

Grant Fraud, Research Billing Irregularities, and Other Scary Research Enforcement Issues

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Session Overview

- Provide a brief overview of the requirements for reporting in Federal Grants (previously found in OMB Circulars A-110, A-21 and A-133)
- Overview of the OMB Uniform Guidance and its impact on Circulars A-110, A-21, and a-133
- Overview of OIG Enforcement Agenda and Recent Grant Fraud Cases
- Brief Overview of Medicare Research Billing Requirements
- Types of Research Billing Issues that can lead to allegations of billing fraud
- Overview of recent Research Billing investigations and settlements
- Provide recommendations for what Universities should do to supplement their Compliance Programs to ensure ongoing compliance with these reporting obligations

PRIOR FEDERAL GRANT COSTING REGULATIONS

Federal Grant Costing Regulations

OMB CIRCULAR A-21

OMB Circular	Regulation Purpose
A-21 (Cost Principles for Educational Institutions)	<ul style="list-style-type: none">• Provide principles for determining the costs applicable to research and development, training, and other sponsored work performed by colleges and universities under grants, contracts, and other agreements with the Federal Government.

- OMB Circular A-21 establishes principles for determining costs applicable to grants, contracts, and other agreements with educational institutions. This regulation:
 - Defines the financial framework for administering Federally sponsored research,
 - Describes the basis for calculating facilities and administrative costs, and
 - Provides a reference section for determining how to charge specific, common costs to sponsored projects

Federal Grant Costing Regulations

OMB CIRCULAR A-21

- Circular A-21 specifically outlines how to **appropriately charge costs** to federally sponsored projects.
 - Costs that do not meet the 4 standards listed below should not be charged to a federally funded sponsored project.

Allowable	Reasonable	Allocable	Consistently Treated
<ul style="list-style-type: none"> • The cost conforms to any limitations or exclusions set forth in the regulations that govern the award (A21, A110, institution or system policies, etc.) and the terms specific to the sponsored award. 	<ul style="list-style-type: none"> • The cost, in its nature or amount, it does not exceed that which would be incurred by a prudent person under the circumstances prevailing at the time the decision was made to incur the cost. 	<ul style="list-style-type: none"> • The goods or services involved are chargeable or assignable to a specific cost objective in accordance with relative benefits received 	<ul style="list-style-type: none"> • The costs incurred for the same purpose, <i>in like circumstances</i>, are either direct costs only or F&A costs only with respect to final cost objectives. (The same types of costs are not charged to awards both as direct costs AND as F&A costs.)

Federal Grant Costing Regulations

OMB CIRCULAR A-110

OMB Circular	Regulation Purpose
A-110 (Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations)	<ul style="list-style-type: none"> • Obtain consistency and uniformity among Federal agencies in the administration of grants to and agreements with institutions of higher education, hospitals, and other non-profit organizations.

- OMB Circular A-110 includes the following components:
 - Subpart A – General
 - Subpart B – Pre-Award Requirements (forms for application, special award conditions, etc.)
 - Subpart C – Post-Award Requirements (financial management, cost sharing, allowable costs, period of availability of funds, etc.)
 - Subpart D – After the Award Requirements

<http://www.whitehouse.gov/omb/circulars/a110/a110.html>

Federal Grant Costing Regulations

OMB CIRCULAR A-133

OMB Circular	Regulation Purpose
A-133 (Audits of States, Local Governments, and Non-Profit Organizations)	<ul style="list-style-type: none"> Obtain consistency and uniformity among Federal agencies for the audit of non-Federal entities expending Federal awards

- OMB Circular A-133 answers the questions:
 - Who is required to have an audit conducted?
 - Who is exempt from having an audit conducted?
 - What is the frequency?
- A-133 applies to non-Federal entities that expend \$500,000 or more in a year in Federal awards.
 - Required annually (or biennial in specific cases) and usually conducted with an institution's Financial Statement audit
 - Performed by an independent audit firm
 - A-133 provides specific guidance to auditors – "Compliance Supplement"

<http://www.whitehouse.gov/omb/circulars/a133/a133.html>

EXTERNAL REPORTING FOR RESEARCH

External Reporting

BACKGROUND

- Universities are responsible for managing the day-to-day financial and programmatic operations of sponsored programs through the use of established internal controls and policies.
- However, the federal government actively monitors federally funded awards through the review of:
 - Financial Reports
 - Progress Reports
 - Invention Reports

External Reporting

COMPLIANCE & TRANSPERNCY CONSIDERATIONS

- Research institutions must consider the following compliance implications related to the submission federal reports.

