NAVIGATING THE RESEARCH FRAUD AND ABUSE AND BILLING RULES

Emily Cook, Partner

Tony Maida, Partner

Health Care Compliance Association, Research Compliance Conference 2022

mwe.com

McDermott Will & Emery

1

AGENDA

- Fraud and Abuse Landscape and Enforcement Examples
- Medicare Billing Rules and Clinical Trials
- F&A Compliance for Researcher and Patient Financial Relationships
- Strategies for Identifying and Addressing Potential Non-Compliance

2

FRAUD AND ABUSE LANDSCAPE AND ENFORCEMENT EXAMPLES

3

EXAMPLES OF CLINICAL RESEARCH FRAUD

- Fabricated research findings
  - Especially if that data is used to support additional grant funding
- Inadequate disclosure or management of conflicts of interest
- Misrepresentations in IRB approval
- Failure to obtain informed consent or providing incomplete/misleading informed consent materials
- False information on the grant application
- Federal health care program billing errors
- Improper inducements or kickbacks by study sponsors
- Inappropriate use of grant funding for a non-grant approved purpose

4

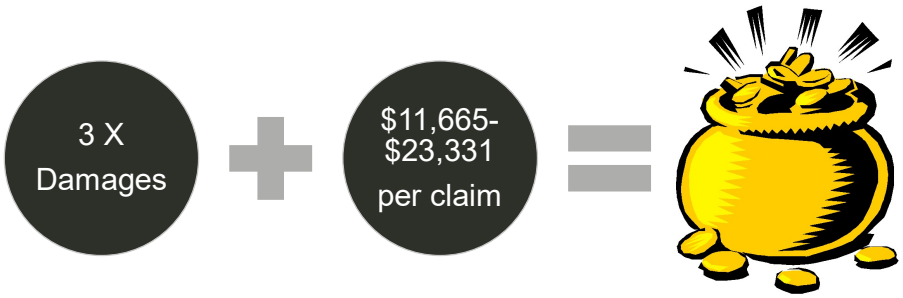
5

HOW THE LAWS ARE ENFORCED: FALSE CLAIMS ACT

- Prohibits **knowingly** presenting, or **causing** to be presented, a claim to the U.S. Government that is **false** or **fraudulent**
  - Claims = requests for payment from any federal program, such as grant or Medicare
- **Knowledge**
  - Actual knowledge
  - Reckless disregard
  - Deliberate ignorance
- **False or Fraudulent**
  - Tainted by non-compliance with another law
  - Not medically necessary
  - Billed item or service billed is not the same as item or service provided

6

FALSE CLAIMS ACT: PENALTIES



7

FALSE CLAIMS ACT ENFORCERS
QUI TAM "RELATORS" AND THE GOVERNMENT

- *Qui tam* actions are brought by private citizen ***whistleblowers*** on behalf of the U.S. government
  - Referred to as "Relators"
  - Frequently former employees/executives, competitors
- Relator "Bounty" = 15 - 30% of the government's recovery
  - FCA provides for the defendant to pay the relator's attorneys' fees if settlement or judgment
- The vast majority of FCA cases are filed by relators
  - Government has an obligation to investigate each case
  - Given the number of relator actions, few resources are left for DOJ to investigate its own affirmative cases

8

THE FBI FEDERAL BUREAU OF INVESTIGATION

CONTACT US | ABOUT US | MOST WANTED | NEWS | STATS

Atlanta Division

Home - Atlanta - Press Releases - 2013 - Emory University to Pay $1.5 Million to Settle False Claims Act Investigation

Twitter (3) Facebook (10) Share

Emory University to Pay $1.5 Million to Settle False Claims Act Investigation

University Overbilled Medicare and Medicaid for Patients Enrolled in Clinical Trial Research at Emory's Winship Cancer Institute

U.S. Attorney's Office — **Northern District of Georgia**
August 28, 2013 — (404) 581-6000

ATLANTA—The United States Attorney's Office for the Northern District of Georgia and Attorney General Sam Olens announced today they have reached a settlement with Emory University, which agreed to pay $1.5 million to settle claims that it violated the False Claims Act by billing Medicare and Medicaid for clinical trial services that were not permitted by the Medicare and Medicaid rules.

