A Hidden Minefield? Navigating Legal and Compliance Risks in Clinical Research Budgeting and Compensation

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- Some content and questions in this presentation have been presented in other forums and programs. They are presented here with a different perspective given the passage of time and/or new developments.

Resources: *Structuring a Compensation Framework for Clinical Research: Mitigating Fraud and Abuse Risks for Healthcare Providers, Navigating FMV in Clinical Research Budgeting, Lessons From Recent Enforcement,* Strafford Legal Webinars

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“It’s all about the money.”

-Over 100 hits on Google, including multiple song lyrics.

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About the Presenter:

- Andrea assists clients to structure, document, manage, problem solve and defend financial arrangements involving healthcare providers, often specifically with respect to the "Big Three" compliance requirements of being fair market value, commercially reasonable & not taking into account volume and value of referrals
  - Formerly a Partner in a national health care valuation and consulting firm specializing in fair market value review, and an attorney with another global law firm representing various hospitals, health care businesses and life sciences companies in both domestic and international matters
  - Former associate counsel for a health system
  - Started career as clinical research coordinator/consultant
- Frequent speaker and author on topics related to healthcare finance, governance, compliance and fair market value for physician/healthcare provider services and why they matter for regulatory compliance and otherwise keeping out of trouble
  - "Rockstar" physicians
  - FMV for clinical research budgeting
  - Defensibility of FMV opinions, ethics and risk mitigation in health care transactions

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General Agenda:

Part I

Review of regulatory risks in requesting, allocating and paying research dollars

Part II

Discussion of recent enforcement actions and litigation

Part III

Trouble Spots and Tips for a compliant process to mitigate risk

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The "Big Three" of Healthcare Compliance:

Fair Market Value

Compensation for items and services should be fair market value

Commercially Reasonable

Compensation should be pursuant to a commercially reasonable arrangement

Not Taking into Account Volume or Value of Referrals

An arrangement/compensation should not be based on volume or value of business referrals

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Why Budgets and Payments Matter in 2022

Stark Law 42 U.S.C. §1395nn	• Strict liability civil statute that prohibits submission of claims to Medicare/Medicaid that result from a referral by a physician with which the entity has a financial relationship (compensation or ownership), unless a specifically-enumerated exception applies • Burden is on a defendant to show that requirements for an exception are met • The most commonly utilized exceptions for physician compensation require the Big Three • Violations trigger repayment obligations, civil monetary penalties and potential Federal exclusion • Historically, alleged violations are associated with very high monetary penalties – examples (among many): ❖ U.S. ex rel Baklid Kunz v. Halifax Health (M.D., Fla)- $85 million settlement on eve of trial in 2015, after facing potential damages in excess of $1 billion; allegations involved all of the Big Three and procedural history included summary judgement for violation of V+V prohibition ❖ U.S. ex rel Drakeford v. Tuomey Healthcare System (D.S.C) - $237 million verdict against health system settled to $74.5 million in 2015; allegations involved all of the Big Three
Federal Anti-kickback Statute (AKS) 42 USC §1320a-7b(b)	• Prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration in exchange for referrals for items or services payable by a Federal health care program- civil and/or criminal penalties • Prosecutions and penalties may apply to parties on both sides of a prohibited arrangement • Parties can comply with voluntary safe harbors or be subject to case by case analysis (to comply with a safe harbor, all requirements of the safe harbor must be completely met) • Safe harbor requirements include the Big Three ❖ United States v. Greber, 760 F.2d 68 (3d Cir. 1985), cert. denied, 474 U.S. 988 (1985)- established "one purpose test" - an arrangement may violate AKS if even one purpose is to induce referrals ❖ U.S. v. Lipkis, 770 F.2d 1447, 1449 (9th Cir, 1985) – If a payment exceeds FMV, it may be inferred that the amount in excess of FMV is a payment for referrals that may implicate AKS ❖ U.S. ex rel Bingham v. HCA (11th Cir, 2019) – Comp that is FMV is not remuneration implicating AKS ❖ U.S. ex rel Chao v. Medtronic PLC (C.D Ca., 2022) – if payments are intended to compensate for referrals, they may violate the AKS, even if the payments are FMV

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Why Budgets and Payments Matter in 2022

