

11



Recent Examples - OIG Audits and Evaluations

Peer review:

Reviews of NIH's Protection of Confidential Information During Peer Review Process <u>https://oig.hhs.gov/oei/reports/oei-05-19-00240.asp</u> <u>https://oig.hhs.gov/oei/reports/oei-01-19-00160.asp</u>

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

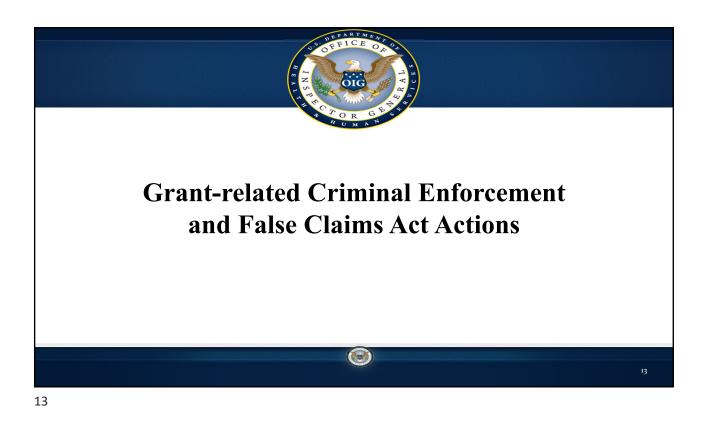
All OIG Audits:

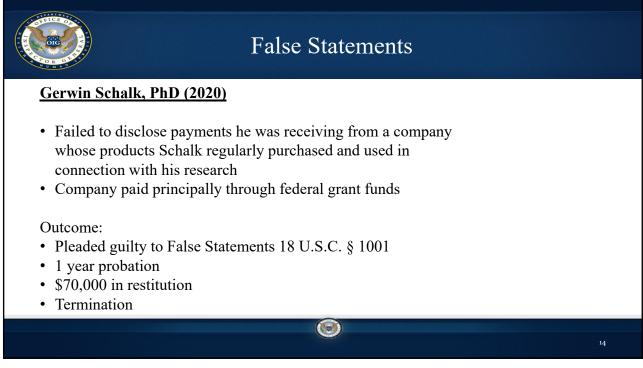
https://oig.hhs.gov/reports-and-publications/oas/index.asp

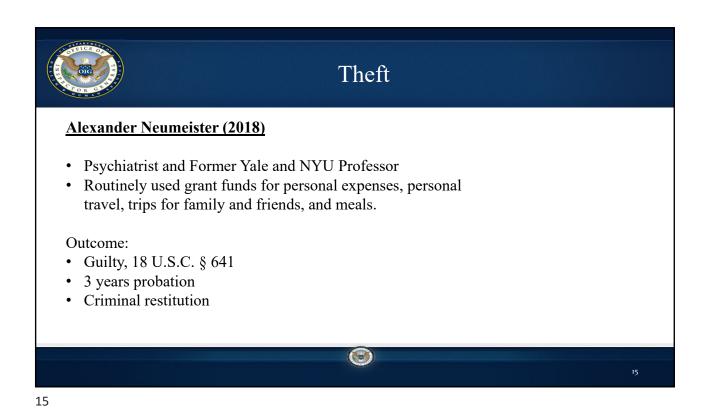
All OIG Evaluations and Inspections:

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









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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