Timely
• Reports must be filed in a timely manner
Allowable
• Include allowable activity supported by general ledger documentation for financial reports and scope of work for the project for progress reports
Award Requirement
• Follow all reporting requirements specified in the Notice of Grant Award
Policy
• Presence of & adherence to the institutional policy requiring review and written approval
Risks
• Failure to submit complete, accurate, and timely reports may result in penalties or enforcement actions

External Reporting

FEDERAL FINANCIAL REPORTS

- Financial reporting provides official documentation of the financial status of expenditures charged to the sponsored award, as required by the Notice of Award or sponsor regulations.
- Before submitting FFRs, recipients must ensure that the information submitted is:
 - Accurate
 - Complete
 - Consistent with the recipient's accounting system

External Reporting

FEDERAL FINANCIAL REPORTS

Federal Agency	Reporting Requirements
<u>DHHS</u>	<ul style="list-style-type: none"> • In August 2008, the OMB issued a Federal Register notice establishing the Federal Financial Report (FFR or SF-425) as the DHHS reporting format. • Reports submitted electronically on a quarterly, semi-annual, or annual basis, as directed by the Federal agency. <ul style="list-style-type: none"> • Quarterly/Semi-Annual interim reports are due 30 days after the end of each reporting period. Annual/Final reports are due 90 days after the end of each reporting period.
<u>NSF</u>	<ul style="list-style-type: none"> • NSF does not require grantees to submit financial status reports for purposes of final grant accountability. • NSF procedures have been designed to extract the final financial data from the entries in ACMS.
<u>USDE</u>	<ul style="list-style-type: none"> • USDE requires financial reporting as a component of the Grant Performance Report (Ed 524B form). <ul style="list-style-type: none"> • Annual reports should include expenditures for the entire previous budget period as well as the expenditures for the current reporting period. • Final reports will include the above as well as expenditures through the entire project period. These reports are due within 90 days of the project period end. • Must also provide an explanation if reported funds have not been drawn down from the G5 System and if funds have not been expended at expected rate.

External Reporting

PROGRESS REPORTS

- Progress reports depict the scientific progress of research to federal sponsors on an ongoing basis.
- These reports ensure that a project is on course with the stated aims listed in its proposal as well as:
 - Provide a summary of the research and state progress made toward the achievement of the originally stated goals
 - List all significant results for research and any resulting publications

External Reporting

PROGRESS REPORTS

Federal Agency	Reporting Requirements
DHHS & NSF & Other Federal Agencies	<ul style="list-style-type: none"> • Implemented the federal-wide Research Performance Progress Report (RPPR) in the Fall of 2012 and its completion is required to continue support of a grant for each budget year within a competitive segment. • RPPR is not used for submitting a Final Progress Report. Final progress reports are due within 90 days of the end of the project period. There is no official form for federal final progress report. • Reports are submitted electronically. • RPPR required for the following federal agencies: <ul style="list-style-type: none"> • DHHS, NSF DHS, DOC, DOD, DOE, DOJ, EPA, NASA, NEH, & USDA
<u>USDE</u>	<ul style="list-style-type: none"> • USDE requires progress reporting as a component of the Grant Performance Report (Ed 524B form). • Project Objectives data will be included to "provide quantitative and/or qualitative data for each associated performance measure and a description of preliminary findings or outcomes that demonstrate that you have met or are making progress towards meeting the performance measure". • Annual performance reports are typically due seven to ten months after the start of the grant's current budget period. Final performance reports are due 90 days after the expiration of the grant's project period.

External Reporting

INVENTION REPORTS

- Awardees are required by the Bayh-Doyle Act to submit the HHS 568 form to report on inventions developed during the course of sponsored funding to federal agencies.

