rel.* Payton (S.D. Ga. Sept. 6, 2017) Conclusory allegations of materiality are insufficient to state an FCA claim.
    - U.S. *ex rel.* Southeast Carpenters Regional Council (N.D. Ga. Aug. 5, 2016)

Legislative and Judicial Updates

Federal Laws, continued

- 11th Circuit and District Court Decisions
  - Statute of Limitations
    - Extension of the statute of limitations for as long as ten years based on the "know or should have known" disclaimer for relators in non-intervened cases (U.S. *ex rel.* Hunt, 11th Cir., (4/11/2018)). The usual statute of limitations is six years or three years from when the facts are known or should have been known.
    - The 11th Cir. held that relators can employ the extended limitations period even in cases where the government has declined to intervene—and that the courts must look to the government official's knowledge (not the relator's).

Legislative and Judicial Updates

Federal Laws, continued

- 11th Circuit and District Court Decisions
  - Pleading with Particularity (Rule 9(b))
    - FCA imposes a strict pleading standard requiring particularized allegations of specific false claims (U.S. *ex rel.* Nancy Chase, 11th Cir., (1/24/2018))(affirming the lower court's dismissal of a whistleblower's **$320 million** FCA suit against a hospice provider). Ms. Chase petitioned the U.S. Supreme Court for review on 8/13/2018.
    - U.S. ex rel. Schaengold, S.D. Ga. (12/12/2014))
  - FCA *qui tam* filed by a competitor
    - United States *ex rel.* Schiff (M.D. Fla. (8/28/2018)) – Dermatologist competitor filed an FCA against another dermatologist for upcoding skin radiation therapies. Case settled for **$4 million** (including State of Florida claims)

Legislative and Judicial Updates

Federal Laws, continued

- 11th Circuit and District Court Decisions
  - Original Source
    - A relator's secondhand knowledge of his employer's billing practices was sufficient to make him an original source relative to the FCA's public disclosure bar. (Saldivar v. Fresenius Medical, 11th Cir. (11/8/2016))
  - Public Disclosure Bar
    - Dismissal of the relator's lawsuit was appropriate because the lawsuit was based at least "in … part" upon the publicly disclosed information cited by defendants. (U.S. *ex rel.* Osheroff, 11th Cir. (1/16/2015))
  - Intent/Knowledge
    - In dismissing this FCA case, the court held that scienter requires a determination that the defendant actually knew or should have known that its conduct violated the regulation in light of any ambiguity present. (U.S. *ex rel.* Phalp, 11th Cir. (5/26/2017)).
    - Existence of a compliance program does not shield a defendant from acting with reckless disregard or deliberate ignorance. (Graves v. Plaza Med. Ctrs. (S.D. Fla. (3/20/2017)).

Legislative and Judicial Updates

Federal Laws, continued

- 11th Circuit and District Court Decisions
  - Statistical Sampling
    - In 2016, the Supreme Court rejected a "categorical exclusion" of statistical sampling to establish Fair Labor Standards Act liability – (Tyson Foods v. Bouphakeo, No. 14–1146 (U.S. 2016)).
    - U.S. ex rel. Paradies (N.D. Ala.) and U.S. ex rel. Ruckh (M.D. Fla.) where both allowed statistical sampling to be admitted. Paradies is on appeal to the 11th Cir. while, in Ruckh, the court (citing Escobar) vacated a $350 million jury verdict in January 2018.
  - Reverse False Claims – FCA liability if the defendant makes or uses a false record or statement to avoid or decrease an "obligation" owed to the U.S. (e.g., using a cost report to conceal the requirement to refund an overpayment or actually retaining an overpayment)

Additional Considerations

Additional Considerations

Friends or Foes - Relationship Between the Chief Compliance Officer and the General Counsel

- Both have compliance responsibilities but with distinctive roles which, at times, can result in potentially conflicting professional obligations.
- The divergence is how each functions to achieve the compliance objective.
- The functions are complimentary but not the same.
  - The GC provides legal advice on how to comply with the law.
  - The CCO, by contrast, incorporates legal considerations while influencing the processes and practices of the entity.

Additional Considerations

Friends or Foes - Relationship Between the Chief Compliance Officer and the General Counsel, continued

- Compliance is a management, not a legal, function.
- Compliance is relied upon by the Board to manage the operations of the company in a manner consistent with relevant rules and the organization's own values and goals.
- Three common models (and pros and cons for each):
  - CCO and GC are one and the same.
  - CCO reports to the GC.
  - CCO does not report to and is independent from the GC.