Providers generally are not permitted to bill Medicare for medical care and services for which the clinical trial sponsor has agreed to pay. Here, the United States and the state of Georgia alleged that Emory University billed Medicare and Medicaid for services the clinical trial sponsor agreed to pay (and, in some cases, actually did pay, thereby resulting in Emory's being paid twice for the same service).

"This settlement demonstrates our office's continued commitment to protect crucial Medicare and Medicaid dollars," said United States Attorney Sally Quillian Yates. "Treatment of cancer is expensive, and Medicare and Medicaid dollars should be reserved for patients who need services that properly may be billed to these programs."

"Our investigation of Emory University revealed the institution's clinical trial false billing and led to today's settlement," said Derrick L. Jackson, Special Agent in Charge of the U.S. Department of Health

9

GRANT FCA SETTLEMENT EXAMPLES

- A private, non-profit university and its health system paid $112.5 M to resolve allegations that it submitted falsified or fabricated results from research conducted by the university health system's laboratory and funded by federal grants from the NIH and EPA over 12 years.
- Biomedical research institution paid $10M to resolve allegations that it used federal grant money for purposes unrelated to its grants by (1) charging projects funded by NIH for time spent on preparing and writing new grant applications, teaching, and engaging in administrative activities; and (2) failing to have a system in place to track the time faculty spent on activities unrelated to NIH-funded research.
- State university paid $801,757 to resolve allegations that its engineering professor who was the principal investigator on the grant proposal falsified documentation provided to the National Science Foundation associated with a grant that the university received.
- A former cancer research physician paid $475,000 to resolve allegations that he submitted false claims under NIH research grants for reimbursement for expenses that benefited the physician, his family and his friends, such as food, hotel and travel fees.
- A principal investigator paid $215,000 to resolve allegations that he submitted false statements on a NIH grant application by signing an assurance certifying that the information submitted with the application was complete, accurate, and truthful despite knowingly including inauthentic data, altering experiment descriptions, falsifying the results of experiments, and mislabeling experiment results.

10

ANTI-KICKBACK STATUTE SETTLEMENT EXAMPLES

- Device manufacturer paid $312M criminal and $310M civil payments to resolve allegations that it paid kickbacks to physicians in form of research grants, free equipment, lavish meals and entertainment.
- Drug manufacturer paid $2.8B to resolve allegations that the company paid kickbacks to prescribers in the form of speaker programs, advisory board memberships, research programs, and honoraria to induce and reward prescriptions.
- Orthopedic device manufacturer paid $16M to resolve allegations that it paid remuneration to an orthopedic surgeon in the form of royalty payments to induce the physician's use and recommendation of the company's products.
- Spinal medical device manufacturer paid $30M to resolve allegations that it kickbacks to spinal surgeons, including sham consulting agreements, sham royalty arrangements, sham research grants, and travel and entertainment, to induce doctors to use its products.
- Device manufacturer paid $48.3M to resolve allegations that it artificially inflated the costs of the brachytherapy seeds used to treat Medicare patients, and used some of the profits to pay for kickbacks that included offers of unrestricted "grant" money, rebates, marketing assistance, conference fee payments, and free medical equipment.

11

HOW THE LAWS ARE ENFORCED: FEDERAL SUNSHINE ACT

- **Overall goal:**
  - To increase transparency in financial relationships between manufacturers and providers, even when the relationships are ones that are permitted by law and consistent with industry ethical codes for healthcare professionals
- **Secondary, indirect goals:**
  - Control health care spending, enhance integrity, and protect patients

12

FEDERAL SUNSHINE LAW: WHO MUST REPORT?

- Applicable Manufacturers:
  - An entity that is operating in the United States, and is:
    1. ***Engaged*** in the production, preparation, propagation, compounding or conversion of a covered drug, device, biological or medical supply, or
    2. An entity under ***common ownership*** with a manufacturer that ***provides assistance or support*** in production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution
- The manufacturer must be engaged in such activities with respect to a **"covered" product**.
  - Generally, a product is **"covered"** if:
    - Payment for it is available under Medicare, Medicaid, or Children's Health Insurance Program ("CHIP") and:
    - It is either a prescription drug or biologic, or a device (including medical supplies) requiring **premarket approval** or **premarket notification**

13

FEDERAL SUNSHINE LAW: WHAT TRANSFERS/INTERESTS COUNT?

