Protecting Indian Health and Human Services Programs and their Beneficiaries: The Basics of Health Care and Grants Management Compliance

Crazy Horse Memorial
Crazy Horse, South Dakota

April 27, 2017
Who We Are

The U.S. Department of Health & Human Services, Office of Inspector General’s (HHS OIG) mission is to protect the integrity of HHS programs – including Medicare, Medicaid, and programs run by the Indian Health Service – from fraud, waste, and abuse. We also strive to protect the health and well-being of the people served by those programs.

Our agency, which was established in 1976, operates in more than 70 offices nationwide. We oversee a department with more than $1 trillion dollars in HHS spending, which represents approximately 1/4 of every Federal dollar spent.

What We Do

We oversee department programs by performing audits, investigations, and evaluations, which results in timely information as well as cost-saving or policy recommendations for decision-makers and the public. We also work to develop cases for criminal, civil, and administrative enforcement.

We also provide the health care industry with guidance to comply with Federal fraud and abuse laws and to educate the public about fraudulent schemes so they can protect themselves and report suspicious activities.

HHS OIG & American Indians and Alaska Natives

HHS and its many agencies operate health and human services programs for American Indians and Alaska Natives (AI/ANs) through this country.

The Indian Health Service (IHS), which has an annual budget of approximately $6 billion, provides or funds a wide range of public health, clinical, and community services to approximately 2.2 million AI/ANs who are members of the 567 federally recognized Tribes located in 35 states. IHS and tribally-run facilities generally also serve as Medicare and Medicaid providers for eligible AI/ANs.

Other HHS agencies provide tribal grants for human services programs, ranging from Head Start to the Low Income Home Energy Assistance Program. OIG provides oversight over all HHS federal health care programs and grant programs that serve AI/ANs – through audits, evaluations, and investigations. We are committed to helping protect the HHS programs in Indian Country from fraud, waste, and abuse so that tribal beneficiaries receive the health and human services that are so important to their well-being.

Contact Us

The OIG website includes guidance that could be helpful to tribes: https://oig.hhs.gov/compliance. And you can report fraud, waste, and abuse in HHS programs by contacting our hotline: 1-800-HHS-TIPS (1-800-447-8477).
For Immediate Release
November 24, 2014

OIG Alerts Tribes and Tribal Organizations To Exercise Caution in Using Indian Self-Determination and Education Assistance Act Funds

Tribes that enter into ISDEAA contracts and Title V Self-Governance compacts with IHS must protect IHS funds from misuse. Further, all tribes that receive Medicare, Medicaid, and Children’s Health Insurance Program (CHIP) reimbursements must ensure that those funds are used in accordance with applicable Federal law, including the ISDEAA and the Indian Health Care Improvement Act (IHCIA).

Recent OIG investigations have revealed that some tribes and tribal organizations, or their officials, have not adequately protected these funds; as a result, the funds have been misappropriated or misused. In some cases, health care services for tribal members have been jeopardized.

Tribes may negotiate ISDEAA contracts with IHS, under which the tribes receive funds to provide health-care-related services directly to tribal members. Similarly, qualifying tribes may sign Self-Governance compacts with IHS and thereby exercise even more flexibility to use the compact funding for those programs, services, and functions that the tribes have agreed to provide. Tribes must use ISDEAA funds only to carry out activities that are authorized by law and included in the contract, compact, or funding agreements entered into with IHS. Use of ISDEAA funds for unallowable purposes is subject to disallowance by the Department of Health and Human Services (HHS).

The Affordable Care Act reaffirmed authority for tribal health programs to seek direct reimbursement from Medicare, Medicaid, and CHIP for health care services provided to

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1 For purposes of this alert, we use the word “tribes” to encompass all recipients of Indian Self-Determination and Education Assistance Act (ISDEAA) contracts and compacts with the Indian Health Service (IHS), including tribal organizations.
3 ISDEAA funds are distributed pursuant to Public Law 93-638, codified at 25 U.S.C. § 450 et seq.
individuals who are also eligible for those programs. Importantly, these reimbursements must be reinvested in health care services or facilities. With respect to compacts, Medicare and Medicaid reimbursements are to be treated as supplemental funding to the tribe’s Self-Governance compact. Tribes that improperly use reimbursements may lose their authority to directly bill Medicare, Medicaid, and CHIP.