Additional Considerations

Friends or Foes - Relationship Between the Chief Compliance Officer and the General Counsel, continued

- CCO and GC are one and the same
  - GC's generally carry more "authority".
  - Allows for consolidation of resources.
  - But…when is he GC is acting as the GC vs. the CCO?
  - When does the attorney-client privilege/attorney work product doctrine attach?
  - In an investigation, can the GC become a witness? Are the GC's files discoverable?
  - What if the matter involves the GC's legal advice, conduct or judgment?

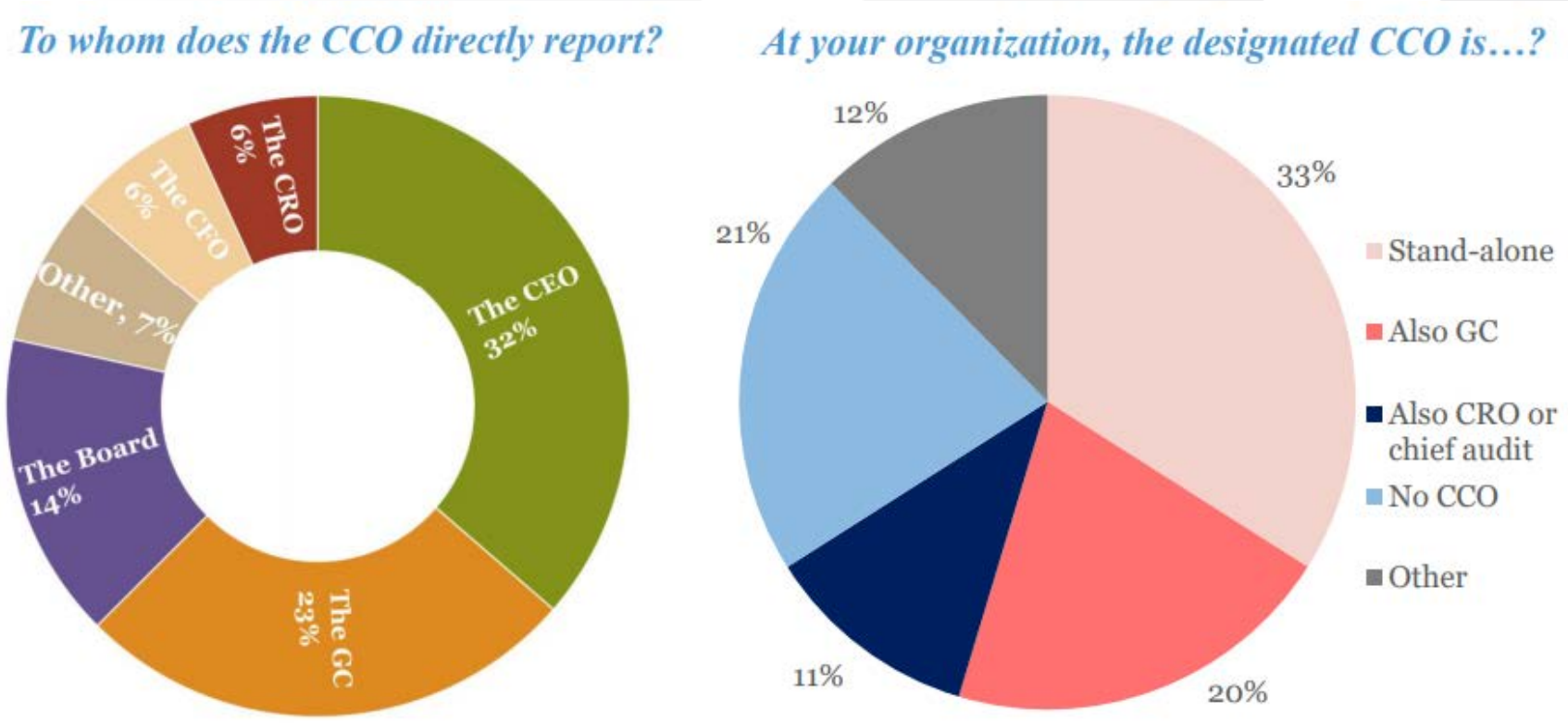
Additional Considerations

Friends or Foes - Relationship Between the Chief Compliance Officer and the General Counsel, continued

- CCO and GC – Two Roles for Two People
  - Easier to preserve attorney-client privilege and attorney work product doctrine
    - CCO's documents are not necessarily privileged
    - GC (or outside counsel) can request an investigation and protect documents from discovery
  - How to become indispensable to each other – importance of accountability, professionalism, competence and trust
  - Provide primary and alternative reporting mechanisms
    - To the CEO
    - To the Board
    - To Outside Counsel
  - Provide a "check" against overzealous internal investigations
  - Avoid territorial power struggles
  - Lawyers can be disbarred for unethical conduct
  - Can a CCO and a GC be a whistleblower?

