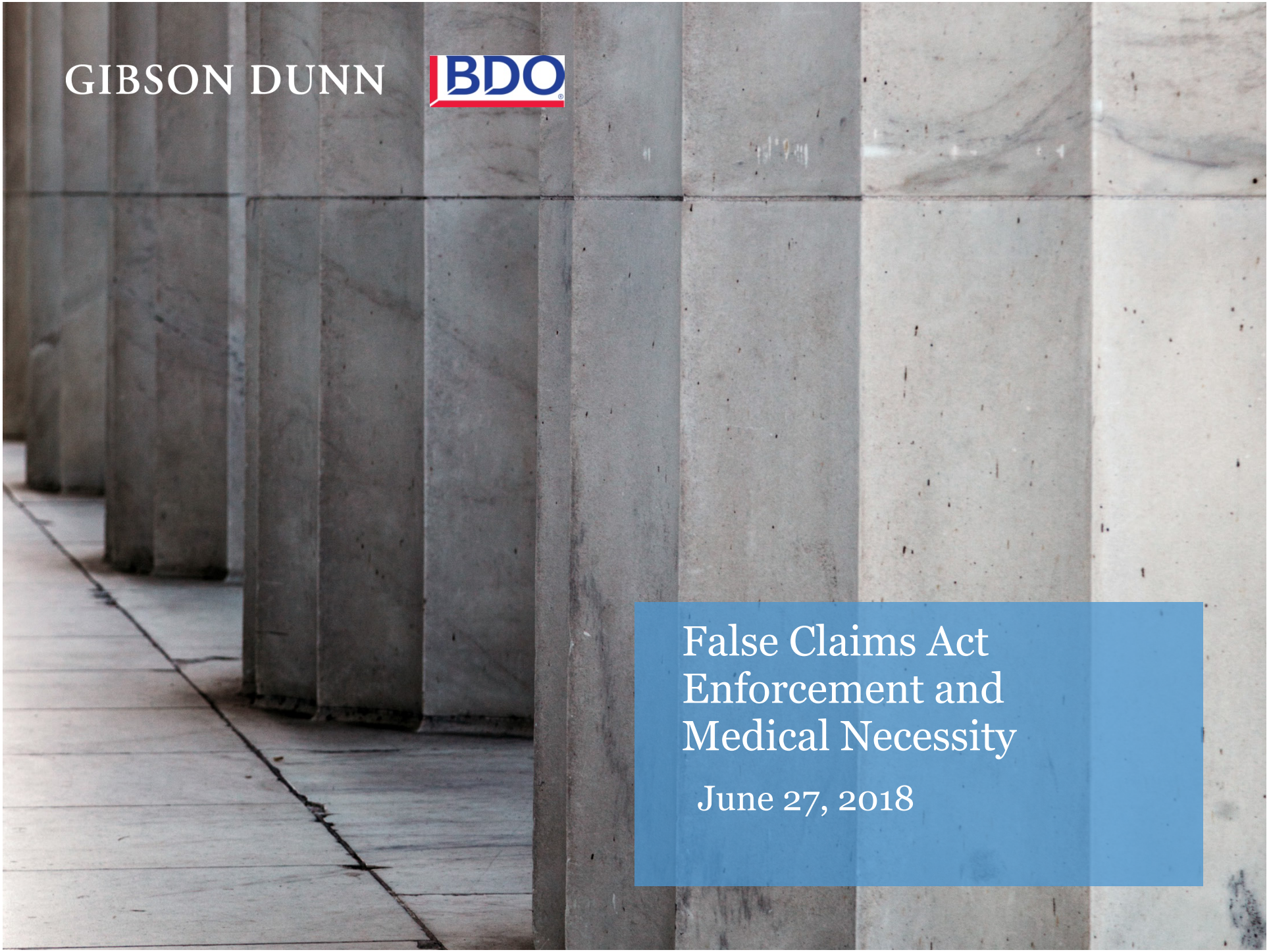
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False Claims Act Enforcement and Medical Necessity
June 27, 2018

MCLE Certificate Information

- Most participants should anticipate receiving their certificate of attendance in four weeks following the webcast.
- Virginia Bar Association members should anticipate receiving their certificate of attendance in six weeks following the webcast.
- All questions regarding MCLE Information should be directed to Jeanine McKeown (National Training Administrator) at 213–229-7140 or jmckeown@gibsondunn.com.

