A Review of the Current Health Care Fraud Enforcement Environment

Brian McEvoy &
Ellen Persons

Polsinelli PC. In California, Polsinelli LLP

AVENUES FOR ENFORCEMENT

- Administrative Enforcement
  - Department of Health and Human Services (HHS)
  - State Level (Department of Community Health)
- Civil Enforcement
  - HHS & FBI
  - DOJ and U.S. Attorneys' Offices
- Criminal Enforcement
  - FBI
  - DOJ and U.S. Attorneys' Offices

- Medicare-Medicaid Anti-Fraud and Abuse Amendments (1977) established MFCUs
- False Claims Act (1986)
- Health Insurance Portability and Accountability Act (HIPAA) (1996)
- Medicare Modernization Act (2003) directed CMS to conduct a demonstration of recovery audit contractors
- Deficit Reduction Act (2005) established Medicaid Integrity Program
- Fraud Enforcement and Recovery Act ("FERA") (2009)
- Patient Protection and Affordable Care Act (2010)

HEALTHCARE FRAUD PREVENTION AND ENFORCEMENT INITIATIVES

- DOJ Criminal Division's Medicare Fraud Strike Force
  - Partnering with U.S. Attorneys' Offices, the MFSF has filed almost 1000 cases, charging over 2100 defendants who collectively billed Medicare $6.5 billion
- Health Care Fraud Prevention and Enforcement Action Team (HEAT) was created in 2009
  - Focused on recurring areas of abuse, such as home health care fraud or durable medical equipment fraud, in targeted cities
  - 2,000+ individuals have been charged with health care fraud-related offenses, resulting in more than 1,400 guilty pleas and 191 convictions after jury trial
- Healthcare Fraud Prevention Partnership (HFPP)
  - Public/private partnership between Federal Government, State officials, law enforcement, private health insurance plans and associations, and health care anti-fraud associations

CURRENT ENFORCEMENT CLIMATE

- Over the past several years, the Federal Government has taken a significantly more aggressive approach to health care fraud enforcement
- Annual loss to the Government as a result of health care fraud is estimated to be between **$70 and $100 billion**
- 10-20% of the annual Medicare and Medicaid budget is spent on fraudulent or false claims
- Regardless of the actual numbers, losses from health care fraud are staggering, resulting in increased efforts on both the civil and criminal sides to root out and prosecute health care fraud

CURRENT ENFORCEMENT CLIMATE

- In June 2018, HHS OIG along with state and federal law enforcement participated in an unprecedented health care fraud takedown
- The record-breaking takedown involved 58 federal districts, approximately $2 billion in false billings and 30 state Medicaid Fraud Control Units
- Charges against 601 defendants, including 165 medical professionals including 32 doctors
- Resulted in 587 exclusions issued including 67 doctors, 402 nurses, and 40 pharmacy services