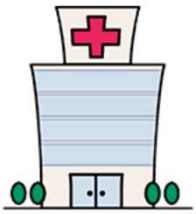
- A Payment or Other Transfer of Value = ***anything with a discernible economic value on the open market in the U.S.***
  - As a general rule, **the payment need not be related to a covered product** (e.g., a charitable donation in the Covered Recipient's name)
- With certain exceptions, Applicable Manufacturers **must report all** Payments or Other Transfers of Value made:
  - → to a Covered Recipient; or
  - → to a Third Party at the request of, or designated by the manufacturer on behalf of, a Covered Recipient
- Must report **direct** AND **known indirect** payments and transfers
- **Takeaway**: You may have obligations to collect information on HCP payments to enable the pharma company to report to Sunshine

14

FEDERAL SUNSHINE LAW: WHO ARE COVERED RECIPIENTS?

(1) Physicians

(2) Teaching Hospitals



CMS annually publishes a list of Teaching Hospitals on which Applicable Manufacturers may rely for the entire reporting year.

(3) Non-Physician Practitioner Covered Recipients

Tip: Beginning 2021, Applicable Manufacturers must collect data about certain additional provider types. This information must be submitted to CMS during the reporting process in 2022.

15

FEDERAL SUNSHINE LAW: A NOTE ON STATE LAWS

- The federal Sunshine Law does not pre-empt state disclosure laws to the extent they require the reporting of information not required to be reported under the federal Sunshine law
  - States such as Vermont, Massachusetts, and California have certain Sunshine or gift ban laws not preempted by the federal Sunshine law

16

MEDICARE BILLING RULES AND CLINICAL TRIALS

17

THIRD-PARTY PAYOR COVERAGE

Medicare

- "Routine costs" in qualifying clinical and device trials
- SSA § 1862(a)(1)(E), (m); Medicare NCD 310.1; Medicare Benefits Manual, Ch. 14; MLN SE0822; Medicare Administrative Contractor (MAC) website

Medicaid

- New law effective January 1, 2022
- Routine costs in qualifying clinical trials
- States must submit State Plan Amendments to implement coverage
- https://www.medicaid.gov/federal-policy-guidance/downloads/smd21005.pdf

18

THIRD-PARTY PAYOR COVERAGE

Private Payors

- Many (but not all) plans subject to state and federal requirements to cover certain costs
  - 42 U.S.C. § 300gg-8 ("Routine patient costs" for individuals participating in approved clinical trial for cancer or other life-threatening disease or condition)
- Federal requirement does not apply to plans issued before March 23, 2010
- State law may expand requirements beyond federal law

19

MEDICARE COVERAGE CLINICAL TRIALS (NCD 310.1)

Automatically Qualified ("Deemed")

- Funded by NIH, CDC, AHRQ, CMS, DOD, and VA
- Supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD, and VA
- Conducted under an investigational new drug application (IND) reviewed by the FDA
- Drug trials that are exempt from having an IND

20

MEDICARE COVERAGE DEVICE STUDIES (21 C.F.R. PART 812)

Category A IDE	Category B IDE

• Routine costs covered if MAC determines the device is used in a trial for the diagnosis, monitoring or treatment of an immediately life-threatening disease or condition	• Routine costs and device covered subject to MAC approval on a case-by-case basis
	  • FDA-approved clinical trial
	  • Device assigned to Category B as described by FDA regulations
	  • Device medically necessary for patient for whom coverage is sought

21

ROUTINE COSTS

Included Items and Services

- Available to patient if he/she were not participating in a clinical trial
- Required for the provision of the investigational item or service
- Required for clinical monitoring of investigational item or service
- Needed for diagnosis or reasonable and necessary care of complications arising from investigational item or service

Excluded Items and Services

- Investigational item or service (unless otherwise covered)
- Provided solely for data collection and analysis
- Provided free of charge by the research sponsor