Agenda

1. **FCA and Medical Necessity Overview**
2. **Medical Necessity Enforcement Trends**
   A. Health Care Providers
   B. Drug & Medical Device Companies
3. **Recent Case Law Developments**
4. **Medical Necessity and The Brand Memo**
5. **An Expert's Perspective**
   A. Practical Lessons from Expert Chart Reviews
   B. Role and Evolution of Payor Reimbursement Policies
6. **Questions**

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FCA & Medical Necessity Overview

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The False Claims Act (FCA)

- The FCA, 31 U.S.C. §§ 3729-3733, is the federal government's **primary weapon to redress fraud**.
- The FCA provides for recovery of **civil penalties** and **treble damages.**
- The FCA requires “knowing" conduct, defined as (1) actual knowledge, (2) deliberate ignorance, or (3) reckless disregard.

31 U.S.C. § 3729(a)(1)	Statutory Prohibition	Summary
(A)	Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval	False/Fraudulent Claim
(B)	Knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim	False Record/Statement
(C)	Knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government	"Reverse" False Claim
(G)	Conspires to violate a liability provision of the FCA	Conspiracy

Overview of Key FCA Theories

Factual Falsity

- False billing (e.g., services not provided)
- Overbilling (e.g., upcoding)

Legal Falsity

- Express certification of compliance with legal requirements
- Submission of claim with representations rendered misleading as to goods / services provided

Promissory Fraud / Fraud in the Inducement

- Obtaining a contract through false statements or fraudulent conduct
- *U.S. ex rel. Marcus v. Hess*, 317 U.S. 537 (1943) (claims by contractors who colluded on bids)

Reverse False Claims

- Improper avoidance of obligation to pay money to the government
- Retention of government overpayment

Key Legal Theories

1. Improper Financial Relationships

- AKS / Stark Law
- Providing anything of value to induce referrals or other business

2. Billing / Coding / Coverage

- False billing (e.g., billing for services not provided)
- Overbilling (e.g., upcoding)

3. Medical Necessity

- Providing services that are not medically necessary
- Inflating volume or value of services provided (e.g., inpatient rather than outpatient care)

4. Quality of Care

- Providing substandard care (e.g., using unqualified personnel)
- Charging the government for "worthless" services

5. Overpayments

- Nexus of "reverse FCA" and the ACA 60-Day Rule

Medical Necessity

- In **Medicare**, concept of "medical necessity" is derived from statute.
  - "No payment may be made. . . for any expenses incurred for items or services, which . . . are not ***reasonable and necessary*** for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A) (Part A & Part B)
  - Similar definition for Part D

- In **Medicaid**, "medical necessity" is a federal and state law requirement.
  - For children, the Early and Periodic Screening, Diagnostic and Treatment Services ("EPSDT") provision of the Medicaid Act, 42 U.S.C. § 1396d(r), requires states to provide "***necessary*** health care."
  - Otherwise, "medical necessity is not explicitly denoted in the Medicaid Act, [but] it has become a judicially accepted component of the federal legislative scheme." *Moore ex rel. Moore v. Reese*, 637 F.3d 1220, 1232 (11th Cir. 2011) (internal citations omitted).
  - Every state has definition (or definitions) of medical necessity.

- Case law establishes that billing for medically unnecessary care would be a false claim, and a violation of the program rules.
  - CMS–1500 requires the billing entity to certify that, among other things, "the services on this form were medically necessary."