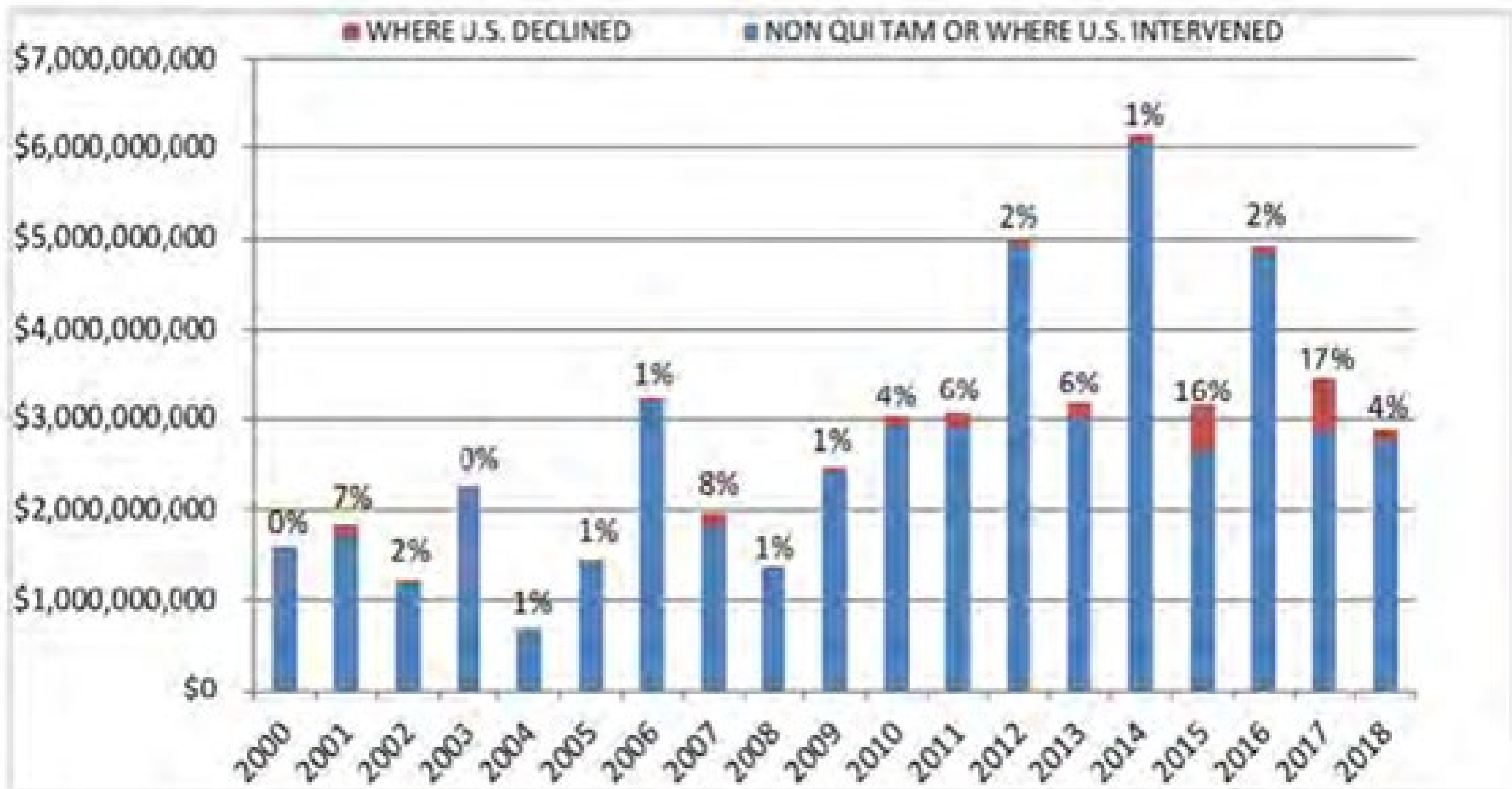
CURRENT ENFORCEMENT CLIMATE

- DOJ opened 967 new criminal health care fraud investigations
  - Prosecutors filed criminal charges in 439 cases involving 720 defendants
  - A total of 639 defendants were convicted of health care fraud related crimes
- DOJ opened 948 new civil health care fraud investigations and had 1,086 civil health care fraud matters pending
- FBI investigative efforts resulted in over 674 operational disruptions of criminal fraud organizations and the dismantlement of more than 148 health care fraud criminal enterprises
- HHS-OIG investigations resulted in 788 criminal actions and 818 civil actions relating to health care fraud and excluded 3,244 individuals and entities from Medicare and Medicaid

CURRENT ENFORCEMENT CLIMATE

- DOJ recovered **$2.8B** in civil FCA recoveries in 2018 down from 2017
  - The majority (**$2.5B**) was recovered from the health care industry (drug companies, medical device companies, hospitals, nursing homes, laboratories, and physicians)
  - $2.1 B related to lawsuits filed under the *qui tam* provisions of the FCA
  - $1.9 B where U.S. intervened
  - $118 million where U.S. declined to intervene
- Lowest recovery by DOJ since 2009
- Overall number of FCA matters also fell for the second consecutive year
  - 767 new cases were filed in 2018
  - 645 were filed by relators

CURRENT ENFORCEMENT CLIMATE



Source: DOJ "Fraud Statistics – Overview" (Dec. 21, 2018)

CURRENT ENFORCEMENT CLIMATE

- One reason for decrease in recoveries in 2018 is Department of Defense government contracting recoveries fell by close to 50%
  - 2017 DOJ recovered $220,079,712
  - 2018 DOJ recovered $107,522,394
- Similarly there was a dramatic decrease in non-HHS and Non-DOD cases
  - 2017 DOJ recovered $823.4 million
  - 2018 DOJ recovered $259.6 million
- Only $370 million of the $2.8B or 13% of recovery were from non-health care cases

CIVIL ENFORCEMENT OF HEALTH CARE FRAUD

- False Claims Act, 31 U.S.C. § 3729
- Prohibits any individual or business from submitting, or causing someone to submit, to the government a false or fraudulent claim for payment
  - Anyone who receives Government funds is subject to FCA
  - Health care industry and health care providers are among the most affected
- *Qui Tam* provision permits private citizens ("Relators") to sue on behalf of the federal government and to share in the recovery

FCA QUI TAM SUITS

- Relator files complaint “under seal”
- Government has 60 days to investigate and decide whether to intervene in the case – this timeframe is usually always extended by the court
- During seal period, Government can issue subpoenas (CIDs), interview witnesses, etc.
- If the Government declines to intervene, the relator can, and often does, pursue the case on his/her own
- DOJ leadership recently indicated that the DOJ will start taking a close look at cases brought by relators and may move to dismiss cases the DOJ believes lack merit (Granston Memo)

GOVERNMENT INTERVENTION?

