OIG’s Grants Oversight Role, Civil Monetary Penalty Authority, and Self-Disclosure Protocol

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Agenda

• OIG’s Role in Grants Oversight
• Recent Audits, Evaluations, and Enforcement
• Grant Fraud Civil Monetary Penalty Authority
• OIG Self-Disclosure Protocol
HHS OIG’s Role in Grants Oversight

OIG Mission

**Mission:** To protect the integrity of HHS programs and the welfare of the people they serve.

**Vision:** To drive positive change in HHS programs and in the lives of the people served by these programs.
OIG Mission

- Multidisciplinary
  - Investigations
  - Audits
  - Evaluations
  - Data Analytics
- Recommendations to HHS
- Improve economy, efficiency, and effectiveness
- Mitigate risk

OIG Oversight – Grants

- HHS grant funds used by qualified parties in manner envisioned by HHS
- Greater compliance = better use of limited resources
- Protects HHS funds and programs
Misspent Research Funds

- Limited public funds
- Financial loss
- Lost opportunity
- Unsound science
- Erodes support for public investment in research

Collaboration and Partnership

- Law enforcement partners – DOJ, FBI
- Other OIGs (NSF, NASA, DoD, and others)
- HHS Operating Divisions
- HHS Suspension and Debarment Official
OIG audits and evaluations have targeted known risk areas, including:

- Sub-Recipient Monitoring
- Reporting of Research Support and Affiliations
- Duplication and Overlap in Funding
- Conflicts of Interest
Recent Examples - OIG Audits and Evaluations

Audit of University of Minnesota’s Subrecipient Monitoring Efforts
https://oig.hhs.gov/oas/reports/region5/51800015.asp

Audit of University of Alabama-Birmingham’s F&A Cost Proposal
https://oig.hhs.gov/oas/reports/region4/41400095.asp

Audit of NIH Controls Related to Duplicate Grant Funding
https://oig.hhs.gov/oas/reports/region2/21902002.asp

Peer review:
Reviews of NIH’s Protection of Confidential Information During Peer Review Process

Reporting Support and Affiliations:
Audit of NIH Procedures and Policies to Ensure Recipients Report Outside Support and Affiliations
https://oig.hhs.gov/oas/reports/region3/31903003.asp

Conflicts of Interest:
Review of NIH’s Oversight of Financial Conflict of Interest Issues
https://oig.hhs.gov/oei/reports/oei-03-19-00150.asp

All OIG Audits:

All OIG Evaluations and Inspections:
https://oig.hhs.gov/reports-and-publications/oei/subject_index.asp
Grant-related Criminal Enforcement and False Claims Act Actions

False Statements

Gerwin Schalk, PhD (2020)

- Failed to disclose payments he was receiving from a company whose products Schalk regularly purchased and used in connection with his research
- Company paid principally through federal grant funds

Outcome:
- Pleased guilty to False Statements 18 U.S.C. § 1001
- 1 year probation
- $70,000 in restitution
- Termination
# Theft

**Alexander Neumeister (2018)**

- Psychiatrist and Former Yale and NYU Professor
- Routinely used grant funds for personal expenses, personal travel, trips for family and friends, and meals.

**Outcome:**
- Guilty, 18 U.S.C. § 641
- 3 years probation
- Criminal restitution

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# Falsified Data

**Duke University (2019)**

- Allegations: between 2006 and 2018, Duke knowingly submitted claims to NIH and EPA that contained falsified or fabricated data or statements related to 30 grants
- Airway Physiology Lab

**Outcome:**
- $112.5 million False Claims Act settlement
Indirect Costs

Columbia University (2016)

• Columbia admitted to applying the higher on-campus indirect cost rate for over 400 mental health research grants, even though the research was primarily performed in space not owned or operated by Columbia.

