Medicare Parts C and D General Compliance Web-Based Training Course January 2018*



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ACRONYMS

The following acronyms are used throughout the course.

ACRONYM	TITLE TEXT
CFR	Code of Federal Regulations
CMS	Centers for Medicare & Medicaid Services
FDR	First-tier, Downstream, and Related Entity
FWA	Fraud, Waste, and Abuse
HHS	U.S. Department of Health & Human Services
MA	Medicare Advantage
MAO	Medicare Advantage Organization
MA-PD	MA Prescription Drug
MLN	Medicare Learning Network®
OIG	Office of Inspector General
PDP	Prescription Drug Plan



INTRODUCTION

The Medicare Parts C and D General Compliance Training course is brought to you by the Medicare Learning Network® *







INTRODUCTION PAGE 2

The Medicare learning Network® (MLN) offers free educational materials for health care professionals on the Center for Medicare & Medicaid Services (CMS) programs, policies and initiatives. Get quick access to the information you need.

- Publications and Multimedia
- Events & Training
- Newsletters & Social Media
- Continuing Education



Hyperlink URL

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProductshttps://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-

MLN/MLNGenInfo/Events-and-Training.html

https:\\www.cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg

https:\\www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-

MLN/MNLGenInfo/Continuing-Education.html

<u>Linked Text/Image</u>

Publications & Mutlimedia

Events & Training Newsletters & Social Media

Continuing Education



INTRODUCTION PAGE 3

This training assists Medicare Parts C and D plan Sponsors' employees, governing body members, and their first-tier, downstream, and related entities (FDRs) to satisfy their annual general compliance training requirements in the regulations and sub-regulatory guidance at:

- 42 Code of Federal Regulations (CFR) Section 422.503(b)(4)(vi)(C)
- 42 CFR Section 423.504(b)(4)(vi)(C)
- Section 50.3 of the Compliance Program Guidelines (Chapter 9 of the Medicare Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual)
- The "Downloads" section of the CMS Compliance program Policy and Guidance webpage

Completing this training in and of itself does not ensure a Sponsor has an "effective Compliance Program." Sponsors and their FDRs are responsible for establishing and executing an effective compliance program according to the CMS regulations and program guidelines.

HYPERLINK URL	LINKED TEXT/IMAGE
https://www.ecfr.gov/cgi-bin/text- idx?SID=c66a16ad53319afd0580db00f12c5572&mc=true&node=pt42.3.422&rg n=div5#se42.3.422_1503	42 Code of Federal Regulations (CFR) Section 422.503
https://www.ecfr.gov/cgi- bin/retrieveECFR?gp=&SID=5cff780d3df38cc4183f2802223859ba&mc=true&r =PART&n=pt42.3.423	42 CFR Section 423.504
https://www.cms.gov/Medicare/Prescription-Drug- Coverage/PrescriptionDrugCovContra/Downloads/Chapter9.pdf	Chapter 9 of the Medicare Prescription Drug Benefit Manual
https://www.cms.gov/Regulations-and- Guidance/Guidance/Manuals/Downloads/mc86c21.pdf	Chapter 21 of the Medicare Managed Care Manual
https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ComplianceProgramPolicyandGuidance.html	CMS Compliance Program Policy and Guidance webpage

INTRODUCTION PAGE 4

Why Do I Need Training?

Every year, **billions** of dollars are improperly spent because of fraud, waste, and abuse (FWA). It affects everyone—**including you**. This training helps you detect, correct, and prevent FWA. **You** are part of the solution.

Compliance is everyone's responsibility! As an individual who provides health or administrative services for Medicare enrollees, every action you take potentially affects Medicare enrollees, the Medicare Program, or the Medicare Trust Fund.



INTRODUTION PAGE 5

Training Requirements: Plan Employees, Governing Body Members, and First-Tier, Downstream, or Related Entity (FDR) Employees

Certain training requirements apply to people involved in Medicare Parts C and D. All employees of Medicare Advantage Organizations (MAOs) and Prescription Drug Plans (PDPs) (collectively referred to in this course as "Sponsors") must receive training about compliance with CMS program rules.