Purpose/Description	Frequency	Guidelines
<ul style="list-style-type: none"> • State all inventions which were conceived or brought to practice during the course the award. • Includes inventions from the original effective date of through completion or termination. 	<ul style="list-style-type: none"> • Should be completed with 90 days of the sponsored project expiration date. • Submit electronically through iEdison, which provides a single interface for all government funding agencies. 	<ul style="list-style-type: none"> • The Bayh-Dole Act “encourages researchers to patent and market their inventions by guaranteeing first rights to a patent for an invention fully or partially funded by a Federal agency to the awardee organization”

<http://www.dodsbir.net/solicitation/inventionreporting.htm>

Internal Reporting

EFFORT REPORTING BACKGROUND

- Effort is the proportion of time spent on any activity and expressed as a percentage of the total professional activity for which an individual is employed by the institution.
- Effort reporting involves:
 - Reasonable estimate
 - Total effort must equal 100%
 - Effort is not based on a 40 hour week
- Effort reports often present total percentages of payroll distributions to be used as a starting point, since it is often assumed that payroll distribution is monitored and revised based on effort expended.
 - These percentages may need to be revised during certification based on actual expended effort
 - This after-the-fact confirmation is necessary for compliant effort reporting

Internal Reporting

EFFORT CERTIFICATION

- Effort reports should be signed by an employee, PI or other responsible official with first-hand knowledge of **all** of an employee's effort, or on individual who used suitable means of verifying that the work was performed.
 - The safest way to meet this requirement is to have each employee or faculty member sign his or her own report.
- Salary is charged based on an **estimate** of how effort will be expended; must then verify how effort was **actually** expended so that charges are appropriate
 - Reporting provides support for salary charged to sponsored awards
 - Documents that effort commitments have been met
 - Supports both salary charging and salary cost sharing

Internal Reporting

EFFORT REPORTING USES

Government Use

- Verify that labor charges are appropriate based on the amount of work performed
- Verify that cost sharing is performed as promised
- Verify that sponsored research is appropriately classified (i.e. included in Organized Research F&A base)

Institution Use

- Management reporting tools
 - Are faculty and others working in areas as expected or promised?
 - Is payroll distribution appropriate?
 - Where is labor cost sharing occurring?
- May be used for other reporting purposes (state teaching requirements, Medicare time reporting)

Internal Reporting

EFFORT REPORTING REQUIRMENTS

A-21: Educational Institutions

- After-the-fact confirmation of personnel costs charged to sponsored agreements
- System must be encompassed into the official records of the institution
- Certification which encompasses all employee activities on an integrated basis (i.e., 100% of effort)
- Certification to be performed by an individual with knowledge of all of the employee's activities

A-122: Other Non-Profit Organizations

- After-the-fact confirmation of personnel costs charged to sponsored agreements
- Certification which encompasses all activities on an integrated basis (i.e., 100% of effort)
- Certification to be performed by an individual with knowledge of all of the employee's activities

OASC-3: Hospitals

- Daily time cards for non-professional staff
- Certification which encompasses all activities on an integrated basis (i.e., 100% of effort)
- Certification to be performed by an individual with knowledge of all of the employee's activities

Internal Reporting

EFFORT REPORTING REGULATION CHANGES

- The OMB Uniform Guidance has set forth new regulations to lessen the administrative burden associated with effort reporting on universities.
- COGR stated that any other system or requirement beyond the four pillars listed below for proper accounting of salaries is prescriptive, burdensome, costly, and does not add value.

Official records that are maintained in the institution's payroll distribution system

Institutional controls and processes ensure payroll charges to Federal awards are appropriate

Institutional controls and processes further identify changes in employee activity and update those changes in the payroll distribution system in a timely manner

A system is in place for after-the-fact confirmation of payroll charges by a responsible person

Internal Reporting

EFFORT REPORTING REGULATION CHANGES

- The final language in the OMB Uniform Guidance:
 - Strengthens the requirements for non-Federal entities to maintain high standards for internal controls over salaries and wages while allowing for additional flexibility in how non-Federal entities implement processes to meet those standards,
 - Promotes general principles of effort reporting while consolidating reporting requirements across entities and eliminated specific examples for institutions of higher education, and
 - Defines different allowable and unallowable compensation activities and provides special considerations for different types of non-federal entities.

Internal Reporting

EFFORT REPORTING REGULATION CHANGES

- The impact of the effort reporting changes on research institutions are minimal, as the general principles of time and effort still apply.
- However, with these changes, institutions have the ability to implement independent practices and develop unique internal controls for certifying time and effort, as long as they follow the federal guidelines.
- Lastly, the complex language and example methods have been eliminated.

