Medicare Parts C and D General Compliance Training

Lesson: Compliance Program Training

- Recognize how a compliance program operates; and
- Recognize how compliance program violations should be reported.

Compliance Program Requirement

- Articulate and demonstrate an organization's commitment to legal and ethical conduct;
- Provide guidance on how to handle compliance questions and concerns; and
- Provide guidance on how to identify and report compliance violations.

What Is an Effective Compliance Program?

- Prevents, detects, and corrects non-compliance;
- Is fully implemented and is tailored to an organization's unique operations and circumstances;
- Has adequate resources;
- Promotes the organization's Standards of Conduct; and
- Establishes clear lines of communication for reporting non-compliance.

Seven Core Compliance Program Requirements

1. **Written Policies, Procedures, and Standards of Conduct** These articulate the Sponsor's commitment to comply with all applicable Federal and State standards and describe compliance expectations according to the Standards of Conduct.

2. **Compliance Officer, Compliance Committee, and High-Level Oversight** The Sponsor must designate a compliance officer and a compliance committee that will be accountable and responsible for the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program.

- The Sponsor's senior management and governing body must be engaged and exercise reasonable oversight of the Sponsor's compliance program.

3. **Effective Training and Education** This covers the elements of the compliance plan as well as prevention, detection, and reporting of FWA. This training and education should be tailored to the different responsibilities and job functions of employees.

Seven Core Compliance Program Requirements (continued)

4. **Effective Lines of Communication** Effective lines of communication must be accessible to all, ensure confidentiality, and provide methods for anonymous and good-faith reporting of compliance issues at Sponsor and First-Tier, Downstream, or Related Entity (FDR) levels.

5. **Well-Publicized Disciplinary Standards** Sponsor must enforce standards through well-publicized disciplinary guidelines.

6**. Effective System for Routine Monitoring, Auditing, and Identifying Compliance Risks** Conduct routine monitoring and auditing of Sponsor's and FDR's operations to evaluate compliance with CMS requirements as well as the overall effectiveness of the compliance program.

- **NOTE:** Sponsors must ensure that FDRs performing delegated administrative or health care service functions concerning the Sponsor's Medicare Parts C and D program comply with Medicare Program requirements.

7. **Procedures and System for Prompt Response to Compliance Issues** The Sponsor must use effective measures to respond promptly to non-compliance and undertake appropriate corrective action.

Compliance Training–Sponsors and their FDRs

- CMS expects that all Sponsors will apply their training requirements and "effective lines of communication" to their FDRs. Having "effective lines of communication" means that employees of the Sponsor and the Sponsor's FDRs have several avenues to report compliance concerns.

Ethics–Do the Right Thing!

- Act fairly and honestly;
- Adhere to high ethical standards in all you do;
- Comply with all applicable laws, regulations, and CMS requirements; and
- Report suspected violations.

How Do You Know What Is Expected of You?

- **Everyone** has a responsibility to report violations of Standards of Conduct and suspected non-compliance.
- An organization's Standards of Conduct and Policies and Procedures should identify this obligation and tell you how to report suspected non-compliance.

What Is Non-Compliance?

Non-compliance is conduct that does not conform to the law, Federal health care program requirements, or an organization's ethical and business policies. CMS has identified the following Medicare Parts C and D high risk areas:

- Agent/broker misrepresentation;
- Appeals and grievance review (for example, coverage and organization determinations);
- Beneficiary notices;
- Conflicts of interest;
- Claims processing;
- Credentialing and provider networks;
- Documentation and Timeliness requirements;
- Ethics;
- FDR oversight and monitoring;
- Health Insurance Portability and Accountability Act (HIPAA);
- Marketing and enrollment;
- Pharmacy, formulary, and benefit administration; and
- Quality of care.

For more information, refer to the Compliance Program Guidelines in the "Medicare Prescription Drug Benefit Manual" and "Medicare Managed Care Manual" on the CMS website.

Non-Compliance Affects Everybody

How to Report Potential Non-Compliance

Employees of a Sponsor

- Call the Medicare Compliance Officer;
- Make a report through your organization's website; or
- Call the Compliance Hotline.

First-Tier, Downstream, or Related Entity (FDR) Employees

- Talk to a Manager or Supervisor;
- Call your Ethics/Compliance Help Line; or
- Report to the Sponsor.

Beneficiaries

- Call the Sponsor's Compliance Hotline or Customer Service;
- Make a report through the Sponsor's website; or
- Call 1-800-Medicare.

What Happens After Non-Compliance Is Detected?

- However, internal monitoring should continue to ensure:
  - There is no recurrence of the same non-compliance;
  - Ongoing compliance with CMS requirements;
  - Efficient and effective internal controls; and
  - Enrollees are protected.