- Government intervention leads to an extraordinarily high success rate
- DOJ data reveals that Government intervention results in the relator's 15-30% share historically being 28 times higher than when the Government declines to intervene
- Furthermore, there is evidence that the returns for the Government are also greater where the *qui tam* case originates from a relator, as opposed to the Government's own independent investigation

OVERVIEW OF FCA

- Sources of Substantive Liability under FCA
  - § 3729(a)(1)(A): "direct" false claims for payment or approval
  - § 3729(a)(1)(B): making false records or false statements to support a false claim
  - § 3729(a)(1)(G): "reverse false claims" provision (creates liability for a knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the United States)
  - "Implied False Certification" Liability

OVERVIEW OF FCA

- Traditional FCA liability arises in cases involving direct claims for payment that are *factually* false
  - EX: a health care provider bills Medicare for goods or services that were never performed or submits a bill containing altered CPT or ICD-9 codes
- False certification liability involves claims that are *legally* false
  - EX: the person or entity submitting the claim for payment has failed to comply with applicable statutes, regulations, or contractual provisions underlying the claim for payment

FALSE CERTIFICATION

- The “legally false” certification can be express or implied
  - An express false certification occurs when the person/entity submitting the claim expressly certifies compliance with ancillary legal requirements
  - “Implied false certification” cases rest on the theory that a person/entity receiving federal funds implicitly certifies, every time it makes a claim for payment, that it has complied with applicable legal requirements, even though no express certification of compliance with those legal requirements has been made
- Many FCA cases rely on the implied certification theory of falsity
  - Theory is particularly attractive to relators in health care cases since providers are subject to thousands of regulations

IMPLIED FALSE CERTIFICATION

- Supreme Court upheld validity of implied false certification as a theory of FCA liability in *Universal Health Services v. United States ex rel. Escobar* (June 2016)
  - Before *Escobar*, there was a deep Circuit split over the validity of the theory
  - After *Escobar*, FCA defendants can no longer attack the validity of the implied false certification theory itself

POST-*ESCOBAR*

- Defense counsel, relator's counsel and the government have diverse views regarding the implications of the *Escobar* decision
  - Defense – focus on "outcome-dependent" materiality standard
    - Must analyze unique facts and circumstances of each case
    - Have to understand what government actually knew about the claims at issue
  - Government – focus on "natural tendency" materiality standard
    - *Escobar* is just a rubber stamp
    - Materiality is found if either "a reasonable man would attach importance to it" in determining a course of action or if "the defendant knew or had reason to know that the recipient of the representation attache[d] importance to the specific matter" in determining a course of action

CIVIL CASE RESOLUTIONS

- FCA carries potentially enormous damages and penalties
  - Damages are always subject to a multiplier (statute allows for up to three times damages)
  - <u>Each</u> false claim is subject to additional penalty – penalties are now $10,957 to $21,916
- Settlement Often Preferred
  - Mandatory and Permissive Exclusion from Federal Healthcare Programs (Medicare, Medicaid, Tricare)
  - Case becomes unsealed and publicity can impact business

SETTLEMENT TRENDS

- Few "huge dollar" settlements
  - AmeriSource Bergen ($625M, FDA repackaging)
  - Health Management Associates ($260M, billing and AKS)
  - HealthCare Partners ($270M, Medicare Advantage data)
- Increase in volume of settlements with physicians and physician practices
  - Kool Smiles ($23.9M, dental services, medical necessity)
- Numerous hospice and LTC settlements
  - Signature HealthCARE ($30M, unnecessary rehab services)
- Hospital and Health System Settlements
  - William Beaumont ($84.5M, non-FMV leases & provider based CT)

CRIMINAL ENFORCEMENT

- Federal statutes commonly used to combat healthcare fraud:
  - 18 U.S.C. § 1347 – Health Care Fraud
  - 18 U.S.C. § 1035 - False Statements Relating to Healthcare matters
  - 18 U.S.C. § 1031 – Major Fraud against the United States
  - 42 U.S.C. § 1320a-7b(b)(2)(A) and (B) – Anti-Kickback Statute (AKS)

WHAT MAKES A CASE CRIMINAL?