Outcome:
• $9.5 million False Claims Act settlement

Time and Effort Reporting

University of North Texas Health Science Center (2018)

• Self-disclosed to OIG and NIH that from 2011 through 2016, it had inaccurately reported time and effort spent by researchers on federally funded grants.
• Outcome: $13 million False Claims Act settlement

Harvard University (2020)

• Self-disclosed to USAO that professor and team overstated the time and effort spent working on certain NIH and PEPFAR grants for which they provided support
• Outcome: $1.3 million False Claims Act settlement
Return of Unobligated Funds

**UT Health Science Center Houston (2018)**

- Allegation: misappropriated unobligated funds remaining at the end of a grant term
- Human Genomics Center

Outcome:
- $2.39 million False Claims Act settlement

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**OIG Civil Monetary Penalty Authority**
Types of Fraud Enforcement Actions

- **Criminal**
  - Prosecutions
  - Judge/Jury
  - Guilt “beyond a reasonable doubt”

- **Civil**
  - Lawsuits
  - Federal False Claims Act
  - Judge/Jury
  - “Preponderance of Evidence”

- **Administrative**
  - Administrative Actions
  - Civil Monetary Penalty
  - Administrative Law Judge
  - “Preponderance of Evidence”

Civil Monetary Penalties Law

1981: HHS given statutory authority to impose civil money penalties, assessments, and/or exclusion upon individual/entities defrauding:

*Federal healthcare programs -- e.g., Medicare, Medicaid, and TRICARE.*
CMPL authority expanded to include fraudulent conduct involving:

*HHS grants, contracts and other agreements.*

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OIG CMP Basics

- Case Sources
- OCIG Evidence Gathering
- Demand Letter
- Appealable to Administrative Law Judge
- Federal Court Appeal
OIG CMP Affirmative Litigation Goals

Deter fraud, waste, and abuse in HHS programs

Complement DOJ Enforcement Activities
• Focus on individual accountability
• Filling enforcement gaps

Amplify Work of OIG
• Build off the work of OAS, OEI, and OI

New CMPL Offenses
42 U.S.C. §§ 1320a-7a(o)(1)-(5)

1. Presenting a false or fraudulent specified claim under an HHS grant.
Specified claims include:

1. Requests for payment to HHS or state agencies administering/supervising HHS grants; and
2. Requests for payment to HHS grantees by other entities if the funds are to be used on HHS’s behalf or to advance an HHS program or interest and if HHS:
   a. provides any portion of the money requested; or
   b. will reimburse the HHS grantee for any portion of the money which is requested.

*Full definition at 42 U.S.C. § 1320a-7a(r)

New CMPL Offenses
42 U.S.C. §§ 1320a-7a(o)(1)-(5)

1. Presenting a false or fraudulent specified claim under an HHS grant.
2. Making a false statement, misrepresentation, or omission in a grant submission.
3. Making or using a false record or statement related to an HHS grant.
4. Concealing or improperly avoiding an obligation owed under an HHS grant.
5. Failure to grant access to OIG.
### What Conduct Could Violate CMPL?

Misstating facts in grant applications, progress reports, certifications, other documents submitted to HHS about, e.g.:

- Qualifications/eligibility
- Expenses and budget details
- Facilities
- Personnel
- Project status or results

### What Conduct Could Violate CMPL?

Submitting false claims:

- Charging for costs not incurred or unallowable costs
- Charging personal expenses against grant
- Charging more than one grant for same work
What Conduct Could Violate CMPL?

Falsifying documents and lying to grant officials:
- Manufacturing time and effort records
- “Dummy invoices”
- Lying to agency officials administering grant
- Falsifying test results or data

Remedies

**Penalties:** between $10,000 and $50,000 per act

**Assessments:** recovery of up to 3 times the total amount of funds involved

**Exclusion:** bar from participation in all Federal health care programs (e.g., Medicare, Medicaid, TRICARE)

-- Exclusion under CMPL is *not* Suspension/Debarment
April 24, 2020 - Notice of Proposed Rulemaking

To update OIG CMP regulations (at 42 C.F.R. §§ 1003 and 1005)

• Incorporates into 42 C.F.R. §§ 1003 and 1005, among other things, OIG’s new statutory authority to impose sanctions for fraud and other improper conduct related to HHS grants, contracts, and other agreements.