What Are Internal Monitoring and Audits?

What Are Internal Monitoring and Audits?

- Internal monitoring activities are regular reviews that confirm ongoing compliance and ensure that corrective actions are undertaken and effective.
- Internal auditing is a formal review of compliance with a particular set of standards (for example, policies and procedures, laws, and regulations) used as base measures.

Lesson Summary

- Organizations must create and maintain compliance programs that, at a minimum, meet the seven core requirements. An effective compliance program fosters a culture of compliance.
- To help ensure compliance, behave ethically and follow your organization's Standards of Conduct. Watch for common instances of non-compliance, and report suspected non-compliance.
- Know the consequences of non-compliance, and help correct any non-compliance with a corrective action plan that includes ongoing monitoring and auditing.

Lesson Review

Knowledge Check

- You discover an unattended email address or fax machine in your office that receives beneficiary appeals requests. You suspect that no one is processing the appeals. What should you do?
- Select the correct answer.

  A. Contact law enforcement

  B. Nothing

  C. Contact your compliance department (via compliance hotline or other mechanism)

  D. Wait to confirm someone is processing the appeals before taking further action

  E. Contact your supervisor

Answer

- Correct answer:

- C: Contact your compliance department (via compliance hotline or other mechanism)

Knowledge Check

A sales agent, employed by the Sponsor's First-Tier or Downstream entity, submitted an application for processing and requested two things: 1) to back-date the enrollment date by one month, and 2) to waive all monthly premiums for the beneficiary. What should you do?

Select the correct answer.

- ○ A. Refuse to change the date or waive the premiums, but decide not to mention the request to a supervisor or the compliance department
- ○ B. Make the requested changes because the sales agent determines the beneficiary's start date and monthly premiums
- ○ C. Tell the sales agent you will take care of it, but then process the application properly (without the requested revisions) – you will not file a report because you don't want the sales agent to retaliate against you
- ○ D. Process the application properly (without the requested revisions) – inform your supervisor and the compliance officer about the sales agent's request
- ○ E. Contact law enforcement and the Centers for Medicare & Medicaid Services (CMS) to report the sales agent's behavior

Answer

- Correct answer:

- D: Process the application properly (without the requested revisions) – inform your supervisor and the compliance office about the sale agent's request

Knowledge Check

You work for a Sponsor. Last month, while reviewing a monthly report from the Centers for Medicare & Medicaid Services (CMS), you identified multiple enrollees for which the Sponsor is being paid, who are not enrolled in the plan. You spoke to your supervisor who said not to worry about it. This month, you have identified the same enrollees on the report again. What should you do?

Select the correct answer.

- A. Decide not to worry about it as your supervisor instructed – you notified him last month and now it's his responsibility
- B. Although you have seen notices about the Sponsor's non-retaliation policy, you are still nervous about reporting – to be safe, you submit a report through your compliance department's anonymous tip line so you cannot be identified
- C. Wait until the next month to see if the same enrollees appear on the report again, figuring it may take a few months for CMS to reconcile its records – if they are, then you will say something to your supervisor again
- D. Contact law enforcement and CMS to report the discrepancy
- E. Ask your supervisor about the discrepancy again

Answer

- Correct answer:

- B: Although you have seen notices about the Sponsor's non-retaliation policy, you are still nervous about reporting – to be safe, you submit a report through your compliance department's anonymous tip line so you cannot be identified.