Recent OIG investigations have uncovered instances in which tribes used ISDEAA funds to support unauthorized activities. In some cases, shared costs were not allocated correctly between IHS and other activities. In others, ISDEAA funds were “borrowed” to meet other tribal expenses. Sometimes Medicare or Medicaid reimbursements were not reinvested in activities furthering the purposes of the original contract or compact and were not even expended for health care services, but instead were used to cover general tribal deficits. In the most egregious cases, funds were converted to personal use, leaving the tribes with dangerous shortages in health care funding for its members.

The purpose of the limitations on uses of ISDEAA funds and Medicare/Medicaid/CHIP reimbursement is to direct urgently needed funding to health care services for American Indians and Alaska Natives. Tribes should be mindful of these restrictions and take steps to ensure that the funding and reimbursements are properly invested in this vital purpose.

Those who commit fraud involving HHS programs are subject to possible criminal, civil, and/or administrative sanctions.

# # #
Agenda

7:45-8:30  Registration

8:30-9:00  Welcome  
Lyndsay Patty, Special Assistant, Office of Evaluation and Inspections, and Conference Moderator

Opening Remarks  
Joanne Chiedi, Principal Deputy Inspector General

9:00-9:30  General Overview and Compliance Programs  
Amitava (Jay) Mazumdar, Deputy Branch Chief, Office of Counsel to the Inspector General  
Andrea Treese Berlin, Senior Counsel, Office of Counsel to the Inspector General

9:30-10:15  Internal Controls — Case Studies  
Patrick Cogley, Regional Inspector General for Audit Services, Kansas City, Office of Audit Services  
Debra Keasling, Assistant Regional Inspector General for Audit Services, Denver, Office of Audit Services  
Moderated By:  
Maritza Hawrey, Assistant Director for Grants and Internal Audits Division, Office of Audit Services

10:15-10:30  BREAK

10:30-11:00  Documentation  
Lucia Fort, Senior Advisor to the Chief of Staff  
Lisa Re, Assistant Inspector General for Legal Affairs, Office of Counsel to the Inspector General

11:00-11:30  Single Audits — Quality Matters  
Tammie Brown, NEAR Audit Manager, National Single Audit Coordinator, Office of Audit Services
11:30-12:15  **The Office of Investigations**  
Charles Hackney, Assistant Special Agent in Charge, Kansas City Regional Office, Office of Investigations

Curt Muller, Inspector, Special Investigations Branch, Office of Investigations

12:15-1:30  **Lunch on your own onsite**

1:30-2:15  **Fraud and Abuse Statutes, Administrative Authorities and Self-Disclosures**  
Andrea Treese Berlin, Senior Counsel, Office of Counsel to the Inspector General

2:15-3:15  **Ask the Experts Breakout Session**
- *Quality of care and service delivery*
  Amy Ashcraft and Lisa Re
- *Compliance programs and other tools for combatting fraud and abuse*
  Andrea Treese Berlin, Jay Mazumdar, and Melinda Golub
- *Internal controls and single audits*
  Tammie Brown, Debra Keasling, Pat Cogley, and Maritza Hawrey
- *Who is OIG and how does OIG work with IHS and tribes?*
  Curt Muller, Charles Hackney, Steve Hanson, Les Hollie, Brian Harris, Anissa Andrews, Corey Dumdei, and Justin Reedy

2:15-3:15  **Ask the Experts Breakout Session**
- *Quality of care and service delivery*
  Amy Ashcraft and Lisa Re
- *Compliance programs and other tools for combatting fraud and abuse*
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3:15-3:30  **Break**

3:30-4:30  **Achieving Quality of Care**  
Lisa Re, Assistant Inspector General for Legal Affairs, Office of Counsel to the Inspector General