Federal False Claims Act (FCA) 31 U.S.C. §3729	• Prohibits knowingly presenting or causing to be presented a false or fraudulent claim for payment by the Federal government • Serves as a "magnifying glass" for violations of the Stark Law, AKS and certain state Medicaid laws, in part due to its qui tam relator provisions (70% of cases are qui tam) • Under the ACA, AKS violations are per se violations of FCA • Per claim penalties with trebling of damages ❖ Universal Health Services v. United States ex rel. Escobar 579 U.S. (2016) – a defendant makes an implied certification of compliance with Medicare/Medicaid requirements, including Stark and AKS, when submitting Medicare/Medicaid claims; a false claim for purposes of FCA is a claim of something that would be material to Government's decision to pay
Federal Tax Exemption IRC 501(c)(3)	• A tax-exempt entity's earnings may not inure to the benefit of a private party • Penalties for violation include intermediate sanctions up to loss of tax-exempt status • To comply, compensation paid should be "reasonable" for the market, specialty and responsibilities • IRC Sec. 162: "reasonable" compensation is the amount that would ordinarily be paid for like services by like enterprises under like circumstances • Generally, the Big Three are regarded as important to 501(c)(3) compliance
State/Local Tax Exemptions, including Property Taxes	• May mirror Federal IRC or have other specific requirements to maintain tax-exemption • Penalties for non-compliance may include loss of tax-exempt status for purposes of income taxes and/or property taxes, and may give rise to criminal liability in some cases (knowing violation of a state false claims act) • Recent enforcement actions/court cases suggest that operations that subsidize for-profit enterprises, and payments that are not FMV for reasonable items or services may cause risk--→ series of cases started with AHS Hosp. Corp. v Morristown (2015) and continues

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Why Budgets and Payments Matter in 2022

Civil Monetary Penalties Laws (CMPL), Including Gainsharing CMP	Gainsharing CMP (§ 1128(a)(b) of Social Security Act, 42 U.S.C. §1320a-7a) - Prohibits inducements to limit items or services to Medicare or Medicaid beneficiaries • Medicare Access and CHIP Reauthorization Act (MACRA) (2015) added the words "medically necessary" between "limit" and "items"; prior to 2015, the gainsharing CMP applied to any arrangement to limit items or services to applicable patients • Incentives and bonus programs that are not designed and implemented with proper safeguards may implicate the gainsharing CMP, even with the post-2015 modification
State Laws re Practice and Billing	• State physician self-referral prohibitions • State anti-kickback statutes and/or fee-splitting prohibitions • State billing and payment laws and rules (anti-supplementation laws, laws/rules against percentage of revenue contracts, state laws/rules limiting scope of practice for some providers, etc.) • State false claims acts • State laws prohibiting corporate practice of medicine, including, in some cases, corporate subsidization of medical practice • Newer (maybe): state anti-bribery laws, possibly enforced through the Travel Act

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Why Budgets and Payments Matter in 2022

Federal Travel Act (aka the "International Travel Act") 18 U.S.C. §1952	• Passed in 1961 • Prohibits travel or use of mail or any facility in interstate or foreign commerce to engage in unlawful activity • Unlawful activity includes violation of the laws of states, the District of Columbia, any United States commonwealth or possession, or the United States, specifically including violation of anti-bribery laws • Criminal statute that carries penalties up to 20 years in prison ❖ U.S. v Barker et al (N.D. Tx) – 14 defendants convicted in 2019 and sentenced for criminal violations of the Travel Act in connection with compensation for surgeries
Foreign Corrupt Practices Act (FCPA) 14 U.S.C. §78dd-1, et seq.	• Passed 1977 • Prohibits making payments to foreign government officials to assist in obtaining or retaining business • Applies to publicly-traded companies and their officers, directors, stockholders and agents; agents can include consultants, distributors, JV partner and certain other parties • Allows for substantial civil penalties and disgorgement of ill-gotten gains • May be implicated by payments to healthcare providers in countries with nationalized healthcare
D&O Liability for Entities in Distress	• E.g.: CMH Liquidating Trust v. Anderson (in re Community Mem. Hospital d/b/a Cheboygan Memorial Hospital) (Bankr. ED Mich., 2018) – lawsuit against directors and officers of bankrupt hospital for poor financial oversight, including non-FMV, non-CR transaction