Medical Necessity

- **American Medical Association Definition**

  "Health care services or products that ***a prudent physician*** would provide to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is: (a) in accordance with ***generally accepted standards*** of medical practice; (b) ***clinically appropriate*** in terms of type, frequency, extent, site, and duration; and (c) not primarily for the economic benefit of the health plans and purchasers or for the convenience of the patient, treating physician, or other health care provider."

- **Medicare.gov "Glossary" Definition**

  "Health care services or supplies needed to diagnose or treat an illness, injury, condition, disease, or its symptoms and that meet ***accepted standards of medicine***."

Medical Necessity

- **Who Determines Medical Necessity?**
  - Treating physician
  - Reviewing physician (e.g., during chart reviews, prior authorizations)
- **What Sources Guide Medical Necessity Determinations?**
  - *Medicare Benefit Policy Manual*: defines Medicare-covered services and related requirements
  - *National and Local Coverage Determinations*: offer interpretations and guidance re: medical necessity
  - *State Regulations & Provider Manuals*: define state-based coverage and program guidelines

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FCA & Medical Necessity Enforcement Trends

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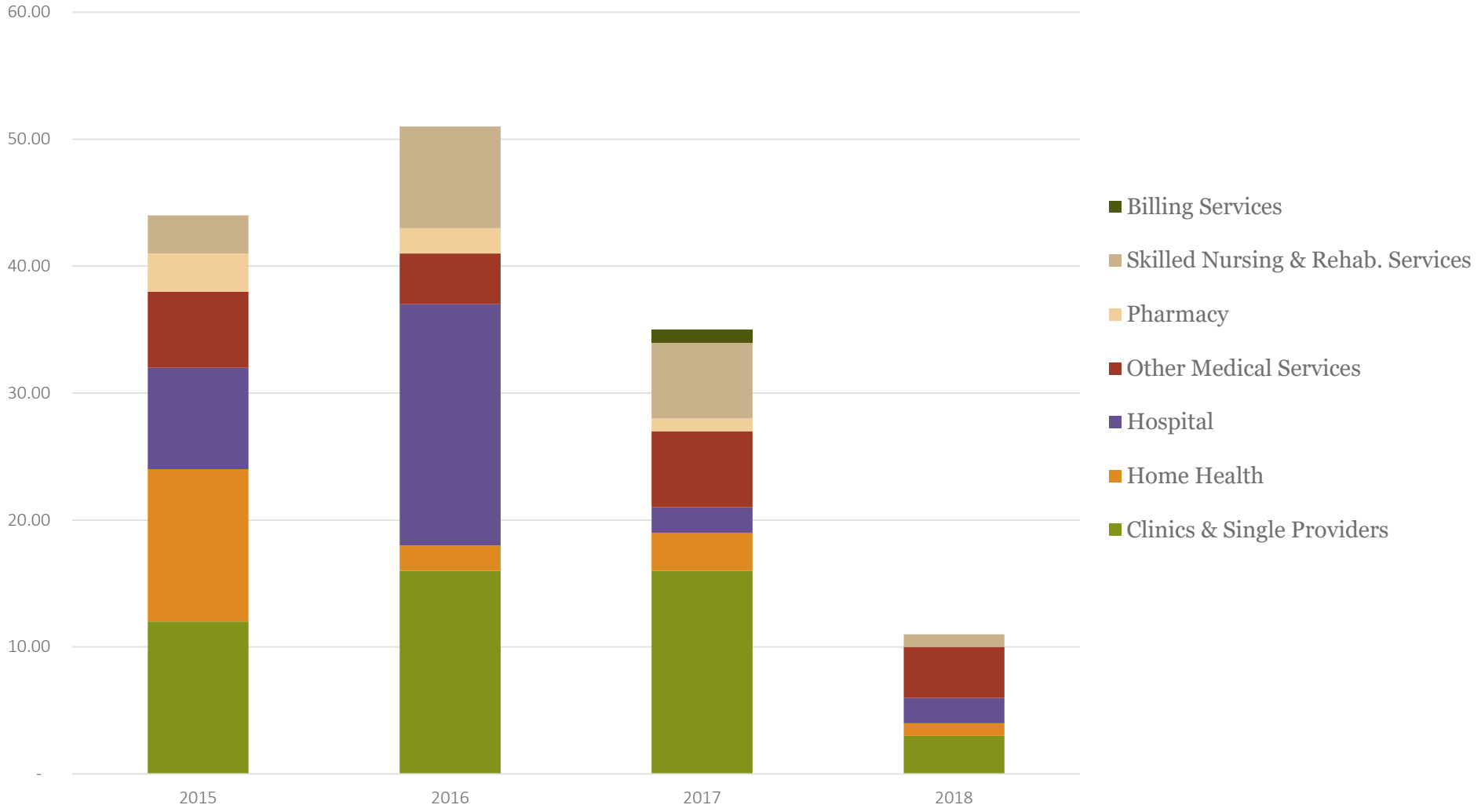
Medical Necessity Enforcement: Provider Type