22

MEDICARE BILLING RULES - GENERAL

Clinical trial number must be reported on claim

- Trial name, sponsor and sponsor-assigned protocol number must be recorded in medical record, but not required on claim

Clinical trial and non-clinical trial services must be reported on separate lines

Items/services not covered because they are provided free of charge do not need to be reported on the bill

- If non-covered item/service must be reported in order for a related covered service to be paid, the non-covered item/service must be reported as non-covered/no cost

23

MEDICARE BILLING RULES - CODING OVERVIEW

Practitioners/Suppliers	Institutional Providers

• Q1 modifier for routine services
• V70.7 diagnosis code
	• Inpatient
	  • V70.7 diagnosis code
	  • Condition code 30
	• Outpatient
	  • Q1 modifier for routine services
	  • Q0 modifier for investigational item/service
	  • V70.7 diagnosis code
	  • Condition code 30

24

MEDICARE BILLING RULES - INVESTIGATIONAL DEVICES

Must notify MAC before billing for items/services related to an IDE trial

Category A	Category B

• Practitioner
  • Routine costs- same as clinical trial
  • Category A device- Bill with Q0 modifier and IDE number
• Institutional- Bill only routine costs using clinical trial guidance (do not report the Category A device)
	• Practitioner
	  • Routine costs- same as clinical trial
	  • Category B device- Q0 modifier, IDE number
	• Institutional
	  • Routine costs- same as clinical trial
	  • Category B device
	  • Inpatient- Revenue Code 0624
	  • Outpatient- Revenue Code 0624, HCPCS code (if applicable), Q0/Q1 modifier, IDE number

25

BILLING CHALLENGES

- Identifying covered items/services
- Applying Medicare secondary payor rules to items/services related to complications of the study item/service
- Appropriate billing of Medicare Advantage claims

26

IDENTIFYING COVERED ITEMS/SERVICES

- Identification of items/services to be furnished in the study
- Analysis of payor coverage for the items/services
- Negotiation with sponsor to allocate funds to non-covered items/services
- Development of clear and consistent clinical trial agreement, budget and informed consent documents
- Clear and detailed budgets

27

MEDICARE SECONDARY PAYOR AND MEDICARE ADVANTAGE

Medicare Secondary Payor

- Medicare will cover costs associated with care for study complications to the extent no other payor is obligated to cover the costs
- If the sponsor or institution agrees to cover the cost of complications if no other payor will, Medicare guidance indicates that Medicare views this as primary coverage and Medicare Secondary Payor rules (including sponsor reporting) apply

Medicare Advantage

- Routine costs for non-IDE trials billed to MAC
  - Except for Coverage with Evidence Development ("CED") trials, which are billed to Medicare Advantage
- Must split outpatient claim if provide study services and non-study services on same date of service
- Provider bills patient for the traditional Medicare cost-sharing amount.
- Medicare Advantage plan is responsible for refunding the patient the difference between Traditional Medicare cost-sharing amount and Medicare Advantage plan's in-network cost sharing
  - Patient must notify Medicare Advantage plan and provide documentation of incurred cost-sharing

28

KEY POINTS TO REMEMBER

- If a sponsor agrees to pay for routine items/services, the sponsor-covered items/services cannot be billed to Medicare
- If the institution promises an item/service to a participant at no cost, the institution-covered items/services cannot be billed to Medicare
- But, institution can apply its existing charity care/uninsured discount policies to research-related charges
- Documentation should be clear and consistent
  - Must support billing decisions

29

IMPORTANCE OF PROPER BILLING

- Items/services billed in error and paid by government payors are overpayments
- Overpayments are subject to refund
- Retained overpayments are subject to False Claims Act penalties
- Improper billing to private payors can have contractual consequences
- Review and identification of improper billing can be time consuming and expensive

30

F&A COMPLIANCE FOR RESEARCHER AND PATIENT FINANCIAL RELATIONSHIPS

31

ANTI-KICKBACK STATUTE ("AKS")

- The AKS prohibits knowingly and willfully:
  - Offering, paying, soliciting, or receiving
  - Anything of value ("remuneration") (direct or indirect, in cash or in kind)
  - In return for or to induce 1) referrals; 2) purchasing, leasing, ordering; or 3) arranging for or recommending purchasing, leasing, or ordering
  - Items or services paid for, in whole or in part, by a federal health care program
- "One purpose" test: if any one purpose is improper, other legitimate purposes may not carry the day

Bottom Line: **No payments to induce referrals or orders of items and services**

32

WHAT DOES "ARRANGE FOR OR RECOMMEND" MEAN?