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Why Budgets and Payments Matter in 2022

1994: OIG "Special Fraud Alert" warns that compensation relationships between pharmaceutical manufacturers and physicians may implicate the AKS if compensation exceeds the fair market value of any legitimate service rendered to the payor by the physician

- Pharma manufacturers are common sponsors of clinical research, under contracts that provide for payments to physicians

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Why Budgets and Payments Matter in 2022

2003: OIG issues *Compliance Program Guidance for Pharmaceutical Manufacturers:* The concept of "**fair market value**" is raised at least five times:

1. [with respect to payments to physicians for research] "Payments for research activities should be **fair market value** for legitimate, reasonable and necessary services."

2. [with respect to contracts for data collection services] "These contracts should be structured whenever possible to fit in the personal services safe harbor; in all cases, the remuneration should be **fair market value** for legitimate, reasonable and necessary services."

3. [with respect to items given to physicians] "If goods or services provided by the manufacturer eliminate the expense that a physician would have otherwise incurred… or if items are sold to a physician at less than their **fair market value** the arrangement may be problematic..."

4. [with respect to factors that should be considered when not complying with a safe harbor] "Do fees for services exceed the **fair market value** of any legitimate, reasonable and necessary services rendered by the physician to the manufacturer?"

5. [with respect to compensation relationships related directly or indirectly to a manufacturer's marketing and sales activities] "At a minimum, manufacturers should... review arrangements for physicians' services to ensure that: (i) the arrangement is set out in writing; (ii) there is a legitimate need for the services; (iii) the services are provided; (iv) the compensation is at **fair market value**; and (v) all of the preceding facts are documented prior to payment."

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Why Budgets and Payments Matter in 2022

2005: OIG Supplemental Compliance Program Guidance for Hospitals advises caution about hospital-physician relationships that are not fair market value

- Research relationships may include contracts and other arrangements to support research being conducted by the hospital or physician

  - "The general rule of thumb is that any remuneration flowing between hospitals and physicians should be at fair market value for actual and necessary items furnished or services rendered based upon an arm's-length transaction and should not take into account, directly or indirectly, the volume or value of any past or future referrals or other business generated between the parties. "

  - "Arrangements under which hospitals (1) provide physicians with items or services for free or less than fair market value, (2) relieve physicians of financial obligations they otherwise would incur, or (3) inflate compensation paid to physicians for items or services, pose significant risk. In such circumstances, an inference arises that the remuneration may be in exchange for generating business."

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Why Budgets and Payments Matter in 2022

2013: Implementation of Physician Payments Sunshine Act/Open Payments Law

- Intended to create transparency about payments flowing from Manufacturers to physicians and teaching hospitals
- Transparency may make seemingly inappropriate payments easier for government enforcement entities to identify
- Transparency raises the possibility of more vigorous government enforcement activity of the laws that are implicated by Manufacturer payments

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Why Budgets and Payments Matter in 2022

2014: OIG "Special Fraud Alert" re laboratory payments underscores that payments to providers to collect data (*e.g.*, for registry studies) may be suspect

- "OIG has become aware of arrangements under which clinical laboratories are providing remuneration to physicians to collect, process, and package patients' specimens."
- "[C]laims that Registries are intended to promote and support clinical research and treatment are not sufficient to disprove unlawful intent... retaining an independent Institutional Review Board to develop study protocols and participation guidelines will not protect a Registry Arrangement if one purpose of the arrangement is to induce or reward referrals."
- "The probability that a payment is for an illegitimate purpose is increased...if a payment exceeds **fair market value** or if it is for a service for which the physician is paid by a third party, including Medicare."