OMB UNIFORM GUIDANCE

OMB Uniform Guidance
BACKGROUND & CONTEXT OF NEW GUIDANCE

- The OMB issued the proposed guidance in 2013 to consolidate eight separate OMB circulars, each with its own unique rules and requirements, into a single regulation governing federal grants to IHEs, non-profits, and tribes.

Reforms to Audit Requirements	Reforms to Cost Principles	Reforms to Administrative Requirements
<ul style="list-style-type: none"> Merges and consistently aligns OMB Circular A-133 and Circular A-50. 	<ul style="list-style-type: none"> Merges and updates OMB cost principle Circulars A-21, A-87 and A-122 and 45 CFR Part 75. 	<ul style="list-style-type: none"> Updates OMB Circulars A-102, A-110 and A-89

- According to the OMB...“the guidance is aimed at eliminating duplicativelanguage in order to clarify where policy is substantively different across types of entities, and where it is not.”

OMB Uniform Guidance

BACKGROUND & CONTEXT OF THE UNIFORM GUIDANCE

Multiple Executive Orders were issued by the President focusing on:

- Eliminating error, fraud, and abuse related to improper payments related to federal sponsored programs
- Greater coordination and review across agencies to simplify redundant, inconsistent, or overlapping requirements, thus reducing costs
- Revising guidance concerning cost principles, burden minimizations, and audits in order to eliminate burdensome, duplicative, or low-priority recordkeeping requirements and effectively tie such requirements to achievement of outcomes



In response to the President's Executive Orders, the OMB:

- Established the Council on Financial Assistance Reform (COFAR) as a governance body to provide policy level leadership for the Federal grants community.
- Set the goal of the reform to *"reduce administrative burdens and risk of waste, fraud and abuse"*
- Started a broad consultative process with stakeholders (as mandated by Executive Order).
- Published proposed guidance in February 2013 for comments and received over 350 comments from a broad range of constituencies (Higher Ed institutions were active participants through COGR, AAAU, APLU).

OMB Uniform Guidance

CHANGES TO EXISTING REGULATIONS

- The Uniform Guidance, which will go into effect at the end of 2014 includes a combination:
 - Current Language from Existing Circulars
 - Revised Language Clarifying and Updating Current Requirements
 - New Language Adding New Requirements
- The Uniform Guidance places greater emphasis and provides a specific framework for necessary, effective institutional internal controls.

Institutional Impact

In many respects the core of federal regulations remains unchanged. However, the change itself should lead institutions to conduct an enhanced review of existing institutional policies and procedures as a result of a renewed awareness of regulations.

Summary of New Guidance

HIGHLIGHTS & INSTITUTIONAL IMPACT

- The updated OMB Uniform Guidance is organized into the 6 subparts and touch on key research topic areas.

Functional Area	Final OMB Uniform Guidance	Institutional Impact
Subrecipient Monitoring	<ul style="list-style-type: none"> • Pass Through Entities must pass on either a negotiated or minimum 10% of MTDC indirect cost rate to subrecipients. • Clarification made limiting the review of performance and financial reports to what the pass-through entity has decided to require to meet their own requirements under the federal award • Only when findings pertain to Federal award funds does the pass-through entity have to follow up and ensure corrective action on weaknesses found. 	<ul style="list-style-type: none"> • Promote 10% MTDC minimum rate facilitates collaboration with subrecipients • Prime awardee institutions decide what responsibilities for monitoring subrecipients, including the review of financial and programmatic reports, to meet their own requirements under federal awards. • Only when findings pertain federal awards provided to subrecipients must the pass-through entity manage corrective actions

Summary of New Guidance

HIGHLIGHTS & INSTITUTIONAL IMPACT

- The updated OMB Uniform Guidance is organized into the 6 subparts and touch on key research topic areas.

Functional Area	Final OMB Uniform Guidance	Institutional Impact
Direct Charging (Admin/ Clerical Salaries)	<ul style="list-style-type: none"> • Explicit language was added to clarify that for these costs to be allowable, they must have the prior approval of the Federal awarding agency. • Additional language was added to allow for this approval after the initial budget approval in order to allow for flexibility in implementation. 	<ul style="list-style-type: none"> • Institutions may charge administrative and clerical salaries directly to a federal award when it is appropriate, allocable and meets the conditions outlined in the federal guidance. The burden for justifying direct costs as allocable to an award remains with the institution.