Kate Goodrich, Director and Chief Medical Officer, CMS, HHS

David R. Wright, Director of Survey and Certification Group, CMS, HHS

Moderated By:
Amy Ashcraft

4:30  **Closing Remarks**  
Joanne Chiedi, Principal Deputy Inspector General

OIG staff will remain onsite until 5:30 to answer questions
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General Overview and Compliance Programs

1. Indian Health Service, Tribes, Medicare, and Medicaid
2. What is the Department of Health and Human Services Office of Inspector General?
   3. The Purpose of a Compliance Program
   4. Key Components of a Compliance Program
   5. Tips for Structuring a Compliance Program
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<th>Presenters</th>
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<tr>
<td><strong>Amitava (Jay) Mazumdar</strong></td>
<td><strong>Andrea L. Treese Berlin</strong></td>
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<td>Deputy Branch Chief</td>
<td>Senior Counsel</td>
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<td>Medicare and Medicaid Reviews</td>
<td>Administrative and Civil Remedies Branch</td>
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Indian Health Service, Tribes, Medicare, and Medicaid
Sec. 1880 of the Social Security Act authorizes Medicare payments to IHS facilities (whether operated by IHS or by a tribe) as long as the requirements for payment are met.

Sec. 1911 does the same for Medicaid.

Tribal entities operating an IHS facility under P.L. 93-638 bill Medicare and Medicaid under these provisions and additional requirements in IHCIA.
OIG 2014 Alert

• Tribes may use P.L. 93-638 funds only for purposes authorized by the law, the contract/compact, and the funding agreement.

• Medicare and Medicaid reimbursements must be reinvested in health care services or facilities. Non-compliance may lead to loss of billing authority.
OIG 2014 Alert

- Find the alert at:
  http://oig.hhs.gov/compliance/alerts/guidance/index.asp
The Affordable Care Act amended the Social Security Act to give the Secretary the authority to require Medicare and Medicaid providers, as a condition for enrollment, to establish a compliance program.

(See Social Security Act Sec. 1866(j).)
What is the Department of Health and Human Services Office of Inspector General (HHS/OIG)?
Office of Inspector General, U.S. Department of Health and Human Services

- Independent oversight agency within HHS
- The Inspector General is appointed by the President
- 1,500 employees, headquartered in Washington
- Oversight conducted from 9 or 10 regional offices, headed by Regional IGs or Special Agents in Charge
Oversight authority established by the Inspector General Act of 1978

- All Federal departments of OIGs
- Responsibilities include—
  - Conduct audits and investigations
  - Recommend policies to the Department to encourage economy and efficiency
  - Prevent and detect fraud, waste, and abuse
- Keep the Department and Congress informed
IG Act authority is limited to “programs and operations” of HHS:

- Medicare and Medicaid
- Indian Health Service
- Administration for Children and Families
- Health Resources and Services Administration
- Substance Abuse and Mental Health Admin.
- And nearly 100 other HHS programs
The Inspector General Act of 1978 gives OIG authority to:

• Have access to all records available to HHS
• Request assistance from other Federal, State, and local agencies
• Require by subpoena the production of all information necessary in the performance of IG Act functions
HHS/OIG “derivative” authority to obtain records

• Parts A (hospital), B (non-hospital), C (managed care), and D (prescription drugs)
  • Providers and entities must maintain information to support claims and for oversight

• Medicaid
  • providers and entities must keep information to support claims
HHS/OIG “derivative” authority to obtain records

• HHS grants
  • program rules require keeping financial and other pertinent records

• P.L. 638
  • Titles I and V require keeping financial information and access to HHS

• Because HHS has access to these, OIG does too.
HHS/OIG also provides technical assistance to health care providers, e.g.:

• Compliance guidance
• Advisory opinions
• Various OIG alerts
• Speeches and presentations before industry groups
The Purpose of a Compliance Program
Compliance Program?

Comply with what?
HHS grantees and health care providers must comply with a variety of rules, regulations, and laws, including:

- Medicare, Medicaid, and private coverage, billing, and coding requirements;
- Medicare conditions of participation;
- HIPAA privacy and security;
- Licensing and certification requirements;
- Drug and alcohol treatment privacy regulations (if applicable);
- Grant rules and regulations;
- The criminal prohibition on physician self-referrals (if applicable);
- And more. . . .
The government has a variety of tools to address non-compliance by grantees and health care entities, including:

- Administrative action, such as exclusion or termination;
- Suits under the False Claims Act;
- Civil Monetary Penalties;
- Disallowances and recovery of payments; and
- Criminal prosecution.