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Why Budgets and Payments Matter in 2022

2015: OIG Fraud Alert re physician compensation arrangements warns that OIG may/will pursue civil, criminal or administrative action against physicians who enter inappropriate payment arrangements

- "Physicians who enter into compensation arrangements such as medical directorships must ensure that those arrangements reflect **fair market value for bona fide services** the physicians actually provide. Although many compensation arrangements are legitimate, a compensation arrangement may violate the anti-kickback statute if even one purpose of the arrangement is to compensate a physician for his or her past or future referrals of Federal health care program business." (emphasis added)

- "OIG recently reached settlements with 12 individual physicians…some of the 12 physicians had entered into arrangements under which an affiliated health care entity paid salaries of the physician's front office staff. Because these **arrangements relieved the physicians of a financial burden they otherwise would have incurred**, OIG alleged that the salaries paid under these arrangements constituted improper remuneration to the physicians." (emphasis added)

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Why Budgets and Payments Matter in 2022

2020: OIG "Special Fraud Alert" re physician speaker programs highlights scrutiny on relationships between physicians/ health care providers and the pharmaceutical and medical device industries → indicative of OIG antenna for "sham" payments, excessive payments and non-monetary benefits of value that may influence prescribing decisions

Nine areas of scrutiny/concern identified in the Special Fraud Alert:

1. No substantive information/value

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4. Company sponsors a large number of programs on the same or a substantially similar topic or product

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9. Company pays health care providers more than fair market value or pays compensation that takes into account to volume or value of past or future business generated

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Why Budgets and Payments Matter in 2022

2021/2022: Fraud and abuse related to research practices appear to be significant items on the government radar

- Several OIG Advisory Opinions (two in 2021 and one in 2022 so far) specifically mention the potential fraud and abuse concerns in waiving co-payment for subjects, as well as in paying providers in connection with clinical research activities (see following slides)
- DOJ CPB priorities for 2022 incl. clinical trial fraud as standalone category of enforcement activity
- New AKS Safe Harbors, effective January 2021, specifically and explicitly exclude pharmaceutical and medical device manufacturers, distributors and wholesalers, as well as laboratories, from being able to utilize the flexibilities of the new exceptions → This seems to signal higher government scrutiny on payments originating from these types of entities, which are common research sponsors
- New Medicare physician fee schedules and billing rules may complicate efforts to ensure fair market value reasonable payments → Parties may need to be extra vigilant in reviewing and updating compensation in research compensation arrangements

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OIG's Eligibility Chart- New Safe Harbors Under 2020 Final Rules (Effective January 2021)

Revisions to Safe Harbors Under the Anti-kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, Final Rule November 20, 2020

Eligibility for the Value-Based Safe Harbors, the Patient Engagement and Support Safe Harbor, and the Personal Services and Management Contracts Safe Harbor for Outcomes-Based Payment

Entity Type	Care Coordination Arrangements 42 C.F.R. § 1001.952(ee)	Substantial Downside Risk 42 C.F.R. § 1001.952(ff)	Full Financial Risk 42 C.F.R. § 1001.952(gg)	Patient Engagement and Support 42 C.F.R. § 1001.952(hh)	Outcomes-Based Payments 42 C.F.R. § 1001.952(d)(2)
Providers and Suppliers (*e.g.*, hospitals, post-acute care providers, and physicians)	Eligible	Eligible	Eligible	Eligible	Eligible
Pharmacies Other Than Compounding Pharmacies	Eligible	Eligible	Eligible	Eligible	Eligible
Compounding Pharmacies (*i.e.*, pharmacies that primarily compound drugs or primarily dispense compounded drugs)	Ineligible	Ineligible	Ineligible	Ineligible	Ineligible
Manufacturer of a Device or Medical Supply (as defined in 42 C.F.R. § 1001.952(ee)(14)(iv))	Eligible, but only for in-kind remuneration that is digital health technology	Ineligible	Ineligible	Eligible, but only for tools and supports that are digital health technology	Ineligible
DMEPOS Suppliers (other than pharmacies or physicians, providers, or other entities that primarily furnish services)	Eligible, but only for in-kind remuneration that is digital health technology	Ineligible	Ineligible	Ineligible	Ineligible
Pharmacy Benefit Managers	Ineligible	Ineligible	Ineligible	Ineligible	Ineligible
Pharmaceutical Manufacturers, Distributors, Wholesalers	Ineligible	Ineligible	Ineligible	Ineligible	Ineligible
Laboratory Companies	Ineligible	Ineligible	Ineligible	Ineligible	Ineligible
Physician-Owned Distributors (PODs)	Ineligible	Ineligible	Ineligible	Ineligible	Ineligible
Health Technology Companies Not Otherwise Covered by an Entity Type on This List	Eligible	Eligible	Eligible	Eligible	Eligible

DISCLAIMER: This chart is current as of the date issued. It is an educational resource; it is not intended to create any rights, privileges, or benefits. Although every reasonable effort has been made to ensure the accuracy of this chart, the ultimate responsibility for complying with the Federal fraud and abuse laws lies with the party or parties seeking compliance with such laws. We refer readers to the final rule published in the Federal Register for additional and official information.