Summary of New Guidance

HIGHLIGHTS & INSTITUTIONAL IMPACT

- The updated OMB Uniform Guidance is organized into the 6 subparts and touch on key research topic areas.

Functional Area	Final OMB Uniform Guidance	Institutional Impact
Direct Charging (Computing Devices)	<ul style="list-style-type: none">• Computing devices are subject to the less burdensome administrative requirements of supplies (as opposed to equipment) if the acquisition cost is less than the lesser of the capitalization level established by the non-Federal entity for financial statement purposes or \$5,000, regardless of the length of its useful life.	<ul style="list-style-type: none">• Computing devices not considered a depreciable asset by an institution's capitalization policy may be charged and treated as supplies. However, institutions must follow the same practices for determining and documenting allocability (direct versus indirect use) when charging computing devices to sponsored awards.

OIG Enforcement Agenda and Recent Grant Fraud Cases

OIG 2017 Work Plan

■ Controls Over Subcontracting of NIH Grant and Contract Work

OIG will assess colleges' and universities' controls over the subcontracting of NIH grant and contract work. Specifically, OIG will determine whether colleges and universities effectively monitor the services subcontracted to other organizations and ensure that Federal funds are spent on allowable goods and services in compliance with selected cost principles and the terms and conditions of the grants and subcontracts. Cost principles for Educational Institutions at 45 CFR 75 are used in determining the allowable costs of work performed by colleges and universities under sponsored agreements

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OIG 2017 Work Plan

NIH

■ Colleges' and Universities' Compliance with Cost Principles

OIG will assess colleges' and universities' compliance with selected cost principles. OIG will conduct reviews at selected colleges and universities on the basis of the dollar value of Federal grants received and input from HHS operating divisions and the offices of the Assistant Secretary for Financial Resources and the Assistant Secretary for Administration.

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Recent Grant Fraud Cases

- 2/10/16: DOJ announces that a Lexington couple admitted in federal court that they submitted false claims related to federal grants from NIH and defrauded the government out of hundreds of thousands of dollars.
 - According to court documents, Ms. Brue certified on behalf of Telehealth Holdings, LLC, a company owned by Jerome Hahn, that company incurred expenses totaling \$222,037 relating to two federal grants Telehealth received from NIH
 - Ms. Brue falsely certified that funds had been spent in accordance with grant rules and regulations
 - Ms. Brue plead guilty to making a false claim against the United States
 - Mr. Hahn plead guilty to conspiracy to defraud the United States
 - On March 30, 2016, U.S. District Judge sentenced Brue to seven months in prison, and an additional seven months on home detention. Brue was also ordered to pay \$222,037 in restitution to NIH.
 - On June 13, 2016, U.S. District Judge sentenced Hahn to four months in prison and an additional six months on home detention. Hahn was also ordered to pay \$222,037 in restitution to NIH

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Recent Grant Fraud Cases

- 7/13/16: U.S. District Court enters a civil judgement against Vesta Brue and her companies, Life Techniques, Inc. and Care Team Solutions, LLC, to resolve False Claims Act allegations regarding defrauding NIH of millions of dollars over 8 years
 - NIH awarded Ms. Brue and her companies five (5) SBIR grants to support development of electronic pillboxes customized for specific patient populations
 - Ms. Brue acknowledged that they:
 - ❖ Made false statements in grant applications about company personnel, facilities and accounting systems;
 - ❖ Falsely stated on grant reports that they had spent grant funds for purposes of the grants and in compliance with grant regulations when in fact spent money on personnel expenses; and
 - ❖ Used grant money on business expenses not allowed under grant regulations, e.g., marketing and promotion expenses.
 - Government complained that Ms. Brue also falsified entries in her companies' accounting ledgers to conceal from NIH auditors that federal funds had been misspent

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Recent Grant Fraud Cases

- 7/14/16: DOJ and HHS OIG announces \$9.5 Million settlement with Columbia University ("Columbia") for improperly seeking and receiving excessive cost recoveries in connection with research grants funded by NIH
 - The United States' Complaint alleged that from July 1, 2003, through June 30, 2015, Columbia impermissibly applied its "on-campus" indirect cost rate - instead of the much lower "off-campus" indirect cost rate - when seeking federal reimbursement for 423 NIH grants where the research was primarily performed at off-campus facilities owned and operated by the State of New York and New York City
 - The Complaint also alleged that Columbia failed to disclose to NIH that it did not own or operate these facilities and that Columbia did not pay for use of the space for most of the relevant period.
 - Columbia Admitted to Seeking and Receiving Cost Recoveries at the Higher "On-Campus" Rate for 423 Research Grants Even Though the Research Was Primarily Performed in Space Not Owned or Operated by Columbia