Additional Considerations

Compliance Department Structure



Additional Considerations

Minimizing Exposure

- Set a compliance-focused "tone from the top"
- Adopt and implement reasonable compliance policies and controls
- Standards and procedures, internal audits, external audits, compliance hotline
- A strong internal compliance program may not prevent a rogue employee from committing fraud, but it may help to defeat scienter • Train employees on compliance policies and reporting options • Monitor and audit
- Investigate and remediate
- Develop standards and procedures to prevent, detect, and respond to improper conduct
- Should you procure "Fraud and Abuse" insurance coverage?

Additional Considerations

Risk Assessment

- Monitor government interactions
- Understand compliance requirements
- Account for internal quality control measures
- Evaluate business partners and transactions
- Have strong HR system in place – most whistleblowers are aggrieved/disgruntled former employees
- Document the government's knowledge, awareness, and ratification of contractual and programmatic deviations
- Take care in responding to billing inquiries as incorrect explanations may be used as evidence of fraud
- Documentation and transparency are key

Additional Considerations

Investigative Responsiveness

- Critical to know of FCA complaints as soon as possible
- Foster an environment in which employees and other interested parties report concerns internally
- Separate the message from the messenger, take allegations seriously and follow up
- *Qui tam* warning signs
    - HR issues;
    - Exit interview statements;
    - Unexpected audits;
    - Requests for billing explanations;
    - Increased web activity; and
    - Former employees contacted

- Proactively engage with and present your case to DOJ and USAO
- The most critical juncture is the government's intervention decision

Additional Considerations

DOJ Guidance of Corporate Compliance Programs

- The February 2017 memorandum issued by the DOJ Fraud Section regarding "Evaluation of Corporate Compliance Programs" provides guidance to companies regarding agency expectations for effective corporate compliance programs.
- In addition to identifying 11 key compliance program evaluation topics, the memorandum includes a corresponding set of "common questions" that DOJ might ask in the context of a compliance assessment during a criminal investigation.
- Companies should take note of these topics and questions in evaluating the adequacy of their own compliance programs.
- The memo can be found at: https://www.justice.gov/criminal-fraud/page/file/937501/download

Additional Considerations

Best Practices

- Understand health care laws and regulations
  - Does the arrangement implicate the Stark Law? Anti-kickback Statute?
  - If yes, does either an exception or a safe harbor apply?
  - Should you get an advisory opinion?
- Ensure accurate billing
- Maintain updated and proper documentation including policies and procedures
- Monitor medical necessity and avoid unnecessary referrals
- Seek guidance from lawyers and government agencies (advisory opinions, etc.)
- If you pay a physician over the 75th percentile, be careful and document (1) business judgment factors, (2) community need and benefit and (3) fair market value and commercial reasonableness

Additional Considerations

Best Practices, continued

- Educate the Board, Executives, Physicians and other Key Employees on health care compliance
- Incorporate into your compliance plans:
  - "Measuring Compliance Program Effectiveness: A Resource Guide" (March 27, 2017) (https://oig.hhs.gov/compliance/compliance-resource-portal/files/HCCA-OIG-Resource-Guide.pdf) and
  - "Avoiding Medicare Fraud & Abuse: A Roadmap for Physicians" (November 2017) (https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Avoiding_Medicare_FandA_Physicians_FactSheet_905645.pdf)

Top Health Law Issues for 2018

- Health Care Mergers, Acquisitions and Consolidation
  - Distressed hospitals
  - Hospitals filing for Chapter 7 or 11 Bankruptcy Protection
- Fraud and Abuse Enforcement
  - USDOJ Criminal Division to review all *qui tam* filings
  - Stark Law, Anti-kickback Statute and FCA Enforcement
    - Physician Recruitment and Employment
    - Operating Physician Practices in the Red
    - The Yates Memo and "Individual Accountability for Corporate Wrongdoing"
- Measuring Effective Compliance Programs
- Cybersecurity
- Alternative Payment Models – Risk-Based and Bundled Payments

Questions?

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