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Why Budgets and Payments Matter in 2022

OIG Advisory Opinions - Dec. 2002 (AO 02-16), Jan. 2004 (AO 04-01) and Sept. 2008 (AO 08-11): OIG Advisory Opinions regarding proposed subsidization of Medicare cost sharing obligations in the context of NIH/government-sponsored clinical trials - OIG opined positively in each case due to safeguards in the proposed arrangements, but noted:

In AO 08-11: "Many clinical trials, including trials qualifying for Medicare coverage, will study items and services for which there are effective, well established treatments already available. In such cases, enrollees could well be induced to forego equally effective or more appropriate care. Moreover, some trial sponsors pay physicians or other providers substantial amounts to recruit patients for, and provider services in, clinical studies. Payments to providers and participating patients present a risk of fraud and abuse."

(language from AO 08-11)

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Why Budgets and Payments Matter in 2022

OIG Advisory Opinions - October 2021 (AO 21-13), Nov. 2021 (AO 21-17) and March 2022 (AO 22-05): OIG Advisory Opinions regarding proposed subsidization of Medicare cost sharing obligations in the context of commercially-sponsored clinical trials - OIG opined positively in each case due to safeguards in the proposed arrangements, but noted:

In all three AOs: "Requestor… would provide remuneration to the investigators and sites participating in the Study in two forms: (i) the opportunity to bill Federal health care programs for items and services related to the study; (ii) a guaranteed payment of beneficiary cost saving, which, in some circumstances, an investigator or site may not be able to collect in full. Both forms of remuneration implicate the Federal [A]nti-kickback statute."

(Identical language in the three AOs)

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Why Budgets and Payments Matter in 2022

A few notes/reminders on AOs:

- ❖ The three most recent positive AOs were based on facts and circumstances that included a representation that the compensation paid to sites and investigators is fair market value for necessary study-related services

→ OIG relied on the representation in making its determination

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- ❖ All AOs are specific to the facts and circumstances of the requestors and have no application to, and cannot be relied upon by, any other party

→ AOs generally cannot be introduced into evidence by a person other than the requestor to prove that they did not violate the law

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- ❖ OIG reserves the right to modify or reconsider

→If facts change or are not as they were presented or appeared, opinion may be rescinded

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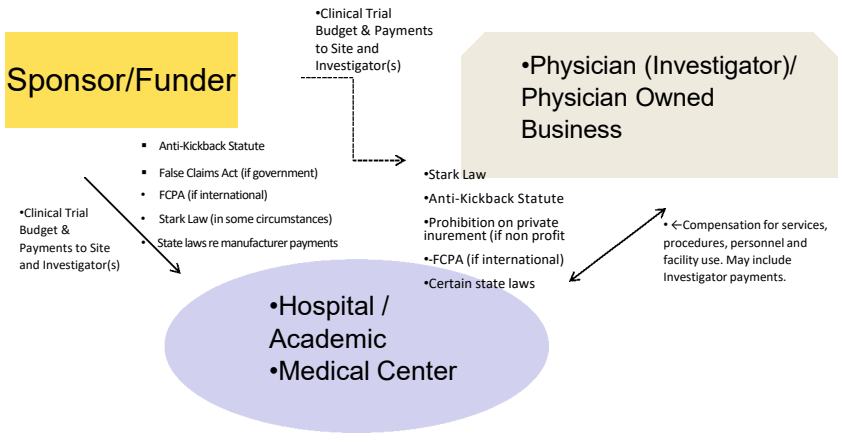
Why Budgets and Payments Matter in 2022:



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Clinical Research Budgeting/Contracting

Money Flow Can Create Risk Areas

- Investigator services
- Physician professional services
- Technical/procedure services
- Clinical research support services (study coordinator, pharmacist, biostatistician, etc.)
- Facilities and space
- Study-specific Items

•Each item may be provided by a different party

•Generally, each item should be paid for at fair market value under a commercially reasonable arrangement