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Provider Case Study: Millennium Health

Millennium Health

- In October 2015, Millennium Health paid **$256 million** to resolve allegations of false claims.

- The government alleged that the provider performed medically unnecessary urine drug and genetic tests, and violated the AKS and Stark Law by providing physicians free urine testing supplies in exchange for referrals; $19.2 million of the total went to resolve additional administrative actions by CMS regarding with billing practices.

- Millennium Health also entered into a 5-year Corporate Integrity Agreement with HHS-OIG.

Provider Case Study: 21st Century Oncology

21st Century Oncology

- In March 2016, 21st Century Oncology and subsidiary South Florida Radiation Oncology LLC agreed to pay **$34.7 million** to resolve allegations of false claims.
- The government alleged that the providers performed and billed for procedures that were not medically necessary. Among other claims, the government alleged that a certain procedure was performed and billed by physicians and physicists who were not properly trained to review and utilize the results.
- The suit was initially filed by qui tam relator Joseph Ting, a former physicist at South Florida Radiation Oncology.

Provider Case Study: Skilled Nursing

Genesis HealthCare Inc.

- In June 2017, skilled nursing facility operator Genesis HealthCare Inc. paid **$53.6 million** to settle 6 *qui tam* lawsuits and government investigations.

- Allegations involved a system-wide theory of medical necessity and upcoding issues, and included claims that the company and its subsidiaries submitted false claims for medically unnecessary hospice services, medically unnecessary therapy services, and care that was grossly substandard or essentially worthless.

- Press release noted that settlement was based on company's ability to pay.

Case Study: Skilled Nursing

Consulate Health Care

- In contrast, skilled nursing facility operator Consulate Health Care went to trial in a case declined by the government and wound up with a jury verdict nearly 6.5x the settlement in Genesis.
- The relator alleged that the defendant artificially increased the amount of care patients required, resulting in inflated reimbursements.
- The jury found the alleged misconduct resulted in $115 million in single damages. Pursuant to the statute, the final verdict was **$347 million**.
- In January, Consulate Health Care **prevailed on a motion to override the jury verdict** based on a lack of materiality under *Universal Health Servs. v. U.S. ex rel. Escobar*.

Case Study: Skilled Nursing

Signature HealthCARE, LLC

- This month, Signature, a Louisville, KY company that owns and operates 115 skilled nursing facilities, paid **more than $30 million** to resolve allegations that it submitted claims for rehab therapy that were not reasonable, necessary, or skilled.

- Among other allegations, the government claimed that Signature automatically placed patients in the level of therapy that received the most reimbursement, rather than evaluating each individually; aimed to provide only the minimum amount of therapy required to bill at a given level of reimbursement; and pressured providers and patients to complete therapy even if a patient was unable or unwilling to do so.

