



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

HCCA 2020 Research Compliance Conference
June 1, 2020

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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



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HHS OIG's Role in Grants Oversight



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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.



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OIG Mission

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



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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



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Misspent Research Funds

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



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Collaboration and Partnership

- Law enforcement partners – DOJ, FBI
- Other OIGs (NSF, NASA, DoD, and others)
- HHS Operating Divisions
- HHS Suspension and Debarment Official



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Audits and Evaluations



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OIG Audits and Evaluations

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



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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>



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Recent Examples - OIG Audits and Evaluations

Peer review:

Reviews of NIH's Protection of Confidential Information During Peer Review Process

<https://oig.hhs.gov/oei/reports/oei-05-19-00240.asp>

<https://oig.hhs.gov/oei/reports/oei-01-19-00160.asp>

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:

<https://oig.hhs.gov/reports-and-publications/oas/index.asp>

All OIG Evaluations and Inspections:

https://oig.hhs.gov/reports-and-publications/oei/subject_index.asp



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Grant-related Criminal Enforcement and False Claims Act Actions



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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:

- Pleaded guilty to False Statements 18 U.S.C. § 1001
- 1 year probation
- \$70,000 in restitution
- Termination



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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



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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



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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



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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



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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”



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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.



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21st Century Cures Act December 13, 2016

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



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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



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

1. Presenting a false or fraudulent *specified claim* under an HHS grant.



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“Specified Claim”

Specified claims include:*

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

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.



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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.



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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



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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



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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



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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



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Grant Fraud CMPL Notice of Proposed Rulemaking (85 F.R. 22979)

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.



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Grant Fraud CMPL Notice of Proposed Rulemaking (85 F.R. 22979)

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



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CMPL Grant Fraud Enforcement Examples



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CMPL Grant Fraud Enforcement Examples – NIH grantee

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



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CMPL Grant Fraud Enforcement Examples – NIH grantee

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



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CMPL Grant Fraud Enforcement Examples – NIH grantee

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



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CMPL Grant Fraud Enforcement Examples – HRSA grantees

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



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OIG Grants Self-Disclosure Protocol



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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

U.S. Department of Health and Human Services
Office of Inspector General

Search Submit a Complaint

About OIG Reports Fraud Compliance Exclusions Newsroom Careers

- Compliance
- Compliance Resource Portal
- Accountable Care Organizations
- Advisory Opinions
- Compliance Guidance
- Corporate Integrity Agreements
- Open Letters
- BAT-STATS
- Safe Harbor Regulations
- Self-Disclosure Information
- Special Fraud Alerts, Bulletins, and Other Guidance

Self-Disclosure Information

The Office of Inspector General (OIG) has several self-disclosure processes that can be used to report potential fraud in Department of Health and Human Services (HHS) programs. Choose the one that applies to you from the following descriptions to learn more.

Self-disclosures should not be reported to the OIG Hotline.

Health Care Provider Self-Disclosures

Health care providers, suppliers, or other individuals or entities subject to [Civil Monetary Penalties](#) can use the [Provider Self-Disclosure Protocol](#), which was created in 1998, to voluntarily disclose self-discovered evidence of potential fraud. Self-disclosure gives providers the opportunity to avoid the costs and disruptions associated with a Government-directed investigation and civil or administrative litigation. Visit the [Provider Self-Disclosure Protocol](#) webpage for more information.

HHS Contractor Self-Disclosures

Contractors are individuals, businesses, or other legal entities that are awarded Government contracts, or subcontracts, to provide services to the Department of Health and Human Services (HHS). OIG's contractor self-disclosure program enables contractors to self-disclose potential violations of the False Claims Act and various Federal criminal laws involving fraud, conflict of interest, bribery or gratuity. This self-disclosure process is available for those entities with a Federal Acquisition Regulation-based contract. Visit the [Contractor Self-Disclosure](#) webpage for more information.


HHS Grant Self-Disclosures

HHS grant recipients or 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.

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.

Visit the [HHS OIG Grant Self-Disclosure Program](#) webpage for more information.