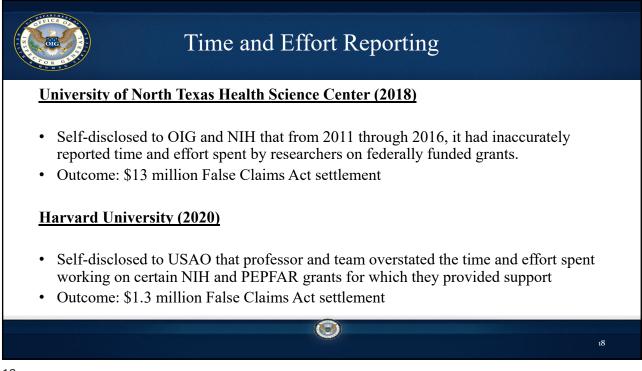
Indirect Costs

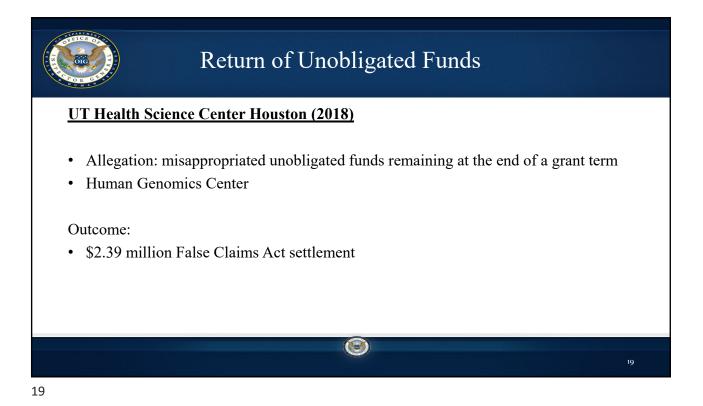
• Columbia admitted to applying the higher on-campus indirect cost rate for over 400 mental health research grants, even though the research was primarily performed in space not owned or operated by Columbia.

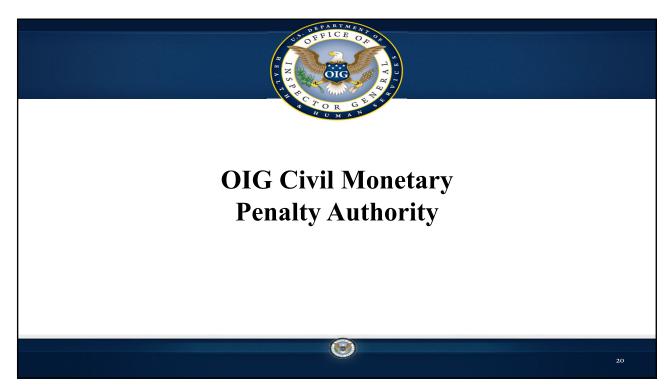
Outcome:

• \$9.5 million False Claims Act settlement

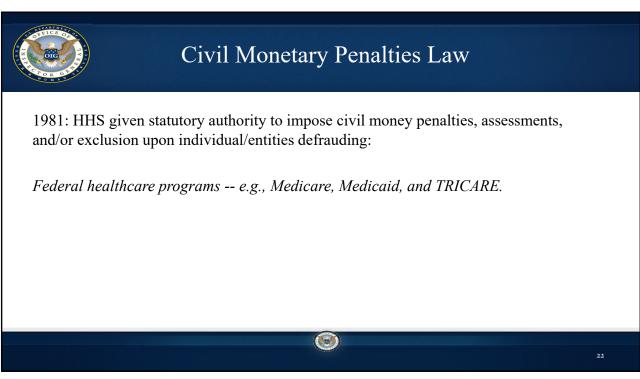
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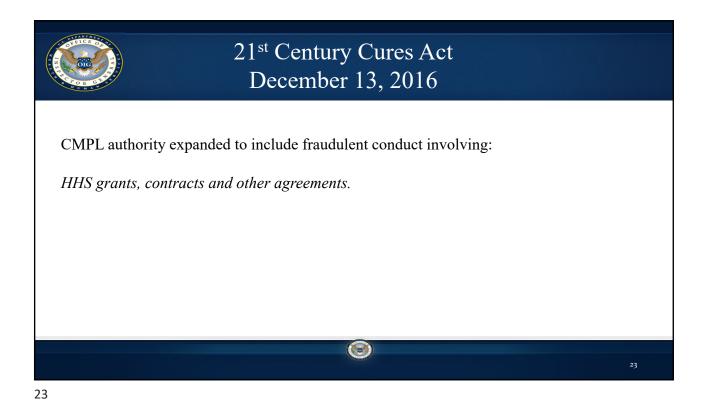