Case Study: Agape Senior Community, Inc.

Agape Senior Community, Inc.

- Relators alleged that defendants caused the submission of false claims for hospice care reimbursement by falsifying physician certifications that patients required such care.
- To prove their case, relators sought to use statistical sampling, but the District Court would not permit the method. The issue was certified for interlocutory appeal, but the appellate court declined to address the issue.
- Relators and defendants then sought to mediate, and reached a $2.5 million settlement; the government vetoed it.
- In August 2017, two years after DOJ vetoed its initial offer, Agape announced it would settle the case **for a mere $275,000.**

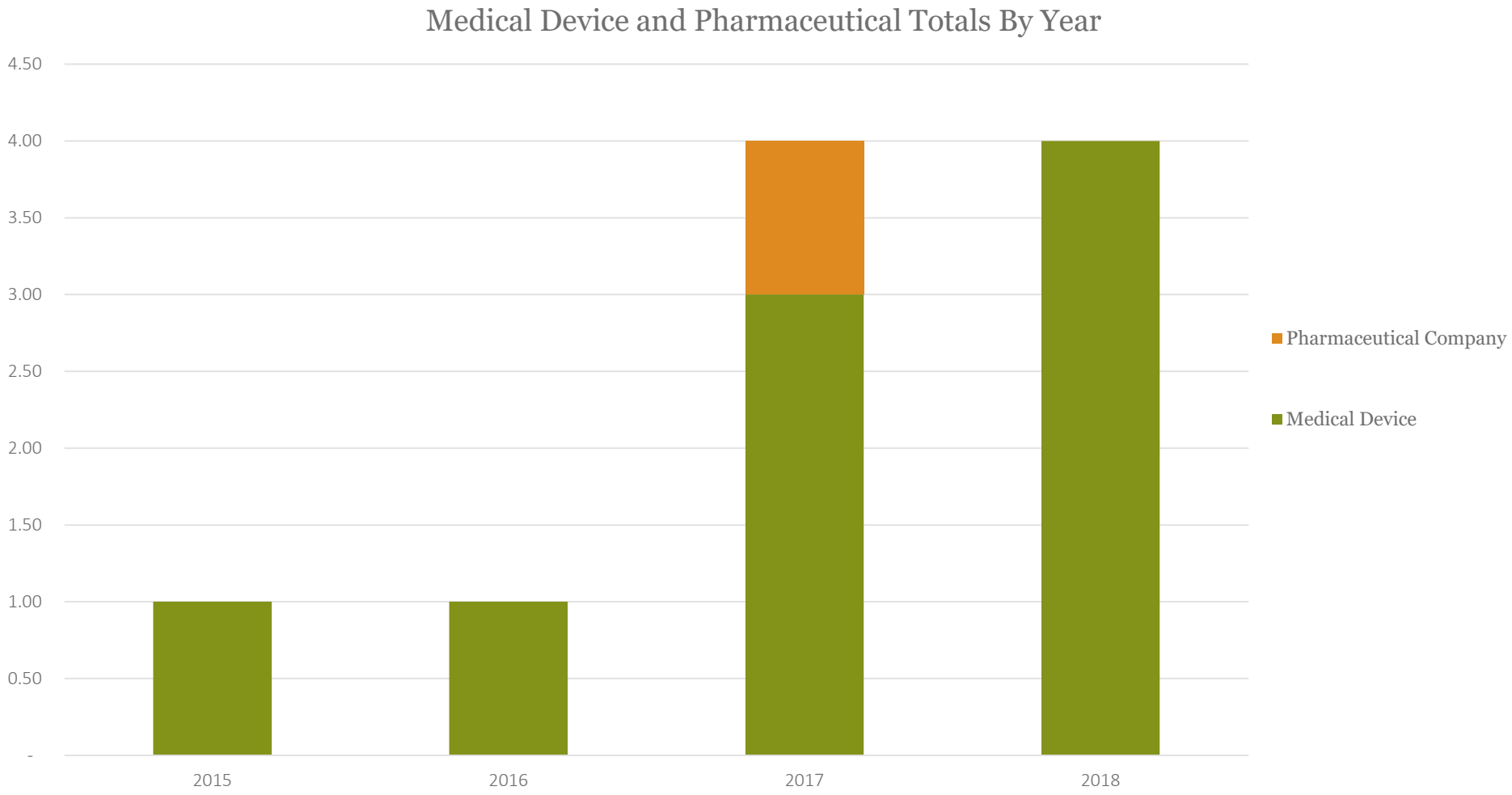
Medical Necessity: Drug & Device Companies