Expressly gives individuals and entities sanctioned for fraud and other related to HHS grants, contracts, and other agreements, the same procedural and appeal rights that currently exist under 42 CFR parts 1003 and 1005 for those sanctioned under the CMPL and other statutes for fraud and other misconduct related to, among other things, the Federal health care programs.

(Issuance of demand letter, appeal to ALJ, rules of evidence, e.g.)

Comments due by June 23, 2020
Dr. Ravi Goyal (2019)

OIG alleged that Dr. Goyal, a researcher performing NIH-funded research at a CA university, submitted invoices to the university without disclosing to the university that the NIH funds the school used to pay those invoices would ultimately flow to a company Dr. Goyal owned.

Outcome:
• $73,975 CMPL settlement
Raiven Healthcare and James Stefansic (2019)

OIG alleged that Raiven Healthcare, a TN biotech company, submitted an NIH grant application that falsely represented that a community mental health center had agreed to recruit participants for the company’s proposed study. NIH had denied the funding application for reasons unrelated to the alleged misrepresentation.

Outcome:
- $40,000 CMPL settlement

Sonata Biosciences (2018)

OIG alleged that a CA biotech company made two unsupported drawdowns after work on its NIH SBIR grant was completed.

Outcome:
- $37,716 CMPL settlement
St. Charles Health Council (2018) and Pecos Valley Medical Center (2019)

OIG alleged that Federally-Qualified Health Centers in VA and NM drew down funds from capital development and infrastructure grants and used funds to cover operating expenses not related to the grants.

Outcomes:
• St. Charles -- $115,000 CMPL settlement
• Pecos Valley -- $70,000 CMPL settlement

OIG Grants Self-Disclosure Protocol
Types of Self-Disclosure

• Mandatory disclosure
  – 45 C.F.R. § 75.113
  – Violations of Federal criminal law that involve fraud, bribery, or gratuity violations
  – Disclose to both:
    • HHS Awarding Agency
    • OIG

• Voluntary disclosures
  – Conduct that violates CMPL or impacts award, but does not trigger the requirements of 45 C.F.R. § 75.113

Self-Disclosure

Self-Disclosure Information

The Office of Inspector General (OIG) has created self-disclosure procedures to be used by contractors, subcontractors, and other individuals who discover violations of Federal criminal law or program requirements and who wish to self-disclose the violations to the OIG in order to avoid, mitigate, or otherwise seek relief through the OIG’s False Claims Act and qui tam whistleblower provisions. Individuals who self-disclose fraud and abuse information to OIG may be eligible for a reward under the OIG’s Financial Integrity Reward Act (FIRA). For more information, please visit the following websites:

- Contractors: [Contractors’ Self-Disclosure](#)
- Subcontractors: [Subcontractors’ Self-Disclosure](#)
- Individuals: [Individuals’ Self-Disclosure](#)
Self-Disclosure

- A framework for evaluating, disclosing, and resolving potential violations of law related to their award
- A way for entities to meet mandatory disclosure obligations and make appropriate disclosures
- Broadly available to recipients, sub-recipients, applicants
Self-Disclosure Submission

Disclosing entity information
- Award information including program official, op-div
- Full description of conduct
  - Date learned of conduct
  - Types of conduct, transactions or claims giving rise to the matter
  - Time period
  - Names of people involved and explanation of roles in matter
  - Estimate of financial harm
- Corrective Action
- Certification

Resolution and Benefits of Self-Disclosure

- Favorable treatment compared to affirmative investigation
- Track record in health care: faster, cheaper, less disruptive
- OIG coordinates with awarding agencies
Self-Disclosure Settlements

To Submit a Self-Disclosure


- Self-disclosures may be submitted by email: [grantdisclosures@oig.hhs.gov](mailto:grantdisclosures@oig.hhs.gov)

- Or by mail to the following address:
  Office of Counsel to the Inspector General  
  Office of Inspector General  
  U.S. Department of Health and Human Services  
  Grant Self-Disclosures  
  330 Independence Avenue SW,  
  Cohen Building, Room 5527  
  Washington, DC 20201
To Report Fraud

1-800-HHS-TIPS

or

OIG website: http://oig.hhs.gov/

Questions?

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