Reporting

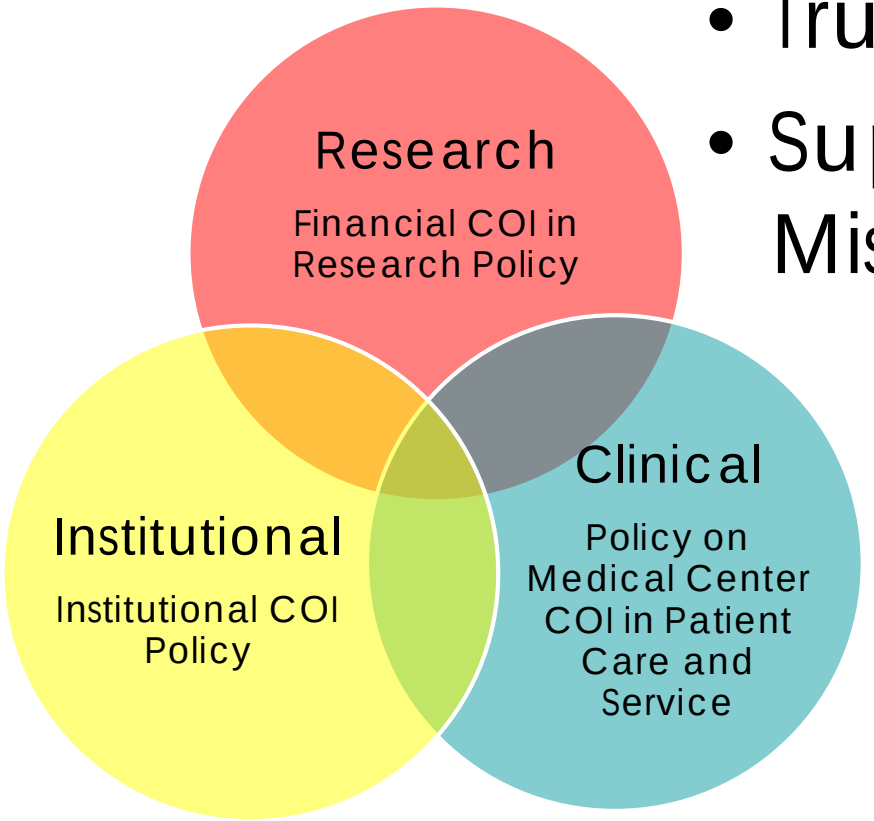
Saint Louis University Compliance Hotline

- Available and answered 24/7
- Caller / reporter may remain anonymous
- Protection provided

RESEARCH COMPLIANCE

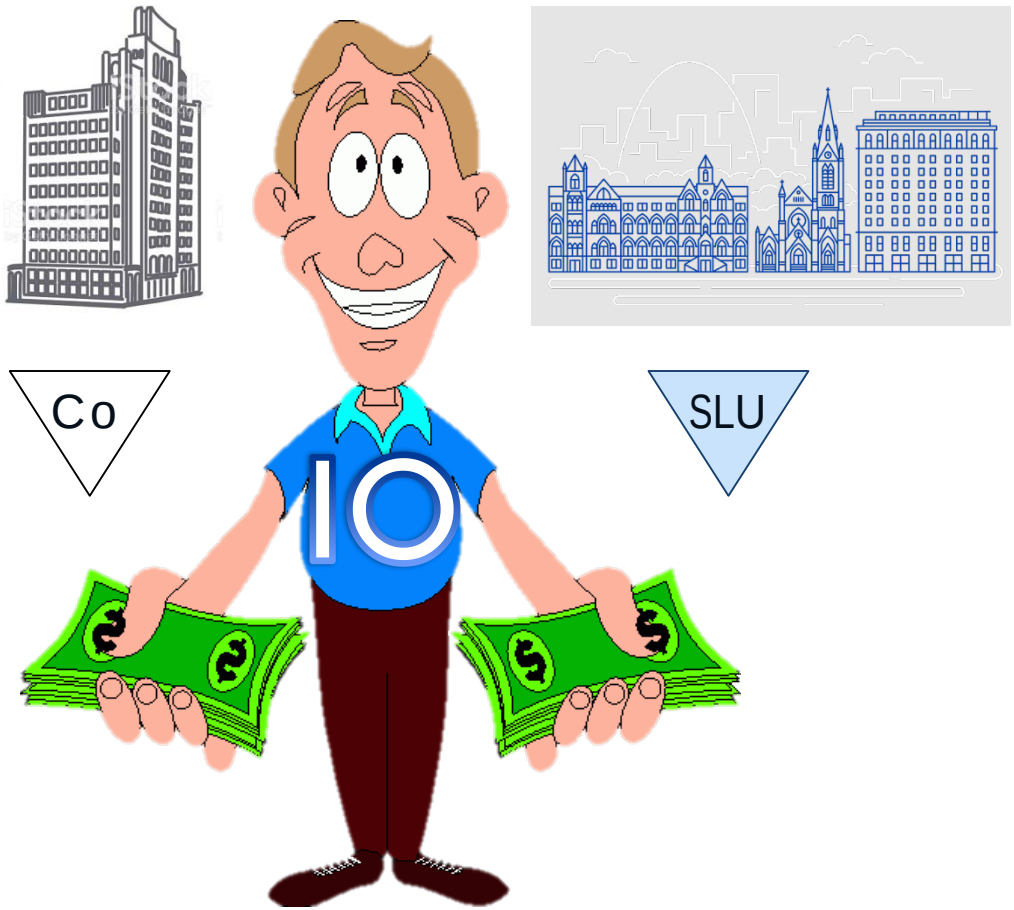
Why does the University care about Conflicts of Interest?