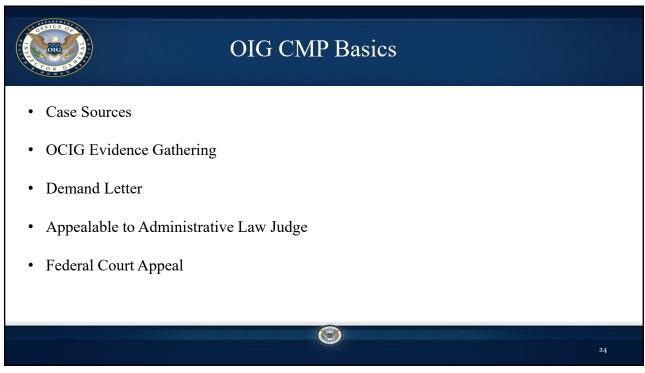




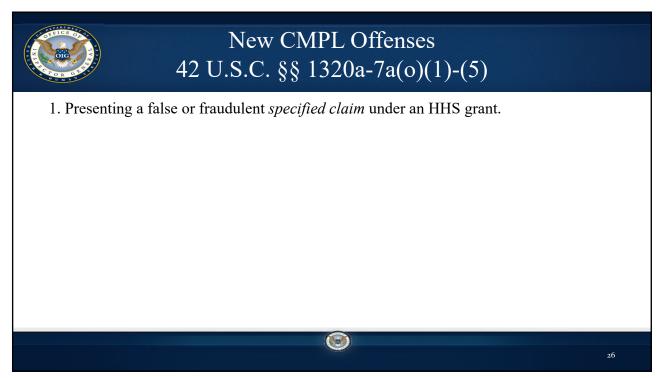


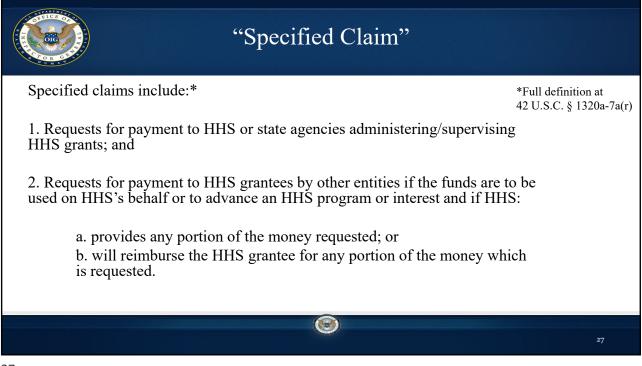




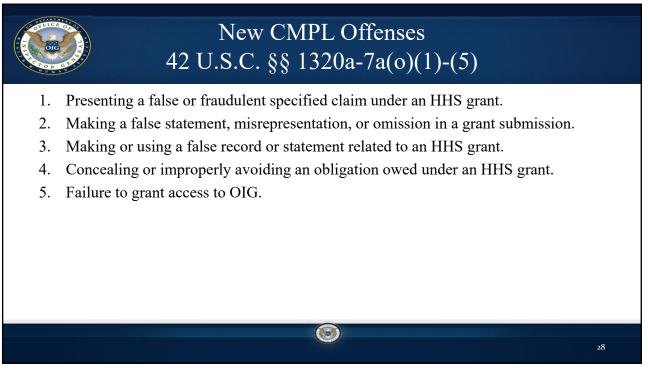


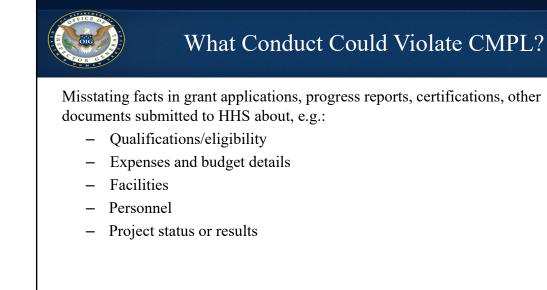


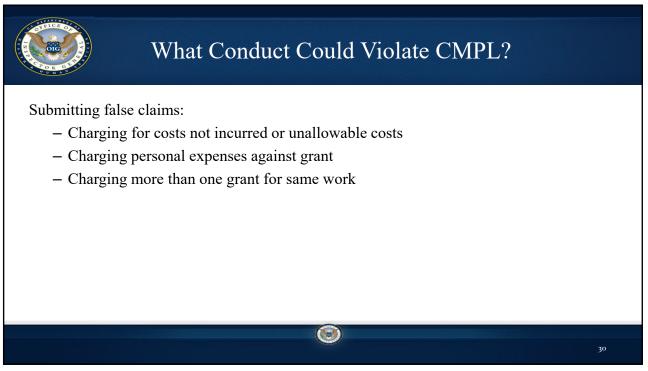


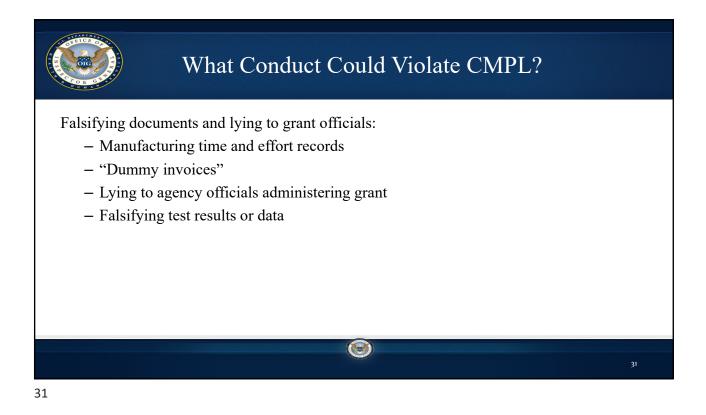


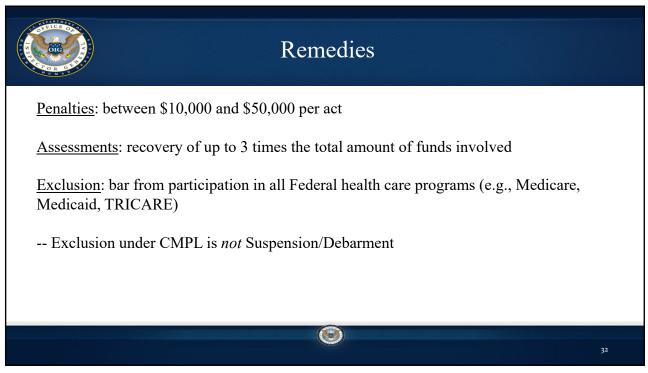


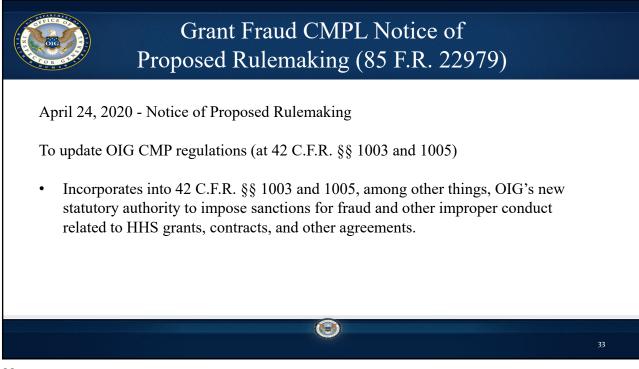




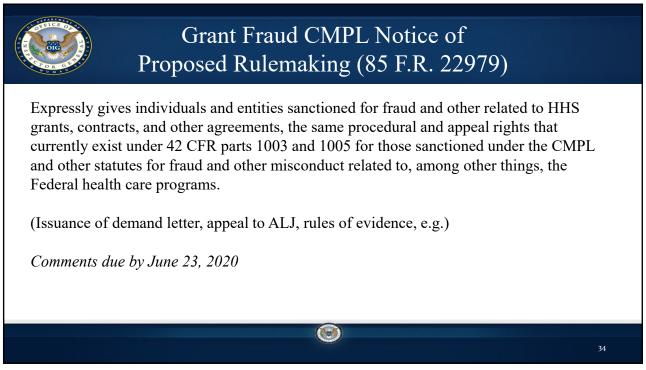


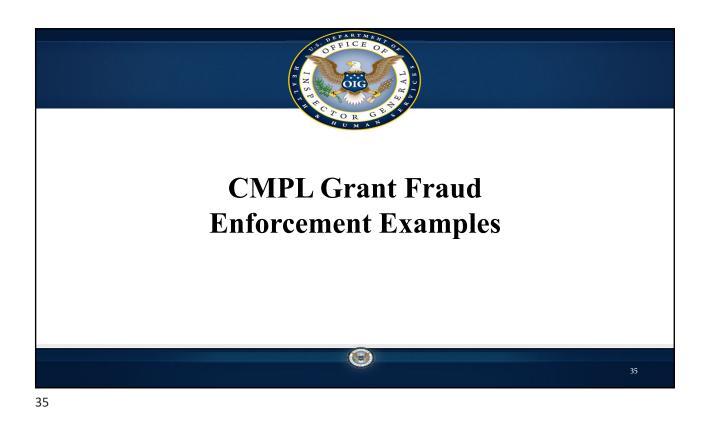


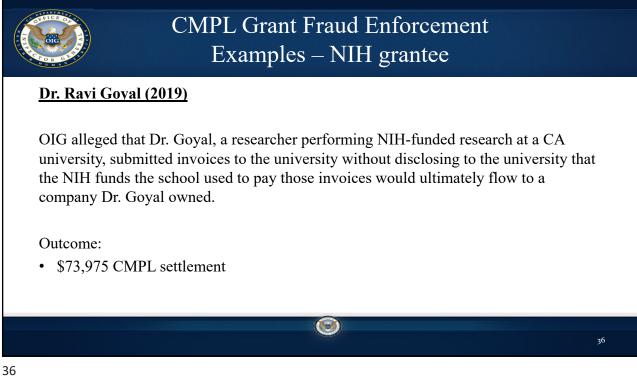








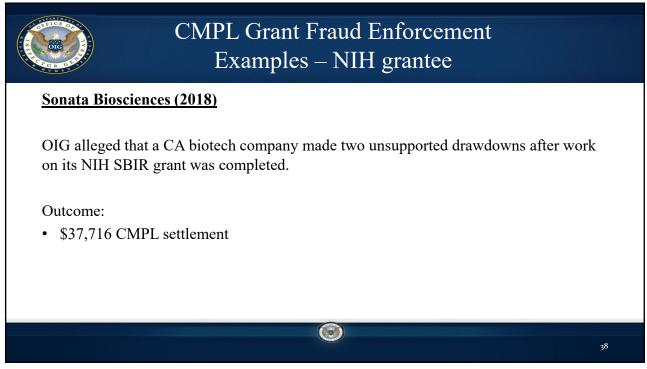