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Why Budgets and Payments Matter in 2022

•**Additional Considerations re clinical research:**

- Increasingly important to being competitive in certain specialty areas (for both physician investigator(s) and hospital(s)/research center(s))
- Required for obtaining Center of Excellence designation for certain service lines (e.g., cancer tx)
- A potential source of ancillary revenue for hospital research centers & physician practices/employers

Common Incentive Types	Common Compensation Methodologies	Common Contexts
Physician incentives to develop clinical research Physician incentives to train/prepare for clinical research	Fixed incentive based on milestone achievement(s) - *e.g.* submitting completed protocol for review Variable incentive based on time commitment	Medical director arrangement Co-management arrangement Employment arrangement Professional services arrangement
Physician incentives to serve as investigator in clinical research Physician incentives to screen/enroll patients for clinical research	Compensation/incentive per subject and/or per study	Pharma/device/lab/life sciences sponsorship and payments/grants Federal grants Institutional/hospital/academic grants

*Depending on circumstances, each of these payments may or may not be part of typical study budgeting, and, therefore, may require caution to ensure against duplicative payment

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Enforcement Actions and Litigation for Illustration

Sample Recent Cases – Health System Payments:

❖**August 2018: FCA Settlement (Qui Tam, Eastern District of MI)** –

Agreed to pay $84.5 million and enter 5-year Corporate Integrity Agreement that includes requirement of independent monitoring

- Settlement resolves allegations brought by Beaumont's Director of Research
- Allegations in the case included that hospital paid for gratuitous research directorships and paid research compensation based on false assumptions and duplicative services
- $82.74 of settlement to Federal government for alleged Medicare violations and $1.76 million to state of Michigan for alleged Medicaid violations

❖**April 2022: U.S. Department of Justice Complaint in Intervention (Filed, Middle District of TN)** - DOJ intervened in relator case and filed complaint against Tennessee hospital/health system for alleged Anti-kickback Statute violations through multiple arrangements with large specialty physician group; one of the alleged violations was through large payments to a research entity of the physician group

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Enforcement Actions and Litigation for Illustration

Sample Recent Cases – Pharma/Life Sciences Payments:

❖**July 2020: Pacira Pharma** -Agreed to pay $3.5 million to settle allegations that it paid kickbacks in the form of research grants

❖**July 2020: Novartis** - Agreed to pay $642 million and enter a Corporate Integrity Agreement to resolve allegations that included improper/sham payments to physicians for various consulting services, and improper payment of patient copays through patient assistance foundations

- ➢Was not a research case specifically, but illustrative of DOJ scrutiny generally
- ➢**Press Release** - "This office will continue to be vigilant in cracking down on kickbacks, however they may be dressed up, throughout the pharmaceutical industry."

❖**August 2020: Prove Biosciences** - VP pleaded guilty to violating the Anti-kickback Statute by paying physicians improper clinical research fees to order genetic tests

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Enforcement Actions and Litigation for Illustration

Sample Recent Cases – Double Dipping/Duplicative Payment:

❖**April 2005: University of Alabama at Birmingham** - Agreed to pay $3.39 million to settle claims that it received excessive payment by both billing Medicare and receiving sponsor payment for research services

❖ **2010: Tenet Healthcare** - Agreed to pay $1.9 million to settle claims related to self-disclosed violation of its 2006 ($900 million) Corporate Integrity Agreement

- Violations were through clinical research payments to the USC Norris Cancer Center (NCC)
- NCC allegedly received payments from sponsors/grants for services that were billed to and paid by Medicare

❖**August 2013: Emory** - Agreed to pay $1.5 million to settle allegations related to double dipping--receipt of payment from research sponsor for services that research sponsor agreed to pay/did pay

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Enforcement Actions and Litigation for Illustration

Sample Recent Cases- Grant Charges:

❖**September 2020: Scripps Research Institute** - Agreed to pay $10 million to settle allegations that it charged NIH research grants improper amounts for various activities, including physician activities

❖**June 2020: University of Virginia** – Agreed to pay $1 million to settle claims that it did not properly calculate and account for amounts charged to research grants

❖**April 2020: Harvard University** - Agreed to pay $1.3 million to settle allegations that it overcharged NIH research grants