Self-Disclosure

- [About OIG](#)
- [Reports](#)
- [Fraud](#)
- [Compliance](#)
- [Exclusions](#)
- [Newsroom](#)
- [Careers](#)

- [Compliance](#)
- [Compliance Resource Portal](#)
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- [Corporate Integrity Agreements](#)
- [Open Letters](#)
- [BAT-STATS](#)
- [Safe Harbor Regulations](#)
- [Self-Disclosure Information](#)
- [Special Fraud Alerts, Guidelines, and Other Guidance](#)

HHS OIG Grant Self-Disclosure Program

Mandatory Disclosures

HHS grant recipients or subrecipients must disclose evidence of potential violations of Federal criminal law involving fraud, bribery, or gratuity violations, potentially affecting the Federal award. Federal regulation, 48 C.F.R. 26.113, mandates disclosures of criminal offenses that non-Federal entities must make with respect to HHS grants. Please note that the Office of Inspector General does not track letters certifying that no violations of Federal criminal law have occurred, and it is not necessary for grant applicants or recipients to submit such certifications to OIG.

Voluntary Disclosures

Recipients of HHS awards may voluntarily disclose conduct creating liability under the Civil Monetary Penalty Law (CMPL), 48 U.S.C. § 1332a-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 48 C.F.R. § 26.113.

Self-Disclosure Guidance

Please review the [HHS OIG Grant Self-Disclosure Program Guidance](#) and the [Grant Self-Disclosure Submission Form](#) for more information.


Both mandatory and voluntary self-disclosures may be submitted by email to grant@disclosure.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-Disclosure
330 Independence Avenue SW,
Cohan Building, Room 5627
Washington, DC 20201

HHS OIG Grant Self-Disclosure Program Guidance


[Grant Self-Disclosure Submission Form](#)

[List of Recently Settled Grantee Self-Disclosures](#)



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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

HHS OIG
Grant Self-Disclosure Program
June 2014



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL





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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



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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



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Self-Disclosure Settlements

About OIG Reports Fraud Compliance Exclusions Newsroom Careers

Fraud
OIG Support/Enforcement
Consumer Alerts
Contract Fraud
Enforcement Actions
Fraud Risk Indicator
Grant Fraud
Healthcare Fraud Control Units
Waiver Fraud Filter Force
OIG Fraud Internal/External
Report Fraud
State-Fraud Control Unit
Business
Whistleblower Protection Coordinator

Grantee Self-Disclosure Settlements

Information on the Grantee Self-Disclosure Protocol can be found on the Self-Disclosure Information page.

2019

08-01-2019
After an audit disclosed conduct to OIG, Oklahoma State University (OSU), Oklahoma, agreed to pay \$15,885.53 for allegedly violating the Civil Monetary Penalties Law. OIG alleged that OSU submitted a schedule of fees and conditions claim to the Indian Health Service (IHS) Tribal Self-Governance Fund and the IHS Special Diabetes Program for Indians. OIG alleged these claims were unallowable because the funds were directed to personal use, including personal travel, entertainment, and personal gifts.

06-24-2019
After an audit disclosed conduct to OIG, The Health Care, Inc. (THC), Maryland, agreed to pay \$11,283.41 for allegedly violating the Civil Monetary Penalties Law. OIG alleged that THC employed an individual that knew or should have known was excluded from participation in Federal health care programs.

03-01-2019
After an audit disclosed conduct to OIG, Michigan State University (MSU), Michigan, agreed to pay \$47,200 for allegedly violating the Civil Monetary Penalties Law. OIG alleged that MSU used federal funds from a cooperative agreement titled "The First Center for Health Equity Institute" awarded by National Institutes of Health - National Institute on Minority Health and Health Disparities to reimburse a subrecipient who paid the subrecipient principal investigator for travel. OIG alleged this conduct violated applicable regulations restricting Federal award recipients from entering into covered transactions with debarred individuals, and the terms and conditions of the IHS

Related Information
• Background
CMP Navigation
• Civil Monetary Penalties and Offenses
• Exclusions
• Exclusions Self-Disclosure Settlements
• Exclusions Self-Disclosure Settlements
• Exclusions Self-Disclosure Settlements
• Exclusions Self-Disclosure Settlements



To Submit a Self-Disclosure

- Disclosure Information: <https://oig.hhs.gov/compliance/self-disclosure-info/index.asp>
- Self-disclosures may be submitted by email: 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/>



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Questions?

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