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Verifying Compliance Program Effectiveness in Managed Care

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Objectives

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- Evidencing Effectiveness includes reviews. Two types of reviews can be especially helpful in evidencing effectiveness or identifying gaps.
- The following are objectives for the session:
 - Define and understand differences between Systems & Transaction Reviews, Evaluations in compliance.
 - Systems & Transactions Reviews, Evaluations can be used to evidence compliance program (CP) effectiveness by any entity.
 - Maximize CP auditing and monitoring in the managed care environment.

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Agenda

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- Compliance Programs
- Risk Assessment
- Corporate Integrity Agreements
- Systems versus Transaction Reviews
 - Definitions
 - Comparative Analysis
 - How to use to evidence CP effectiveness

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Perspective

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- Enrollment on the Rise
 - Medicare Advantage enrollment increased 5.7 % between 2009 & 2010, with 11.1 million beneficiaries in Medicare Advantage plans, or almost 1 in 4 (24 %) Medicare beneficiaries.
 - A smaller number of firms dominate Medicare Advantage enrollment both nationally and in most states.
 - × <http://www.kff.org/medicare/upload/8080.pdf>
 - Medicaid rosters swelling due to economic conditions.
 - Nearly half of the nation's Medicaid beneficiaries are enrolled in Medicaid health plans.
 - Total Medicaid managed care enrollment is 72%.
 - × http://www.mhpa.org/_upload/MMC%20Primer%202%20Scope%20dec%202010.pdf
- Increased Scrutiny
 - Limited resources, more demand, more limited MCOs.

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Compliance Program

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- Seven Fundamental Elements of an Effective Compliance Program:

1. Implementing written P&Ps and standards of conduct;
2. Designating a compliance officer and a compliance committee;
3. Conducting effective training and education;
4. Developing effective lines of communication;
5. Enforcing standards through well-publicized disciplinary guidelines and developing P&Ps that address dealings with sanctioned individuals;
6. Conducting internal monitoring and auditing; and
7. Responding promptly to detected offenses, developing corrective action, and reporting to the Government.

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Compliance Program

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- Managed Care Organizations

- Same seven element of an effective compliance program apply.
- Auditing and Monitoring is key.
- Risk Assessment:
 - ✦ Using Systems and Transaction Reviews can be incorporated into the overall Compliance Program Risk Assessment Process.

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Compliance Risk Assessment

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Step 1. Risk Identification and Assessment, including Prioritization

- Establish Risk Universe
- Consider Internal and External Risks to identify a reasonable and manageable short list of risk areas
- Assess Risk Events and Determine Risk Exposure (Risk Exposure = Probability * Impact) and determine those with highest priority, highest expected risk exposure scores

Example of Internal Risks:

- Issues that have been identified by Internal Audit

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Example of External Risks:

- Recent suspension by CMS of Health Net and intermediate sanctions on Arcadian Management Services and Universal American Corporation

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Compliance Risk Assessment

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Step 2. Risk Remediation and Mitigation

- Implement Internal Controls
- Update and Implement Policies and Procedures
- Train Appropriate Personnel

Step 3. Risk Area Auditing and Monitoring

- Highest Risk Areas

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Step 4. Risk Reporting and Communication

- Board and Executive Staff

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Corporate Integrity Agreement

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- Corporate Integrity Agreement Common Elements:
 - Hire a compliance officer/appoint a compliance committee;
 - Develop written P&Ps and standards;
 - Implement a comprehensive employee training program;
 - Retain an IRO to review claims submitted to federal health care programs;
 - Establish a confidential disclosure program;
 - Restrict employment of ineligible persons;
 - Report overpayments, reportable events, and ongoing investigations/legal proceedings, and
 - Provide an implementation report and annual reports to the OIG on the status of the entity's compliance activities.

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Systems & Transaction Reviews

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- Simply risk assessment strategy by government?
 - Mandatory risk prevention strategy imposed on the entity.
- Objectives:
 - Avoid improper billing.
 - Avoid relapse by the entity under the CIA.

- Eventually...*mandatory?*

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Systems & Transaction Reviews

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- Both reviews consider whether a system, such as a Compliance Program, is effective but from a different angle or perspective:
 - (a) How is it designed? and
 - (b) Is it working i.e., producing the results we want?