- Government says marketing activities meet "arrange for or recommend"
- Marketing Analysis Factors:
  - The identity of the party engaged in the marketing or promotional activity and the marketer's relationship to the prospective customer
  - The nature of the marketing or promotional activity
  - The nature of the item or service being promoted or marketed
  - The target audience
  - The compensation methodology to the marketer/promoter
  - Disclosure

33

AKS: ENFORCEMENT PENALTIES

AKS enforcement exists in three forms	
Criminal	AKS is a criminal statute • Felony subject to up to $100,000 fine and ten years in prison
Civil	Civil prosecution under FCA: • Up to 3 times damages and $23,331 penalty per claim • Settlements typically range 2-3 times damages • CIA with OIG
Administrative	• Civil money penalties of up to 3 times amount of kickback and $100,000 per kickback • Exclusion from participation in Federal health care programs ("FHCP")

34

AKS "SAFE HARBORS"

- Regulations that protect certain arrangements even if intent is to induce referrals
- Must meet all elements
- Voluntary
- Narrowly drafted on purpose

AKS: EXAMPLES OF SAFE HARBORS

- Safe harbors generally correspond to common types of business arrangements, such as:
  - Investment interests
  - Equipment rental
  - **Personal services and management contracts**
  - Discounts
  - Employment compensation
- Failure to fit within a safe harbor does not mean an arrangement violates the AKS
- Facts and circumstances must be considered to determine the level of risk posed by the arrangement

AKS ANALYTICAL FRAMEWORK: PURPOSE OF AKS IS TO PREVENT FOUR PROBLEMS

37

AKS: FINANCIAL RELATIONSHIPS WITH PHYSICIANS

- Prominent area of government scrutiny because of physicians' "gate-keeper" role in delivering healthcare that produces Medicare costs
- However, physician expertise is often legitimately needed
- Compliance Planning:
  - The arrangement has a **legitimate business purpose**
  - Payments are **consistent with fair market value** for services actually provided

38

BENEFICIARY INDUCEMENT STATUTE

- Administrative penalties for providing certain types of remuneration to a Medicare or Medicaid beneficiary (patients)
- Law does not directly apply to manufacturers, but does apply to providers such as physicians or health care providers
  - Creates compliance issues in structuring patient incentive and engagement programs
  - Several new exceptions were created in 2017 for promoting access to care
    - Still requires careful factual analysis to fit within exception
- Remuneration implicating the Beneficiary Inducement Law could potentially be pursued under the AKS

39

HOW DO THESE LAWS APPLY?

- Examples:
  - Consultants / speakers' bureau
  - Research grants or payments for collecting data
  - Samples
  - Medical education sessions
  - Gifts / entertainment / meals
  - Product discounts and rebates / other price concessions
  - Sales and marketing
  - Clinical decision support tools
  - Patient engagement activities (such as refill reminders)

40

RISK AREA: COMPENSATION

- PI compensation
  - Study specific compensation → ensure FMV
  - Royalties
    - Ensure that the physician makes a novel, significant, or innovative contribution to the development of a product, technology, process, or method, subject to intellectual property protections
    - No requirement to purchase/order/recommend products
    - Carve out PI and PI groups purchases of product or technology
  - Research grants → ensure for appropriate, bona fide research
- Patient compensation for participating in research
  - Ensure approved by IRB and reasonable

41

RISK AREA: SEEDING STUDIES

- The government has investigated pharmaceutical companies for allegedly creating research studies that were primarily intended to market or "seed" the companies' products with physicians
- Factors indicating suspect research studies:
  - Lack of well-defined objectives and other research design deficiencies
  - The study data/results are not used by/useful to the manufacturer for a legitimate scientific purpose
  - Broad physician eligibility
  - Study conceived of and run by the marketing department
  - Disproportionately high investigator fees
  - Suspect investigator recruitment (thought-leaders vs. high prescribers)
  - New product in a crowded marketplace
  - Post-market studies