*A good compliance program will help you avoid all of these.*
Key Components of a Compliance Program
Seven Fundamental Elements

1. Written policies and procedures
2. Compliance professionals
3. Effective training
4. Effective communication
5. Enforcement of standards
6. Internal monitoring
7. Prompt response
Tips for Structuring a Compliance Program
Where Can I Look for Guidance?

OIG.HHS.GOV

Compliance 101
Provider Education
Voluntary Tribal Compliance Agreement

Other Integrity Agreements
Fraud Alerts
Tribal Alert
Grant Fraud
Ten Practical Tips

1. Make compliance plans a priority now

2. Designate (and empower!) an individual or team responsible for compliance
Ten Practical Tips

3. Know risk areas

4. Manage your sub-awards
Ten Practical Tips

5. Educate your employees

6. Carry a message of compliance from top to bottom
Ten Practical Tips

7 Conduct audits

8 Just because someone else does something doesn't mean you can or should
Ten Practical Tips

9. Open lines of communication

10. When in doubt, ask for help
Highlights from Voluntary Tribal Compliance Agreement

• Compliance Committee
• Independent Review Organization
• Training and Education Requirements
• Policies and Procedures
• Screening for Excluded Individuals
• Annual Reporting
Fundamentals vs. VTCA

Seven Fundamentals
- Written policies and procedures
- Compliance professionals
- Effective training
- Effective communication
- Enforcement of standards
- Internal monitoring
- Prompt response

Highlights of VTCA
- Compliance Committee
- Independent Review Organization
- Training and Education Requirements
- Policies and Procedures
- Screening for Excluded Individuals
- Annual Reporting
Questions?
INTERNAL CONTROLS – CASE STUDIES

Patrick Cogley – Regional Inspector General for Audit Services, Kansas City
Debra Keasling – Assistant Regional Inspector General for Audit Services, Denver
April 27, 2017
Objectives

- Why Have a Good Internal Control Structure
- Case Studies of Poor Internal Controls
- Best Practices to Help Prevent Errors, Fraud and Abuse
- Internal Control Resources
OMB Uniform Grant Guidance

• 2 CFR § 200.62 Internal control over compliance requirements for Federal awards: A process implemented by a non-Federal entity designed to provide reasonable assurance that
  • Transactions are properly recorded and accounted for,
  • Transactions are executed in accordance with Federal statutes, regulations, and the terms and conditions of the Federal award, and
  • Funds, property, and other assets are safeguarded against loss from unauthorized use.
Internal Control Requirements

• Required by 2 CFR § 200.303 “The non-Federal entity must establish and maintain effective internal controls over the Federal award that provides reasonable assurance that the non-Federal entity is managing the Federal award in compliance with Federal statutes, regulations, and the terms and conditions of the Federal award.
• Should be in compliance with GAO Standards and COSO standards.
What is internal control?
Framework that includes;
--5 components of internal control (includes Control Activities)
--17 principles of Internal Control
Management should design control activities to achieve objectives and respond to risks.

Management should design the entity’s information system and related control activities to achieve objectives and respond to risks.

Management should implement control activities through policies.
Uniform Guidance
Automated Systems

Uniform Guidance encourages efficient use of information technology and shared services:

• Updated provisions account for the efficient use of electronic information, as well as the acquisition and use of the information technology systems and shared services that permeate an effective and modern operating environment.