You may need to complete FWA training within 90 days of your initial hire. More information on other Medicare Parts C and D Compliance trainings and answers to common questions is available on the CMS website. Please contact your management team for more information.

Learn more about Medicare Part C

Medicare Part C, or Medicare Advantage (MA), is a health insurance option available to Medicare beneficiaries. Private, Medicare-approved insurance companies run MA programs. These companies arrange for, or directly provide, health care services to the beneficiaries who enroll in an MA plan.

MA plans must cover all services Medicare covers with the exception of hospice care. They provide Part A and Part B benefits and may also include prescription drug coverage and other supplemental benefits.

Learn more about Medicare Part D

Medicare Part D, the Prescription Drug Benefit, provides prescription drug coverage to Medicare beneficiaries enrolled in Part A and/or Part B who enroll in a Medicare Prescription Drug Plan (PDP) or an MA Prescription Drug (MA-PD) plan. Medicare- approved insurance and other companies provide prescription drug coverage to individuals living in a plan's service area.

HYPERLINK URL	LINKED TEXT/IMAGE
https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-	Medicare Parts C and D compliance trainings and answers to
MLN/MLNProducts/Downloads/Fraud-Waste Abuse-Training 12 13 11.pdf	common questions



INTRODUCTION PAGE 6

Navigating and Completing This Course

Anyone who provides health or administrative services to Medicare enrollees must satisfy general compliance and FWA training requirements. You may use this course to satisfy the general compliance training requirements.

This course consists of one lesson and a Post-Assessment. Successfully completing the course requires completing the lesson and scoring 100 percent on the Post-Assessment. This course uses cues at various times to provide additional information and functionality. You do not have to complete this course in one session; however, you must complete the lesson before exiting the course. You can complete the entire course in about 25 minutes.

Visit the CMS <u>Resources</u> page for disclaimers, a glossary, and frequently asked questions (FAQs). You may find this information useful as you proceed through this course.



INTRODUCTION PAGE 7

Course Objectives

After completing this course, you should correctly:

- Recognize how a compliance program operates
- Recognize how compliance program violations should be reported



LESSON: COMPLIANCE PROGRAM TRAINING

LESSON PAGE 1

Introduction and Learning Objectives

This lesson outlines effective compliance programs. It should take about 15 minutes to compete. After completing the lesson, you should correctly:

- Recognize how a compliance program operates
- Recognize how compliance program violations should be reported



Compliance Program Requirement

The Centers for Medicare & Medicaid Services (CMS) requires Sponsors to implement and maintain an effective compliance program for its Medicare Parts C and D plans. An effective compliance program must:

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



What Is an Effective Compliance Program?

An effective compliance program fosters a culture of compliance within an organization and, at a minimum:

- 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
- Establishes clear lines of communication for reporting non-compliance

An effective compliance program is essential to prevent, detect, and correct Medicare non-compliance as well as fraud, waste, and abuse (FWA). It must, at a minimum, include the seven core compliance program requirements.



Seven Core Compliance Program Requirements

CMS requires an effective compliance program to include seven core 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 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. Tailor this training and education to the different employees and their responsibilities and job functions.

Seven Core Compliance Program Requirements (continued)

Effective Lines of Communication

Make effective lines of communication accessible to all, ensure confidentiality, and provide methods for anonymous and good-faith compliance issues reporting 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.



LESSON PAGE 6

Compliance Training: Sponsors and Their FDRs

CMS expects 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!

As part of the Medicare Program, you must conduct yourself in an ethical and legal manner. It's about doing 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
- Report suspected violations



How Do You Know What Is Expected of You?

Now that you've read the general ethical guidelines on the previous page, how do you know what is expected of you in a specific situation?

Standards of Conduct (or Code of Conduct) state the organization's compliance expectations and their operational principles and values. Organizational Standards of Conduct vary. The organization should tailor the Standards of Conduct content to their individual organization's culture and business operations. Ask management where to locate your organization's Standards of Conduct.

Reporting Standards of Conduct violations and suspected non-compliance is everyone's responsibility.