- Cases involving drug and device companies show DOJ's interest in medical necessity issues in the Anti-Kickback Statute ("AKS") and off-label promotion contexts.

- Even though manufacturers do not make medical necessity judgements FCA liability can exist where manufacturer **"causes"** a false claim, or false record or statement material to a false claim, by a physician or pharmacy. In some instances, companies may also be liable for sales direct to consumers of medically unnecessary products.

- DOJ is pursuing cases on the grounds that AKS violations and off-label promotion result in harm to the government through ***overutilization*** of products and services that are ***not medically necessary***.
  - According to government, off-label promotion can be akin to use of drugs for medically unnecessary purposes, notwithstanding physicians' judgment.
  - According to government, kickbacks can lead physicians to overutilize or overprescribe drugs and devices for medically unnecessary purposes.

Medical Necessity Enforcement: Drug & Device Companies



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Case Study: D.S. Medical L.L.C.

United States ex rel. Cairns v. D.S. Med., L.L.C.
2017 WL 1304947 (E.D. Mo. Apr. 7, 2017)

- Government alleged illegal kickback payments and, as proof, proffered evidence that devices and services provided by physicians were not medically necessary.
- Federal judge ruled that the government could support kickback claims with evidence regarding the medical necessity of the services and devices used by the physician.
- The government contended evidence would distinguish the physician's use of the devices in question from other physicians' use, and so help show the physician's state of mind regarding the financial implications of his use of the distributor's devices.
- Court recognized it was a "somewhat close question," but that the evidence was "probative of [the physician's] intent."

Case Study: Celgene

United States v. Celgene Corp.
226 F. Supp. 3d 1032, 1051 (C.D. Cal. 2016)

- The government accused Celgene of AKS violations and off-label promotion.
- The court explored how *Escobar*'s materiality standard might be applied to pharmaceutical companies accused of off-label promotion.
- Allegations of off-label promotion may be "material" for purposes of government payment because "***Medicare Part D may only reimburse covered part D drugs . . . used for a medically accepted indication***." (Internal quotations omitted.)
- Court found that this at least created a genuine issue of disputed fact over medical necessity of a prescription under Part D.

Case Study: Aegerion

Aegerion

- Government alleged that Aegerion engaged in misconduct in connection with promotion of its cholesterol drug, Juxtapid.
- Among other violations, DOJ alleged that Aegerion engaged in off-label promotion and AKS violations that resulted in alleged ***falsification of medical necessity statements*** and prior authorizations submitted to federal health care programs.
- As part of a global resolution of criminal and civil claims, Aegerion agreed to pay more than $40 million to settle these and related allegations.

Case Study: DJO Global

DJO Global Inc.

- Government alleged that a DJO subsidiary pushed medically unnecessary and excessive transcutaneous electrical nerve stimulation (TENS) electrodes .
- Sales representatives allegedly contacted TRICARE beneficiaries and induced them to order excessive TENS electrodes by acting as though the beneficiaries had indicated a need for them.
- DJO agreed to pay $7.62 million.