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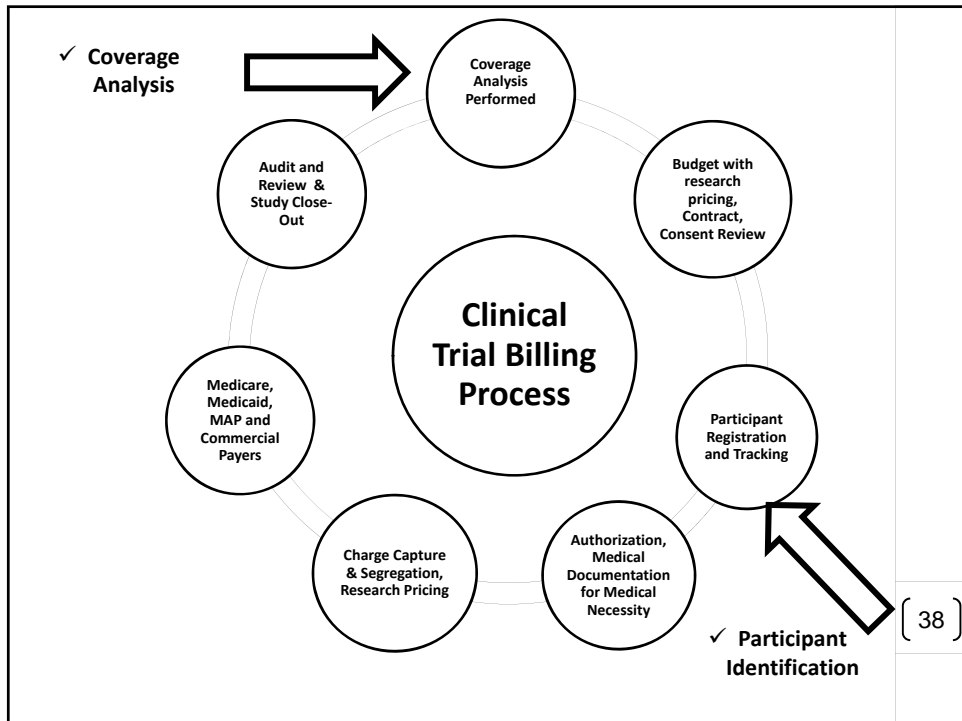
Recent Grant Fraud Cases

- 7/29/16: United States Government sued a Lexington man, Jerome Hahn, and the Lexington-based medical device company he owns, Telehealth Holdings, LLC, for violations of the False Claims Act alleging that they defrauded the government by submitting false claims in connection with federal grants.
 - According to the Complaint, Telehealth received three grants from the government worth over \$600,000 to develop a sleep apnea monitoring system and for the development of pillboxes customized for specific patient populations.
 - The Complaint alleges Hahn and Telehealth did the following:
 - ❖ Made false statements in the grant applications about Telehealth's personnel, facilities and accounting systems;
 - ❖ Falsely stated on grant reports that they had spent grant funds for purposes of the grants and in compliance with grant regulations when in fact spent money on personnel expenses;
 - ❖ Used grant money on business expenses not allowed under grant regulations, e.g., marketing and promotion expenses;
 - ❖ Spent over \$100,000 in grant funds for foreign goods and services, when grant regulations require recipients to use American goods/workers; and
 - ❖ Falsified accounting ledgers entries and created false invoices in order to conceal that federal funds had been misspent

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Research Billing Irregularities

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CLINICAL TRIAL BILLING RULES

- Drug Studies
 - Clinical Trial Policy (CTP):
 - The National Coverage Determination (NCD 310.1) delineating routine costs in a qualifying clinical trial
- Device Trial Studies:
 - Device Regulations found in Medicare Benefit Policy Manual, Ch. 14
 - Stipulates coverage based on FDA category determination (Category A and B)
 - Requires Medicare approval in all cases
- Coverage with Evidence Based Development
- Everything else
 - Is there something investigational or experimental?
 - If yes, then see above.
 - If no, then defer to MAC for approval or defend as "reasonable and necessary"