• Technology should be leveraged to improve control activities and reduce risk when cost-beneficial to do so.
Payroll Issues

- Salary payments - paper checks or direct deposit 2-days prior to the end of the pay period
  - Allowed employees salary advance
  - Duplicate Salary payments totaling $82,175 over a 2-year period to seven employees

- Excessive Retirement Benefits - Employees received a percentage of their gross wages as a retirement benefit
  - Allowed advances on retirement benefits
  - Allowed to request advance for several consecutive pay periods
  - Eight employees – excessive retirement benefits of $65,696 for 1-year
Payroll Issues

▶ Overtime Payments
  ➢ Two exempt employees received overtime payments - $31,800
  ➢ Non-exempt employees received overtime even though employee did not work a 40 hour work week (took annual or sick leave) - $12,360

▶ Excessive Annual Leave Benefits
  ➢ Employees received and used 548 hours of excessive annual leave totaling about $11,300
Best Practices/Control Activities

- All salary and retirement advances, earned and used leave, etc. should be tracked in payroll system in automated environment instead of tracking outside of payroll system.
- Establish a policy that requires employees to complete a “Request for Payroll Advance” form with written justification (should be based on hardship situation) and have form approved by manager and a payroll supervisor.
- Install computer edits to stop an employee from receiving more in salary and benefits than they are entitled.
- Managers should have access to payroll exception reports (Overtime, Payments in Excess of Specified Thresholds, etc.).
- Policies should be established to (1) authorize compensatory time in lieu of overtime, and (2) require supervisors to approve all overtime requests in advance.
Potential False Propane Delivery Tickets

Low-Income Home Energy Assistance Program - assist low-income households in meeting their immediate home energy needs

- Client complaints that they did not receive amount of propane ordered
- Invoices for propane did not support amount paid by Tribe
Best Practices/Control Activities

- Install meter on propane trucks to show digitally the amount of propane poured per client
- Consider a GPS location system to digitally show the location of the pour
Incorrectly Completing Federal Reports

Low-Income Home Energy Assistance

- Federal Reports Unsupported or Completed Incorrectly
  - Did not use financial information, such as general ledgers, to support reports
  - Did not compare budgeted grant funds to expended grant funds to ensure unobligated grant funds were returned to Federal Government
  - Because the tribe did not use general ledgers to complete Federal Financial reports, they need to refund to the Federal Government about $720,000
Best Practices/Control Activities

- Track money spent or pre-paid by grant year
- Use general ledgers to complete financial information (i.e. expended grant funds and unobligated grant funds) for Federal reports
- Establish a policy that requires a comparison of budgeted amounts to actual expenditures periodically throughout the year. Increase LIHEAP benefits if funds are available.
LIHEAP – Eligibility

- Administration for Children and Families (ACF) allows Tribes to define income for program eligibility
- Tribe included income types on LIHEAP application (wages, Social Security income, unemployment, leases etc.)
- Application not clear whether royalty income was considered income
- 10 Clients received $21,147 over 3 years in unallowable benefits
- 1 client had unreported income of $800,000 and received unallowable benefits totaling $4,425
Best Practices/Control Activities

- Tribe should formally define what it considers income
- Ensure that the applicants fully understand what is considered income by defining income in application instructions
- Contact BIA to determine who received royalty income
Internal Control Resources

- *Standards for Internal Control in the Federal Government* – by the Comptroller General of the United States dated September 2014
  
  
- Committee of Sponsoring Organizations of the Treadway Commission (COSO) - *Internal Control – Integrated Framework*
  
DOCUMENTATION

Julie K. Taitsman, M.D., J.D.
Chief Medical Officer
Office of Inspector General
U.S. Department of Health and Human Services
Documentation Is Important

- Patient Safety
- Program Integrity
- Provider Protection

DOCUMENTATION!
Complete Accurate Timely and Secure
Specificity

I DON'T ALWAYS GET SUCKED INTO A JET ENGINE

BUT WHEN I DO, I USE ICD-10 CODE: V97.33XD
Technology Agnostic
QUESTIONS

http://www.oig.hhs.gov
Single Audits – Quality Matters

Tammie S. Brown, CPA, CFE
Audit Manager
U.S. Department of Health & Human Services
Office of Inspector General
Office of Audit Services
National External Audit Resources
National Single Audit Coordinator

The Basics of Health Care and Grants
Management Compliance Conference
Crazy Horse Memorial
Crazy Horse, South Dakota
April 27, 2017
Single Audit Importance for Proper Grants Management