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 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
- Quality of care

For more information, refer to the Compliance Program Guidelines in the Medicare Prescription Drug Benefit Manual and Medicare Managed Care Manual

Know the Consequences of Non-Compliance

Failure to follow Medicare Program requirements and CMS guidance can lead to serious consequences, including:

- Contract termination
- Criminal penalties
- Exclusion from participating in all Federal health care programs
- Civil monetary penalties

Additionally, your organization must have disciplinary standards for non-compliant behavior. Those who engage in non-compliant behavior may be subject to any of the following:

- · Mandatory training or re-training
- Disciplinary action
- Termination





HYPERLINK URL	LINKED TEXT/IMAGE
https://www.cms.gov/Medicare/Prescription-Drug-	Medicare Prescription Drug Benefit Manual
Coverage/PrescriptionDrugCovContra/Downloads/Chapter9.pdf	
https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf	Medicare Managed Care Manual

NON-COMPLIANCE AFFECTS EVERYBODY

Without programs to prevent, detect, and correct non-compliance, we all risk:

Harm to beneficiaries, such as:

- Delayed services
- Denial of benefits
- Difficulty in using providers of choice
- Other hurdles to care

Less money for everyone, due to:

- High insurance copayments
- Higher premiums
- Lower benefits for individuals and employers
- Lower Star ratings
- Lower profits



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.

Don't Hesitate to Report Non-Compliance

When you report suspected noncompliance in good faith, the Sponsor can't retaliate against you. Each Sponsor must offer reporting methods that are:

- Anonymous
- Confidential
- Non-Retaliatory



What Happens After Non-Compliance Is Detected?

Non-compliance must be investigated immediately and corrected promptly. Internal monitoring should ensure:

- No recurrence of the same non-compliance;
- Ongoing CMS requirements compliance;
- Efficient and effective internal controls; and
- Protected enrollees.



LESSON PAGE 13

What Are Internal Monitoring and Audits?

Internal monitoring activities include regular reviews confirming ongoing compliance and taking effective corrective actions.

Internal auditing is a formal review of compliance with a particular set of standards (for example, policies, 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.

Compliance is Everyone's Responsibility!

Prevent: Operate within your organization's ethical expectations to prevent noncompliance!

Detect & Report: Report detected potential non-compliance!

Correct: Correct non-compliance to protect beneficiaries and save money!



LESSON PAGE 15

Lesson Review

Now that you completed the lesson, let's do a quick knowledge check. The Post-Assessment course score is unaffected by answering the following questions.



Knowledge Check

Select the correct answer:

You discover an unattended email address or fax machine in your office receiving beneficiary appeals requests. You suspect no one is processing the appeals. What should you do?

- 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

Correct Answer: C



Knowledge Check

Select the correct answer.

A sales agent, employed by the Sponsor's first-tier, downstream, or related entity (FDR), 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?

- 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

Correct Answer: D



Knowledge Check

Select the correct answer.

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

- A. Decide not to worry about it as your supervisor instructed—you notified your supervisor last month and now it's his
 responsibility
- B. Although you know 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 to avoid identification
- 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

Correct Answer: B



Knowledge Check

Select the correct answer.

You are performing a regular inventory of the controlled substances in the pharmacy. You discover a minor inventory discrepancy. What should you do?

- A. Call local law enforcement
- B. Perform another review
- C. Contact your compliance department (via compliance hotline or other mechanism)
- D. Discuss your concerns with your supervisor
- E. Follow your pharmacy's procedures

Correct Answer: E



LESSON PAGE 20

You've Completed the Lesson!

You have completed the CMS Medicare Learning Network ® portion of Part 1 of Saint Louis University's Annual Compliance Update Training. There is additional content at the end of the Appendices specific to Saint Louis University. Please listen carefully as you will be tested over the additional material.



Appendix A: Resources

RESOURCES PAGE 1 OF 1

Disclaimers

This Web-Based Training (WBT) course was current at the time it was published or uploaded onto the web. Medicare policy changes frequently so links to the source documents have been provided within the course for your reference.

This course was prepared as a service to the public and is not intended to grant rights or impose obligations. This course may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations, and other interpretive materials for a full and accurate statement of their contents.

The Medicare Learning Network® (MLN)

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& Human Services (HHS).

Glossary

For glossary terms, visit the <u>Centers for Medicare & Medicaid Services Glossary</u>.