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Determining A Qualifying Clinical Trial

Must be **one** of 4 types of trials deemed to meet 7 desirable characteristics

1. Funded by NIH, CDC, AHRQ, CMS, DOD or VA

OR

2. Supported by center or cooperative group funded by NIH, CDC, AHRQ, CMS, DOD or VA

OR

3. Conducted under an investigational new drug application (IND) reviewed by the FDA

OR

4. IND exempt under 21 CFR 312.2(b)(1)

Must meet **all three** necessary requirements

1. Evaluate an item or service that falls within a Medicare benefit category

2. Have therapeutic intent

3. Enroll patients with diagnosed disease

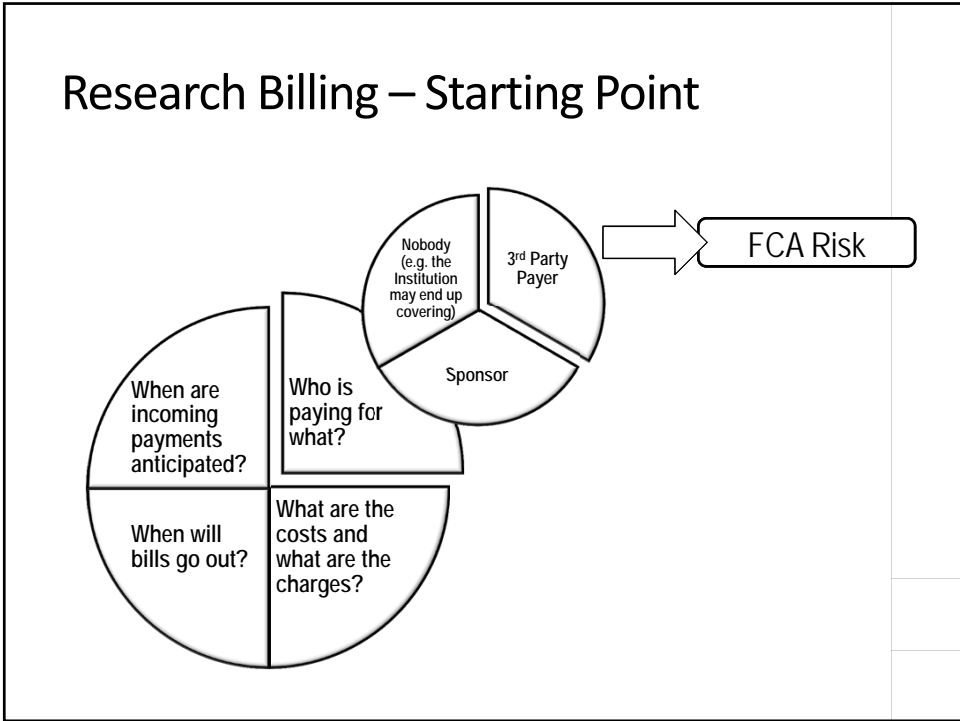
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Regulatory / Enforcement Framework for Research Billing

- Enforcers:
 - Department of Justice (DOJ)
 - Office of Inspector General (OIG)
 - Federal Bureau of Investigations (FBI)
 - State Attorney General
 - Health Care Fraud Prevention & Enforcement Action Team (HEAT)
 - The DOJ-HHS Medicare Fraud Strike Force is a multi-agency team of federal, state, and local investigators designed to fight Medicare fraud. The Force uses Medicare data analysis techniques and an increased focus on community policing to combat fraud.

Research Billing Compliance Risks

- 1 **FCA Violations**
- 2 **Double Dipping**
Payments from sponsors and from 3rd party payers for same item/service
- 3 **Inducement**
Investigator incentives may entice stacking of patients in studies
- 4 **Kickback**
Residual research account balances



Billing Irregularities and The False Claims Act

- A crime to knowingly make a false record or file a false claim
- Violations can result in significant fines and penalties
- Financial penalties to the person or organization includes recovery of three times the amount of the false claim(s), plus an additional penalty of \$5,500.00 to \$11,000.00 per claim
- **Example**