- Obtain assurance on the financial integrity of funded programs
- Identify possible noncompliance and other issues early
- Lower risk of future noncompliance
- Strengthen your ability to secure additional funding
Procuring Quality Single Audits

• Must comply with procurement standards in accordance with 45 CFR 75.326 through 75.335 of Subpart D
  • Positive efforts to utilize small businesses, minority–owned firms, and women owned business enterprises.
  • Ensure the objective and scope within the proposal are clear.
  • Obtain a copy of the auditor’s latest peer review. (required to provide per GAGAS)
  • No audit cost allowed if Audits are not conducted in accordance with appropriate standards and the Single Audit Act requirements.
Evaluation Factors to Consider

• Relevant Experience and Commitment to Quality
• Responsiveness to Request for Proposal (RFP)
• Availability of Staff with Professional Qualifications and Technical Abilities
• Peer Review Results
• Price (only after quality)
• Precluded Auditor
  • Indirect Cost Proposal
  • Independence
Important Contract Elements

- Stipulations on Additional Required Work
- Stipulations on Staffing Experience Levels to Work on the Audit
- Stipulation on Access to Audit Documentation
- Stipulation that Audit Reports Issued to the Entity are the Exclusive Property of the Auditee
- Management’s Responsibilities
Resolving Audit Findings

• Cooperative Audit Resolution
• Addressing Underlying Cause not just the Symptom
• Impact on Future Audits
The Office of Investigations

Charles Hackney
Assistant Special Agent in Charge
Kansas City Regional Office
DHHS - Office of Inspector General

Curt L. Muller
Inspector
Special Investigations Branch
DHHS - Office of Inspector General
Our Mission

OI’s mission is to protect the integrity of HHS programs.

OI conducts investigations of fraud and misconduct related to HHS programs, operations and employees.

- Criminal
- Civil
- Administrative
Working together

• There are 6 components who carry out this mission.
  • Immediate Office (IO)
  • Office of Policy and Management (OMP)
  • Office of Audit Services (OAS)
  • Office of Evaluation and Inspections (OEI)
  • Office of Counsel to the Inspector General (OCIG)
  • Office of Investigations (OI)
HHS FY 2016 Budget

$1,093 Billion in Outlays

- Medicare: 53%
- Medicaid: 32%
- Other Mandatory Programs: 2.2%
- TANF: 2%
- Discretionary Programs: 8%
- Children’s Entitlement Programs: 3%
Sources of OIG Referrals

State, Local & Tribal Agencies
Areas of Investigation

• Medicare & Medicaid fraud
• Prescription drug diversion
• Grant fraud
• HHS Employee misconduct
• Benefit enrollment fraud
• Tribal 638 program fraud
• Identity theft in relation to other fraud
• Other health insurance fraud
HHS Grant Funding

• Did you know that the Department of Health and Human Services is the largest grant-making organization in the Federal Government?

• In fiscal year (FY) 2015, HHS awarded approximately $410 billion in grants and over $21 billion in contracts.
HHS Grant Examples

• Low Income Home Energy Assistance Program (LIHEAP)
• Tribal Temporary Assistance to Needy Families (TANF)
• Child Care and Development Fund (CCDF)
• Head Start
• Tribal Child Support
Types of fraudulent conduct

- Theft/embezzlement (grant administrators/program directors)
- Bribery of Tribal officials and contractors
- Grantees and recipients providing false information on applications
- False documents including invoices and
- Unauthorized/inflated salaries (staff, family, friends)
- Wages paid yet no work performed
- Grant funds used for personal travel and other items of personal enhancement.
Fraud, Waste, and Abuse

THE FRAUD TRIANGLE

Pressure
Motivation or Incentive to Commit Fraud

Rationalization
Justification of Dishonest Actions

Opportunity
The Knowledge and Ability to Carry Out Fraud

The Fraud Triangle by Donald R. Cressey
The Special Investigations Branch (SIB) addresses allegations involving the approximately 85,000 HHS employees (Political Appointees, Senior Executive Service, Commissioned Corps and Traditional Government Workers) working for the Department including those with:

- Office of the Secretary
- Office of Inspector General
- National Institutes of Health
- Centers for Disease Control and Prevention
- Indian Health Service
- Food and Drug Administration
- Centers for Medicare & Medicaid Services
REPORT HEALTH CARE FRAUD

Call the OIG hotline: 800-HHS-TIPS
4 4 7 8 4 7 7

Report fraud and misconduct relating to Medicare or Medicaid services.