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Recent Case Law Developments

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Statistical Sampling

U.S. ex rel. Conroy v. Select Medical Corporation
No. 3:12-cv-00051 (S.D. Ind. Apr. 12, 2018)

- Relators sought to use statistical sampling to prove False Claims Act liability of Select Medical Corporation, a facility in Indiana, and a physician based on medically unnecessary admissions to long term care facilities and artificial increase of length of stay.
- The court rejected relator's attempt, instead ordering that discovery was limited to the Indiana facility.
- The court explained that the use of sampling "ignores what the plaintiffs would ultimately need to prove," and that "fraud will have to be proved on a claim-by-claim basis based on the patient's actual medical condition and actual medical care."
- DOJ challenged the court's ruling; the court has not yet responded.

Statistical Sampling (*cont'd*)

U.S. ex rel. Wollman v. The General Hospital Corporation
No. 1:15-cv-11890 (D. Mass. Mar. 30, 2018)

- Relator alleged that defendants committed fraud when they billed Medicare and Medicaid when a physician performed "overlapping" surgeries; relator provided significant detail regarding the occurrence of overlapping surgeries and then alleged statistical data to conclude that orthopedic surgeons performed the overlapping surgeries on Medicare patients in violation of the FCA.
- The court granted defendants' motion to dismiss without prejudice, determining that relator had failed to plead specific details regarding the actual submission of claims.
- The court declined to apply the pleading standard announced in *U.S. ex rel. Duxbury v. Ortho Biotech Products*, 579 F.3d 13 (1st Cir. 2009), which permits a relator to provide statistical evidence to strengthen an inference of fraud, because relator did not allege that defendants induced third parties to file false claims.

Case Study: AseraCare Inc.

AseraCare Inc.

- Government alleged that AseraCare submitted false claims to Medicare for hospice services for ineligible beneficiaries.
- In March 2016, the Northern District of Alabama granted summary judgment for AseraCare because the government **failed to show evidence of objective falsity.**
- The District Court ruled that without allegations that the physicians relied upon false information, or that clinicians failed to disclose important information to them, the government's case rested on a **"contradiction based on clinical judgment or opinion [which] alone cannot constitute falsity under the FCA as a matter of law."** *U.S. ex rel. Paradies v. AseraCare, Inc.*, 2016 WL 1270521 (N.D. Ala. Mar. 31, 2016).
- The government has appealed this case to the 11th Circuit; no decision has yet been issued.

Objective Falsity

Other courts have similarly declined to find objective falsity where care and services were provided according to provider's clinical judgment. *See, e.g.*:

- *U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, 2016 WL 3449833 (N.D. Tex. June 20, 2016) (finding difference of subjective medical opinion insufficient to create a fact issue as to falsity)
- *U.S. ex rel. Polukoff v. St. Marks Hospital*, No. 2:16-cv-00304 (D. Utah Jan. 19, 2017) (finding that representations to the government based on a physician's determination that a procedure was "medically reasonable and necessary" could not be proven objectively false)

Objective Falsity (*cont'd*)

- *United States v. Paulus*, 2017 WL 908409 (E.D. Ky. Mar. 7, 2017) (declining to find objective falsity where disagreements in expert testimony demonstrated that the degree of the diagnosis made by defendant physician was not an "objectively verifiable fact")
- *U.S. ex rel. Dooley v. Metic Transplantation Lab*, No. CV 13-07039 (C.D. Cal. June 27, 2017) (holding that defendants could only be found to have submitted objectively false claims if they, in their medical opinion, knew that their selection of the tests at issue was not medically necessary)
- *U.S. ex rel. Winters v. Gardens Regional Hospital and Medical Center*, No. CV 14-08850 (C.D. Cal Dec. 29, 2017) (granting motion to dismiss, in part based on finding that questions of medical judgment regarding the appropriateness of hospital admissions could not provide the basis for a false claim)

Objective Falsity (*cont'd*)

But some courts have allowed cases to proceed past motions to dismiss where alleged false claims seem to be predicated on clinical judgments:

- *U.S. ex rel. Groat v. Boston Heart Diag. Corp.*, 2017 WL 2533341 (D.D.C. June 9, 2017) (denying motion to dismiss because the Court could not determine, without weighing the evidence, whether relator's allegations regarding medical necessity stem from a mere difference of clinical judgment)
- *U.S. ex rel. Hinkle v. Caris Healthcare, L.P.*, 2017 WL 3670652 (E.D. Tenn. May 30, 2017) (denying motion to dismiss where government sufficiently alleged that the relevant physicians could not have legitimately exercised their clinical judgment because they relied on false information from defendants)

The Brand Memo

- 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.

- January 25, 2018 DOJ internal memorandum 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 (ACE cases), and
  - (2) using "its enforcement authority to effectively convert agency guidance documents into binding rules."

Former Associate Attorney General Rachel Brand

The Brand Memo (*cont'd*)

- Medical necessity cases, in particular, often involve reliance on non-binding guidance and recommendations (e.g., Medical Benefit Policy Manual and national and local coverage determinations).

- DOJ may now be more limited in its ability to wield such guidance affirmatively.

- Guidance may still be relevant for other reasons:

  - DOJ "may continue to use agency guidance documents ***for proper purposes***":
    - where a guidance document "simply explain[s] or paraphrase[s] legal mandates from existing statutes or regulations"; or
    - as "evidence that a party read such a guidance document to help prove that the party had requisite knowledge of the mandate."

  - Nothing in the Brand memorandum suggests that the government will be able to use this policy decision to limit a defendant's use of guidance documents ***to defend*** itself.

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An Expert's Perspective

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Practical Lessons from Expert Chart Reviews

- The government's position in medical necessity reviews highlights the importance of documentation
  - Auditors take the position that if the care wasn't documented, it is as though it wasn't done, and providers may not bill for it
  - The government may also take the position that even if the care is documented, if the language does not provide explanation for why the care is reasonable and necessary, it could be a false claim.
  - Furthermore, notes and orders must have a legible and dated signature.
- EMRs help improve consistency, but are only part of the solution
  - Providers should consider how to make documentation best reflect the individualized care being provided
    - Auditors may be skeptical of notes that are copied or lacking specificity

Practical Lessons from Expert Chart Reviews

- Key practical points for physicians to consider:
  - Emphasize the importance of high quality documentation as evidence of the good care they are providing
  - Training about the process and necessary components of good clinical documentation.
  - Use the lens of an educated lay person to calibrate documentation
  - Physicians have an important role to play in disputes with CMS and other payers
    - May help compile and summarize the information needed to show medical necessity of the services to payers

Role and Evolution of Payor Reimbursement Policies

- Payor policies are designed to influence patient and physician behaviors, and thus they can change as payor goals and standards of practice change
  - Changing policies and standards of practice highlight the importance of good clinical documentation

- Example: Emergency Departments
  - Recent announcement by several major payors in several markets of their intention to deny care provided in an emergency department for a diagnosis that was not truly emergent.
  - Previously the Prudent Layperson Standard generally applied in emergency department care.
  - Now even if the patient had justification for thinking he or she had an emergency, reimbursement may be denied if the ultimate diagnosis was one that was not emergent.
  - Thus, the ED physician must now not only clearly document why the care was medically necessary but why it was medically necessary in an emergency department at that time.

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Questions?

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Karen Meador

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Sam Nazzaro

Sam Nazzaro is Global Forensics Managing Director of BDO. As top-level compliance counsel, former federal prosecutor and forensic advisor, Sam has more than 20 years of experience in regulatory and legal compliance, domestic and international advocacy, complex forensic investigations, and litigation. He assists global companies, healthcare providers and others in investigating fraud and corruption and managing/mitigating risk. He has successfully investigated, managed and led healthcare fraud/false claims matters, complex AML investigations and sensitive high-profile international governance projects.

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