Item/Service	Claim Amount	Triple Damages	Subtotal	Penalty	Potential Total
Lab Test	\$200	\$600	\$800	\$11,000	\$11,800
CT Scan	\$1000	\$3000	\$4000	\$11,000	\$15,000
Hospital Admission	\$20,000	\$60,000	\$80,000	\$11,000	\$91,000

Billing Irregularities

- Drug Studies
 - Not performing a Coverage Analysis
 - Not following the Clinical Trial Policy (CTP)
 - Billing Medicare Advantage Programs for drug trials
- Device Trial Studies
 - Not following Device Regulations found in Medicare Benefit Policy Manual, Ch. 14
 - Billing incorrectly for the Device itself (Category A or B)
 - Lack of Medicare approval
- Coverage with Evidence Based Development
 - Not reporting CED with the NCT#
 - Not knowing that you have a CED trial or registry at your facility

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Billing Irregularities

- Billing for services not rendered
- Billing for services that are already paid by the sponsor, promised to be paid or promised free in the informed consent
- Billing for services that are for research-purposes only or are part of a non-qualifying clinical trial
- Billing Medicare for device trials without Centers for Medicare and Medicare Services (CMS) approval
- Bill Medicare Advantage Plans (Part C) when claims should be directed to the Medicare Administrative Contractor
- Billing for items or services not supported by required documentation
- Billing without proper codes, modifiers or NCT #

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Billing Irregularities Waiving Patient Payments

Government Payers

- The OIG has long taken the position that routine waiver of patient responsible amounts can constitute a type of healthcare fraud (OIG Special Fraud Alert, 1994).
- The OIG takes the position that waiver of co-payment is misstating the actual charge.
 - If a doctor states that his charge for a visit is \$100, but routinely waives the 20 percent copayment, the OIG feels the actual charge is \$80.
 - Medicare should be paying 80 percent of \$80 (or \$64), rather than 80 percent of \$100 (or \$80).
 - As a result, the Medicare program is paying \$16 more than it should for this item.

Billing Irregularities Waiving Patient Payments

Private Payers

- Insurance network contracts have long contained a provision that the physician will seek to collect the patient-responsible portion.
- Insurance auditors have begun to request evidence of attempts to collect coinsurance.
- Manuals state that the physician must actually collect this payment.
- If the physician cannot provide proof, the insurance company may demand repayment of benefits or terminate the contract.

Billing Irregularities Waiving Patient Payments

Two federal statutes prohibiting waivers of co-payments

- **Beneficiary Inducement Statute 42 U.S.C. 1320a-7a**
 - Prohibits the offer or payment of "remuneration" to a beneficiary by any person/entity if the person/entity knows (or should know) that the remuneration is likely to influence the beneficiary to obtain items or services from a particular supplier.
 - "Remuneration" specifically includes waivers or reductions of copayment amounts, **except when....**
- **Medicare Anti-Kickback Statute, 42 U.S.C. 1320a-7b(b)**
 - Prohibits, among other things, the offer or payment of remuneration to induce a person to purchase a Medicare or Medicaid-covered item or service.
 - The anti-kickback statute does not include a definition of "remuneration." It is generally accepted that the term includes transferring "anything of value."

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The Game Changer Settlement

- Rush University Medical Center \$1M - December 2005
 - Improperly billed Medicare for physician and hospital cancer research services as routine costs under the Medicare Clinical Trial Policy
 - Voluntary self-disclosure to DOJ in 2003
 - Was among the first settlements related solely to Medicare's CTP on clinical trials
 - Was principally the result of a lack of communication

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Recent Settlements

- Tenet USC Norris Cancer Hospital \$1.9M Settlement
 - Overbilling with oncology trials
 - Certain services performed in the course of cancer research studies that were not reimbursable by Medicare were billed when they should not have been
 - Billed for services paid for by sponsor and billed for service in non-qualifying studies
 - Self disclosure

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Recent Settlements

- University of Alabama Birmingham \$3.39M Settlement
 - Falsely billed Medicare for researcher's time spent on patient care when no patients had been seen
 - Falsely billed Medicare for clinical research trials that were also billed to the sponsor of the research grants

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Recent Settlements

- Emory University \$1.5M Settlement
 - Falsely billing Medicare and Medicaid for clinical trial services that were not permitted by the Medicare and Medicaid rules.
 - The clinical trial sponsor agreed to pay for services which in some instances was not ever invoiced by Emory to the sponsor per the contract.
 - Some services were promised free in the informed consent.

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