Phone: 1-800-HHS-TIPS
Fax: 1-800-223-8164
TTY: 1-800-377-4950

Mail: Office of Inspector General
U. S. Dept. of Health and Human Services
Attn: Hotline
PO Box 23489
Washington, DC 20026
Questions?

Thank you for your attention!

Questions?
1. The False Claims Act
2. Civil Monetary Penalties Law
3. The Anti-Kickback Statute
4. The Prohibition on Certain Physician Referrals (Stark Law)
5. The Inspector General’s Exclusion Authority
6. The Self-Disclosure Process
Presenter

Andrea L. Treese Berlin
Senior Counsel
Administrative and Civil Remedies Branch
U.S. Department of Health and Human Services
Office of Counsel to the Inspector General
Civil Cases

RELIATIONSHIPS
• Anti-Kickback Statute
• Prohibition on Certain Physician Referrals (Stark)
• Civil Monetary Penalties Law
• Exclusion

BILLING
• False Claims Act
• Civil Monetary Penalties Law
• Exclusion
The False Claims Act

31 U.S.C. Sections 3729-3733
The Federal False Claims Act

- Prohibitions on knowingly making--
  - False claim;
  - False record or statement;
  - Reverse false claim; or
  - Conspiracy.
- Treble damages.
- Per claim penalties.
The False Claims Act

Common Issues:

- Medical necessity
- Arrangements
- Worthless services
- 60 day repayment
- Data-driven cases
Civil Monetary Penalties Law

42 U.S.C. Section 1320a-7a
Types of Civil Monetary Penalties (CMP) Cases

- Kickbacks
- Physician referral (Stark) violations
- False or Fraudulent Claims
- Billing while excluded
- Select Agents
- Patient dumping (EMTALA)
- About 40 other OIG CMPs
Civil Monetary Penalties Law – Key Points

• Aside from 42 U.S.C. 1320a-7a, there are other CMPs are codified outside the CMPL, but incorporate the CMPL intent standards and procedures.

• CMPL is most often used by OIG as an alternative to civil action under the False Claims Act.

• DOJ authorization is required for a CMPL action, 42 U.S.C. § 1320a-7a(c)(1).

• OIG must prove the elements of a CMP action by preponderance of the evidence; Respondent has the burden to prove any mitigating factors and affirmative defenses.

• Six Year Statute of Limitations, 42 U.S.C. § 1320a-7a(c)(1).

• CMP, Assessments, and Exclusion available for most CMP cases.

• Administrative Law Judge Proceeding/Hearing, 42 U.S.C. § 1320a-7a(c)(2).
The Anti-Kickback Statute

42 U.S.C. § 1320a-7b(b)
The Anti-Kickback Statute

- Offer, Payment, Solicitation, or Receipt
- Remuneration
- Referrals
- Knowingly and Willfully
- Safe Harbors
Violations of the Anti-Kickback Statute

- Criminal
- Civil Monetary Penalties
- Exclusion
- False Claims Act Liability
- Non-Payment
- Refunds to Beneficiaries
Advisory Opinions (Ad Ops)
Ad Op FAQs
The Prohibition on Certain Physician Referrals (Stark Law)

42 U.S.C. Section 1395nn
Three Questions

• Is there a referral by a physician for a Medicare designated health service (DHS)?

• Does the physician have a financial relationship with the entity furnishing DHS?

• Does the financial relationship fit in an exception?
  • If not, there’s probably a violation
Violations of Stark Law

• Non-payment
• Refunds to beneficiaries
• Civil Monetary Penalties
• Exclusion
• False Claims Act Liability
Nutshell Stark

• Technical violations matter.

• Fair Market Value (FMV) matters even more.

• Evolving case law.