CMPL Grant Fraud Enforcement Examples – NIH grantee Raiven Healthcare and James Stefansic (2019) OIG alleged that Raiven Healthcare, a TN biotech company, submitted an NIH grant application that falsely represented that a community mental health center had agreed to recruit participants for the company's proposed study. NIH had denied the funding application for reasons unrelated to the alleged misrepresentation. Outcome:

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• \$40,000 CMPL settlement



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.

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Outcomes:

- St. Charles -- \$115,000 CMPL settlement
- Pecos Valley -- \$70,000 CMPL settlement



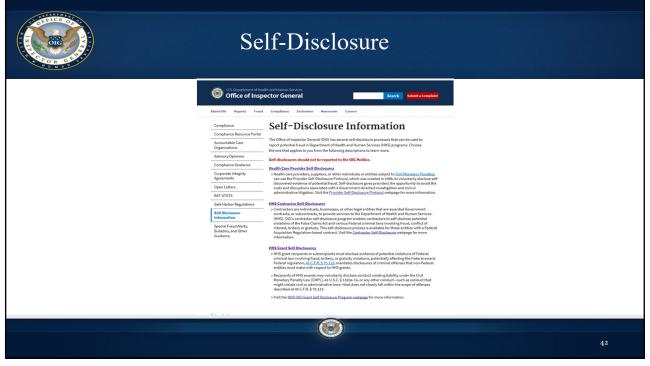


Types of Self-Disclosure

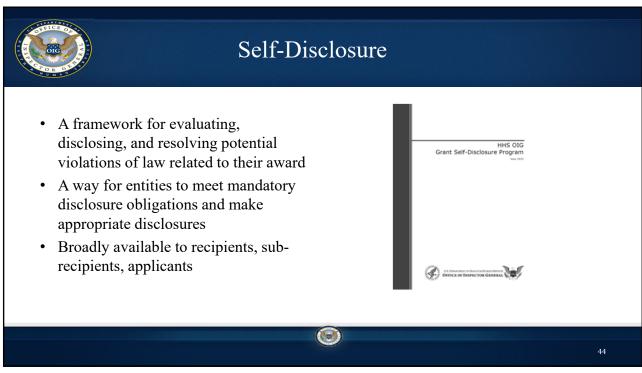
- Mandatory disclosure
 - 45 C.F.R. § 75.113
 - Violations of Federal criminal law that involve fraud, bribery, or gratuity violations
 - Disclose to both:
 - HHS Awarding Agency
 - OIG
- Voluntary disclosures
 - Conduct that violates CMPL or impacts award, but does not trigger the requirements of 45 C.F.R. § 75.113

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41









Self-Disclosure Submission

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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

45