- Difference between civil liability and criminal liability depends entirely on the circumstances
- Often a question of intent
  - Civil liability may arise regardless of knowledge or fault – reckless disregard is sufficient
  - Criminal cases often arise where the apparent wrongdoing could only have been carried out with knowledge that their actions were illegal
  - Criminal cases also arise where there are allegations of patient harm

DOJ CRIMINAL DIVISION ROLE IN QUI TAM PROCESS

- September 2014 - Formal adoption of a new policy under which Civil Division must share **all** *qui tam* complaints with the Criminal Division as soon as the cases are filed
- Result has been an increase in parallel proceedings
- Government benefits of parallel proceedings
  - Sharing expertise, resources, and evidence
  - Comprehensive remedies
  - Efficiencies in investigation and resolution
- Government risks of parallel proceedings
  - Different disclosure obligations for the Government
  - Grand jury information cannot be shared with Civil Division

DOJ CRIMINAL DIVISION ROLE IN QUI TAM PROCESS

- September 2015 - Memorandum Re: Individual Accountability for Corporate Wrongdoing (“Yates Memo”)
  - Announced formal policy of combating corporate crime by targeting and seeking accountability from the individuals involved in the wrongdoing
  - Reiterated and formalized mandatory coordination among civil and criminal divisions in cases of corporate malfeasance
  - Applies to both Criminal and Civil investigations
  - Outlined 6 “key steps” for federal prosecutors to follow in order “to most effectively pursue the individuals responsible for corporate wrongs”

CHANGES TO YATES MEMO

- Rod Rosenstein remarks on cooperation credit (Nov. 2018) during International Conference on the FCPA
- Still a focus on pursuing individuals involved in corporate fraud
- "Investigations should not be delayed merely to collect information about individuals whose involvement was not substantial, and who are not likely to be prosecuted"
- To qualify for cooperation credit in criminal cases companies need to identify individuals who were substantially involved in wrongdoing

CHANGES TO YATES MEMO

- In the civil context, companies no longer have to "admit the civil liability of every individual employee" to qualify for cooperation credit
- To qualify for *any* cooperation credit companies must identify all wrongdoing by senior officials, including members of senior management or the board of directors
- Cooperation credit no longer "all or nothing"
- Can now negotiate civil releases for individuals who do not warrant additional investigation in the corporate civil settlement
- Ability to pay may be considered

GRANSTON MEMO

- January 2018, Michael Granston, Director of Civil Frauds of DOJ issued memo
- Directs DOJ lawyers to consider dismissing meritless FCA whistleblower cases
- Factors to consider:
  - Meritless *qui tams*, parasitic or opportunistic *qui tams*, safeguarding classified information, addressing egregious procedural errors, interference with agency policies
- Memo is likely rooted in DOJ's desire to limit adverse rulings and to avoid expending resources on monitoring and responding to discovery requests in meritless cases

THE BRAND MEMO

- January 25, 2018, Associate Attorney General Rachel Brand issued the Brand Memorandum
- Specifically prohibits DOJ civil litigators from treating guidance documents from federal agencies as binding authority
- Previously DOJ used a company's non-compliance with these guidance documents as affirmative proof of non-compliance with underlying law
- Now non-compliance with guidance documents alone cannot support an FCA action

2019 ENFORCEMENT PRIORITIES

- Opioid Usage –Opioid Detection Unit
- Home Health
- Physician Compensation Arrangements
- Hospice
- Long Term Care
- Anesthesia Arrangements

KEY TAKEAWAYS

- Stakes have never been higher for FCA defendants given the greater prospect of parallel criminal and civil investigations
- Path to resolution of even the most seemingly unremarkable FCA cases are fraught with uncertainty
- Increased risk of criminal prosecution as a result of Main Justice's routine and systematic review of civil *qui tam* complaints not limited to corporate healthcare providers
- Healthcare providers and executives at greater risk of being personally and criminally accountable for alleged health care fraud

PREVENTATIVE MEASURES

- Companies should have robust compliance programs in place that are more than window-dressing
- Compliance programs should be designed to ensure compliance with regulations and other legal requirements
  - Without an underlying legal violation, there can be no implied certification claim
  - Without at least recklessness, there can be no viable FCA claim
- The Government increasingly uses absence of an effective compliance program to show recklessness

CLOSING THOUGHTS

- Fostering a corporate culture in which compliance is not a secondary concern, but a primary concern, may also aid in preventing the creation of whistleblowers; such an environment may encourage problems, if they arise, to stay in house and be resolved via a self-report or other less costly measures

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