- Federal Regulations
- Accreditation Standards
- University Policies



- Trust is essential
- Supports our Mission

What is an Institutional COI?

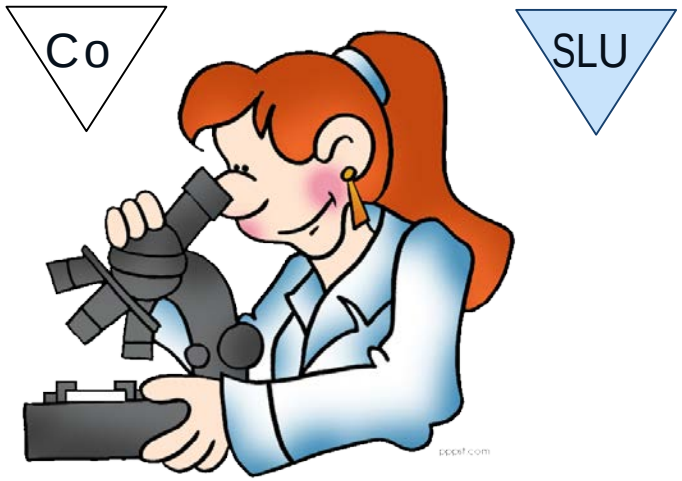


Situation where a SLU Institutional Official receives Something of Value that could create a perception of bias in any University research, education, clinical, or business transaction

What is a Clinical Conflict of Interest?

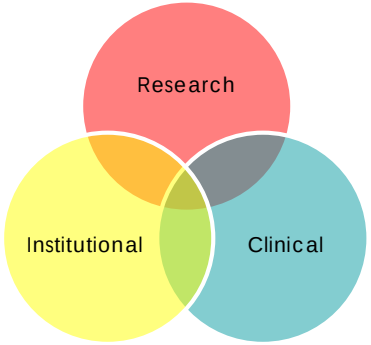
Situation where a SLU healthcare employee receives something of Value from industry that could create a perception of bias or questions the "Patient-Centeredness" of one's actions

What is a
Research Conflict of Interest?



Situation where a Researcher receives an outside financial benefit from their research sponsor that could directly & significantly affect the design, conduct or reporting of their research

How does this work?



The University values its role as a leader in healthcare & supports the creative ways in which our faculty work with external entities to commercialize innovations & bring therapies to patients.

The intent of identifying an ICOI is not to prohibit or discourage outside relationships, but to manage them, as to not compromise or appear to compromise the integrity of SLU's mission.

CONTRACTS

SLU*Care* Contracting Basics

Any contracting related to SLU*Care* must go through the legal review process.

If a contract is related to a New Business Initiative, it must also go through the Business Practice Change review process.

Please contact SLU*Care*'s Contracts Manger, Susan Caldwell, at **314-977-6890** as early in the conceptualization process as possible.

Authorized Individuals

The University maintains an approved list of individuals with the authority to sign contracts on behalf of the University.

These individuals, and **only** these individuals, should be signing University contracts.

Office of the General Counsel

314-977-2506

EXPORT CONTROLS

Export Controls

Federal Export Control regulations restrict the following exports:

- Tangible goods: technology, letters, software, or packages
- Communication: email and phone conversations
  - “Deemed Export”
- International travel
- Foreign Visitors/Vendors

Export Control Requirements

- International Travel
  - TMP
  - Clean Computers
- Research Agreements
- CDA/NDA
- Foreign Visitors/Vendors
  - Honorariums

Risk Management

Professional Letter of Indemnity and Liability Coverage at SLU

- Here at the University, we cover:
  - Faculty, Fellows, Residents, Medical Students, other staff
- For all occurrences that happen during your performance of duties for Saint Louis University
  - SMHC and CGCH: SSM indemnifies
- University is self-insured, and has excess coverage through commercial insurance
  - $2,000,000 per incident
  - Excess Coverage of an additional $25,000,000 per policy period

You Are Not Covered If...

- The injuries result from acts or omissions while under the influence, and criminal or intentional acts.
- Acts outside the normal course and scope of healthcare activity for the University.
- Claims or suits that are not promptly disclosed or reported.
- Failure to cooperate with Defense Counsel/Office of the General Counsel.

Reporting Incidents to Risk Management

- After an incident happens, please report immediately.
  - Call **(314) 977-URPT (8778)**
- If you have any questions about whether it should be reported, please call.

Health Sciences Center Office of the General Counsel 314-977-5767

When to Call Risk

- Adverse events with significant harm:
  - Medication Error, Fall, Treatment Complications, etc.
- Complications during procedures
- Unanticipated or Unexplained Death
- Retained Object
- Anesthesia Problems

Post-Assessment