HYPERLINK URL	LINKED TEXT/IMAGE
https://www.cms.gov/apps/glossary	Centers for Medicare & Medicaid Services Glossary

APPENDIX B: JOB AIDS

Job Aid A: Seven Core Compliance Program Requirements

The Centers for Medicare & Medicaid Services (CMS) requires that an effective compliance program must include seven core 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

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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 fraud, waste, and abuse (FWA). This training and education should be tailored to the different responsibilities and job functions of employees.

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.

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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.

Job Aid B: Resources

Compliance Education Materials: Compliance 101

Health Care Fraud Prevention and Enforcement Action Team Provider Compliance Training

Office of Inspector General's (OIG's) Provider Self-Disclosure Protocol

Part C and Part D Compliance and Audits - Overview

Physician Self-Referral

Avoiding Medicare Fraud & Abuse: A Roadmap for Physicians

Safe Harbor Regulations

HYPERLINK URL	LINKED TEXT/IMAGE
https://oig.hhs.gov/compliance/101	Compliance Education Materials: Compliance 101
https://oig.hhs.gov/compliance/provider-compliance-training	Health Care Fraud Prevention and Enforcement Action Team
	Provider Compliance Training
https://oig.hhs.gov/compliance/self-disclosure-info/protocol.asp	Office of Inspector General's (OIG's) Provider Self-Disclosure
	Protocol
https://www.cms.gov/medicare/compliance-and-audits/part-c-and-part-d-compliance-	Part C and Part D Compliance and Audits - Overview
<u>and-audits</u>	
https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral	Physician Self-Referral
https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-	Avoiding Medicare Fraud & Abuse: A Roadmap for Physicians
MLN/MLNProducts/MLN-Publications-Items/CMS1254524.html	
https://oig.hhs.gov/compliance/safe-harbor-regulations	Safe Harbor Regulations

REPORTING

Saint Louis University Compliance Hotline

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

SAINT LOUIS UNIVERSITY COMPLIANCE



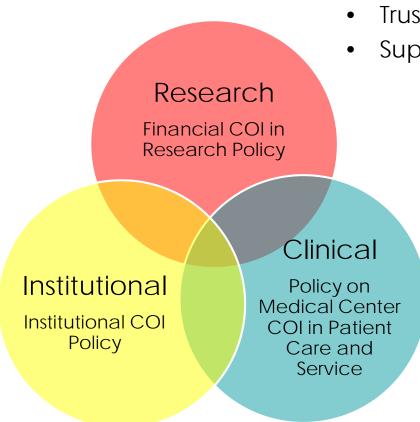
TOLL FREE HOTLINE 877-525-KNOW



RESEARCH COMPLIANCE

Why does the University care about Conflicts of Interest?

- Federal Regulations
- Accreditation Standards
- University Policies





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 Patient Care Conflict of Interest?



Situation where a <u>SLU</u>
<u>healthcare employee</u>
receives something of
Value <u>from industry</u> that
could create a
perception of bias or
questions the "PatientCenteredness" of one's
actions

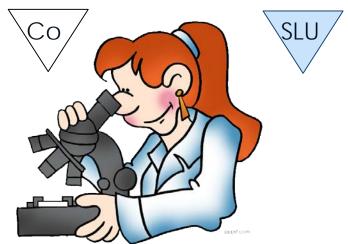




What is a Research Conflict of Interest?





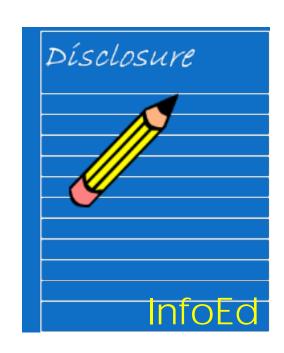


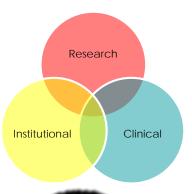
Situation where a
Researcher receives an outside financial benefit from their research sponsor that could directly & significantly affect the design, conduct or reporting of their research





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.





CONTRACTS

SLUCare 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 Manager, 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

You have completed Part 1 of Saint Louis University's Annual Compliance Update. Please exit the presentation and proceed to the quiz in Banner, and then continue with Part 2.