See CMS Advisory Opinions at:
cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html
The Inspector General’s Exclusion Authorities

Section 1128A of the Social Security Act
42 U.S.C. Section 1320a-7
Exclusion from Federal Health Care Programs
Section 1128 of the Social Security Act

Mandatory – Section 1128(a)
• Conviction of “program related” crime;
• Conviction of patient abuse and neglect;
• Felony conviction of health care fraud; and
• Felony conviction relating to controlled substances.
• Five year minimum.

Permissive – Section 1128(b)
• 16 authorities, including:
  • Certain misdemeanor convictions;
  • Loss of state license to practice;
  • Failure to repay health education loans; and
  • Failure to provide quality care.
Length of Exclusion

Generally defined period, but certain may be indefinite in length.

Must apply for and be granted Reinstatement.

Directions for application can be found at www.oig.hhs.gov.
What can you do?

Contact the OIG.

Negotiate a voluntary exclusion. Effective upon signing.
Procedure for Exclusions

**Derivative Exclusions** – Implemented and then the excluded individual or entity has a right to a hearing.

**Affirmative Exclusions** – By agreement or hearing.

See 42 C.F.R. sections 1001 *et. seq.* and www.hhs.gov/dab
OIG Self-Disclosure
Self-Disclosure

• Should I disclose?

• Where should I disclose?
  • Contractor
  • OIG
  • DOJ
  • CMS

• Get some advice.
Resolution

• OIG - Civil Monetary Penalties Law settlement.

• DOJ - False Claims Act settlement.

• No Corporate Integrity Agreement (if cooperative).
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 entites subject to Civil Monetary Penalties can use the Provider Self-Disclosure Protocol, which was created in 1999, 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 violations. 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 Grantee Self-Disclosures
- HHS grantees or subrecipients may voluntarily disclose evidence of potential violations of Federal criminal laws involving fraud, bribery, or gratuity violations, potentially affecting the Federal award. 45 C.F.R. 75.113 notes mandatory disclosures of criminal offenses that non-Federal entities must make with respect to HHS grants. Recipients submitting disclosures in connection with this requirement should include the subject reference line “Mandatory Grant Disclosure.” Recipients choosing to disclose conduct that may not fit squarely within the scope of offenses described in 45 C.F.R. 75.113, should include the following subject reference line “Mandatory Grant Disclosure.”

I'm looking for

- Accountable Care Organizations
- Advisory Opinions
- Compliance 101 and Provider Education
- Compliance Guidance
- Corporate Integrity Agreements
- Open Letters
- RAT-STATS
- Safe Harbor Regulations
- Self-Disclosure Information
- Special Fraud Alerts, Bulletins, and Other Guidance

EXCLUSIONS DATABASE
Self-Disclosure Protocol

Providers who wish to voluntarily disclose self-discovered evidence of potential fraud to OIG may do so under the Provider Self-Disclosure Protocol (SDP). Self-disclosure gives providers the opportunity to avoid the costs and disruptions associated with a Government-directed investigation and/or civil or administrative litigation.

Have you or any of your affiliates submitted a self-disclosure to the OIG in the past or currently have one pending? If so, please identify the submission date of the self-disclosure and list the name of the entity and affiliate.
On-Line Submission
OIG Self-Disclosure Protocol

- Make sure the submission is complete.
- Consult OIG’s website at: oig.hhs.gov.
Benefits of Self-Disclosure

• Cooperative Process.

• Likely a smaller settlement amount.

• Usually no integrity obligations.
Achieving Quality of Care

April 27, 2017

Crazy Horse Memorial, Crazy Horse, South Dakota
Panelists:

Kate Goodrich, MD
Director of Center for Clinical Standards and Quality and
Chief Medical Officer, CMS

Julie K. Taitsman, MD, JD
Chief Medical Officer, OIG

David R. Wright, MPA
Director of Survey and Certification Group,
Center for Clinical Standards and Quality, CMS

Moderator:

Amy Ashcraft, MPA
Deputy Regional Inspector General for Evaluation and Inspections (Dallas), OIG
Agenda:

Overview

Introductory remarks

Questions and discussion

Closing
Thank you!

For follow up questions, please contact Amy Ashcraft at Amy.Ashcraft@oig.hhs.gov