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Trouble Spots and Tips

Focus Areas:

1. Matching budget line items to actual services
2. Identifying and accounting for hidden value and costs
3. Identifying and avoiding duplicative payments/remuneration
4. Appropriately addressing expectations of "profit" from research funding
5. Recognizing that some investigators are Rockstars and warrant compensation accordingly, but (i) not every single one is a Rockstar; and (ii) even bona fide Rockstar status is not relevant/applicable in every single budgeting circumstance

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Trouble Spots and Tips

Focus Areas/Trouble Spots

1. Matching budget line items to actual services

- Key questions: Who does what? How long does it take? What resources are involved?
- De-bundle services and convert them to personnel time (hourly rates) and/or fixed value components

2. Identifying and accounting for hidden value and costs

E.g., Clinical research support services are provided by individuals who are not dedicated full-time to the study and might not be initially identified

- Certain individuals (study coordinator, pharmacist, etc.) may be needed only part-time or sporadically; services may be needed immediately "on demand" when a patient-subject is identified and enrolled, but it is unknown when or how often patient-subjects will be identified
- Part time, on demand services might garner a premium in the marketplace (consider hourly cost of locums or temps versus full time exclusively dedicated employees)

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Trouble Spots and Tips

Focus Areas/Trouble Spots

3. Identifying and avoiding the possibility of duplicative payments/remuneration

- Some physician professional services and technical services that are provided in research may be payable by Medicare or other payors
- The amount paid by those payors is generally payment in full for the services that correspond to the relevant billing code → only the fair market value of *incremental* services that are not covered by the billed code should be paid by the site/ sponsor contract
- Generally need to keep abreast of billing rule changes affecting the applicable therapeutic area

To Note: In some cases, there are very different 2021 and 2022 Medicare Physician Fee Schedules (compared to 2020 and prior).

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Trouble Spots and Tips

Focus Areas/Trouble Spots

4. Appropriately addressing expectations of "profit" from research funding

- Study budget should cover all costs at fair market value
- Some margin may be part of fair market value for individual services, even if not part of a fair market value budget overall
- "Profit" can be a tricky concept from a fraud and abuse perspective → profit should not generally be in payments in excess of fair market value

5. Recognizing that some investigators are Rockstars and warrant compensation accordingly, but not every single one is a Rockstar, and this status isn't always relevant regardless

- There are "Rockstar" investigators who are renowned in their field and whose unique expertise suggests a higher market value for their investigator services
- Generally, investigators are individuals at the top of their field, but not all are "Rockstars"
- General guidance is to adopt clear criteria for Rockstars (and Rockstar compensation), and evaluate investigator payments case by case

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Trouble Spots and Tips

Takeaway Tips

1. Create a research budgeting and/or research compensation policy or "toolkit."
2. Update the policy or toolkit at least every two years to account for market changes.
3. As part of or as an adjunct to the policy or toolkit, provide a summary of and/or access to fair market value ranges for per-service and per-item rates for common budget items, as well as general guidance on how to apply them in a commercially reasonable manner.
4. As part of or an adjunct to the policy or toolkit, create process guardrails to ensure appropriate consideration of legal and regulatory boundaries and questions.
5. Include in the process guardrails specific triggers for higher level case-specific review of arrangements- legal review, fair market value review, etc. - triggers may include:
    a) Questions about the form or structure of payments
    b) Questions about potentially duplicative payments
    c) Non-typical or hidden value and costs
    d) Concerns about payments at the low or high of FMV
    e) Unique services or service providers, such as but not limited to, as "Rockstar" investigators

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Trouble Spots and Tips

Takeaway Tips

6. Compile a list of Best Practices to inform the policy/toolkit and any secondary review of payments resulting from the process guardrails.
7. Identify an individual or workgroup to review data, billing rules, enforcement trends to inform Best Practices - include counsel and/or compliance officer in addition to business and clinical leaders in determining/ articulating Best Practices.
8. Coordinate regular up-to-date education for all staff engaged in financial activities related to research.
9. Create communication among "front line" staff that negotiate payments, counsel who draft agreements and audit/business staff who monitor funds flow.
10. Document and audit as appropriate- "A short pencil beats a long memory" ("Memories fade but documents can last forever").

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Questions?

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