42

STRATEGIES FOR IDENTIFYING AND ADDRESSING POTENTIAL NON-COMPLIANCE

43

RIDING THE “WAVE” TO COMPLIANCE

44

COMPLIANCE PROGRAMS OVERVIEW

- The U.S. Department of Health and Human Services ("HHS"), Office of Inspector General ("OIG") provides voluntary Compliance Program guidance; this is publically available.
- 7 Key Elements of the a Compliance Program

1. Implementing written policies, procedures, and standards of conduct;
2. Designating a Compliance Officer;
3. Conducting appropriate employee training and education regarding policies, procedures, and practices;
4. Developing effective lines of communication regarding compliance matters;
5. Enforcing policies, procedures, and standards pursuant to published guidelines;
6. Conducting internal monitoring and auditing; and
7. Responding promptly to detected compliance problems & implementing corrective action for detected problems.

- Activities include creating an anonymous hotline to report compliance concerns and screening employees for exclusion from federal health care programs
- A Compliance Program can include fraud and abuse, data privacy & security, FDA, quality management, etc. and should be tailored to the size and risk profile of the company

45

COMPLIANCE POLICY HIGHLIGHTS

- Consider incorporating certain principles from the **AdvaMed Code** and/or the **PhRMA Code on Interactions with Health Care Professionals**.
  - These are voluntary code of conducts for companies that develop and market medical technologies or conduct biopharmaceutical research which outlines best compliance practices on certain topics, particularly on interactions with healthcare professionals.
- IRB involvement and approval of PI and patient compensation

46

COMPLIANCE ACTIVITIES

- Bank statement reconciliations
- Regular conflict of interest disclosures and reviews
- Keep thorough documentation
- Internal controls and review procedures for grant submissions and performance
- Include research in the organization's risk assessment process

47

PREVENTING, IDENTIFYING AND REFUNDING IMPROPERLY BILLED SERVICES

- Develop and implement an organization-wide process that supports identification and proper billing of research-related services
- Conduct routine internal audits to identify problems
- Use internal audit findings to develop corrective action plans and process improvements
- Track refunds of government payor claims identified in error

48

HHS-OIG'S GRANT SELF DISCLOSURE PROGRAM

- **Mandatory Disclosures**
  - HHS grant recipients/ subrecipients must disclose evidence of potential violations of Federal criminal law involving fraud, bribery, or gratuity violations, potentially affecting the Federal award. Federal regulation, 45 C.F.R. § 75.113, mandates disclosures of criminal offenses that non-Federal entities must make with respect to HHS grants.
- **Voluntary Disclosures**
  - Recipients of HHS awards may voluntarily disclose conduct creating liability under the Civil Monetary Penalty Law (CMPL), 42 U.S.C. § 1320a-7a, or any other conduct—such as conduct that might violate civil or administrative laws—that does not clearly fall within the scope of offenses described at 45 C.F.R. § 75.113.
- https://oig.hhs.gov/compliance/self-disclosure-info/grant.asp

HHS-OIG GRANT SELF DISCLOSURE PROGRAM

- Disclosers should complete the OIG Grant Self-Disclosure Submission Form: https://oig.hhs.gov/compliance/self-disclosure-info/files/Grant%20Self%20Disclosure%20Submission%20Form.pdf
- Grant disclosures may be submitted to grantdisclosures@oig.hhs.gov
- Benchmark 1.5 multiplier of damages and presumption of no integrity agreement

HHS-OIG GRANT SELF DISCLOSURE PROGRAM

- Submission Content (unique to the Grant Self Disclosure Program)
  - Grantee information (e.g., DUNS number, nature of the entity, etc.)
  - Award Information (e.g., HHS agency, type of award, purpose of grant)
  - Description of the conduct (including the types of conduct and the names/ roles of the persons involved)
  - Estimate of the financial impact to the Federal government and a description of the method for calculating the financial impact
  - List of all Federal agencies from whom the discloser is currently receiving awards

51

THANK YOU

tmaida@mwe.com
212-547-5492

ecook@mwe.com
310-284-6113

52