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Systems Review

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- As defined by OIG:
“The purpose of the Systems Review is to identify problems and weaknesses that resulted in overpayments. A Systems Review is a ‘walk through’ of the system(s) and process(es) that generated the sampling unit in error.”

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Source: <http://oig.hhs.gov/fraud/cia/faq.asp>

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Systems Review

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- **Systems Approach:**
 - Considers programs an ongoing “system” of rules and controls that guide activity.
 - **Process / implementation** is reviewed in Systems Reviews that examine internal controls channeling activity (both human & technological).
 - At issue is the process that led to the error.
 - Requires root-cause analysis to determine “why” the process is off course.
 - Reviewer should consider: process flow, work flow, nodes in system of decision making, and technology affecting the claim.

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Systems Review

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- **Systems Review may involve:**
 - Developing a flow chart of the work / process flow for claim;
 - Reviewing written P&Ps and appropriate dissemination of them;
 - Reviewing implemented internal controls that safeguard against the risk in deviating from controlled claims process.
 - Reviewing training and guidance that affect manual or soft controls that have human decision making components.
 - Reviewing technical configurations, the change control process, and hard controls/triggers within information systems (i.e., patient accounting system, HIM & EMR systems).
 - Checking for red flags that could entail escalating the issue.

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“Walking” the Claim

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- Systems Review in the context of claims processing:
 - “Walk” the claim through the entire system; and
 - Detect where system failure originated.
- **The purpose of the Systems Review is to detect any failures in existing internal controls and to avoid their reoccurrence.**

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Transaction Review

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- Transaction Review Approach:
 - Achievements and **outcomes / performance** are reviewed through audits or tests (e.g., coding accuracy, payment error rate, fair market value, contracts compliance).
 - Review results of the system at a point in time.
 - OIG did not as explicitly define.

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Transaction Review

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- Common themes in CIAs include:
 - Some form of audit of a universe of items;
 - Often deal with statistical sampling rather than 100% reviews; and
 - Involves audits that check the performance or outcome of the system.
- **Transactions Reviews do not focus on whether there is a process in place, but what results the process generates.**

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Transaction Review


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- Transaction Reviews may be understood as audits or tests that involve:
 - Reviewing all or samples from a universe of items.
 - Selecting a statistical sampling of items, such as claims, patients, arrangements, physicians, enrollment plans, etc.
 - Projections such as overpayment extrapolation or occurrence rate projection;
 - Thresholds not to be exceeded or to be met, e.g. error rate, accuracy rate, completion rate, etc.
- Checklists with characteristics of measure to determine if an item is compliant or correct.
- “Pass/Pass-with-Findings/Fail” results.

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Systems v. Transaction Reviews



Review Type Audit	Component	Review Activity	Question Answered
System Review	Process/Structure	Internal Controls/ Flow Chart/ Root-Cause Analysis/ Explain	Why?
Transaction Review	Outcome/ Performance/ Achievement	Audit/ Test/ Verify	What? How much? Pass/Fail?

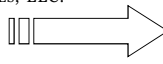
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Systems v. Transaction Reviews



- Differences:
 - Two distinct goals and needs.
 - Each answer different questions.
 - Each follow different logical sequences.
- **Systems reviews answer why something is wrong and are more invasive and time consuming and often follow "failed" Transactions reviews.**

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Failed Transaction Review

Systems Review

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Trends in Corporate Integrity Agreements

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- CIAs may be:
 - More stringent; and
 - May require Systems Review(s) *regardless of the outcome of a Transaction Review* and not just when a Transaction Review fails.
 - Examples: AstraZeneca and Spectranetics CIA
- What is the possible indication?
 - OIG's objective is to aggressively prevent the risk of improper payments and compliance violations by an entity under a CIA and is not only outcomes focused, but also process focused.
- We can conclude that using both types of reviews can be part of a proactive risk management strategy and used to assess a compliance program, i.e., whether it is an effective system.

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Benefits

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Systems Review

- A useful tool in risk mitigation efforts and implementing risk control strategies.
- Provides a roadmap to clarify work flow and procedural issues.

Transactions Review

- Supports internal auditing and monitoring through statistical auditing and extrapolation methods.
- Statistical auditing and sampling presents a powerful method to detect problems and patterns in a variety of risk areas with limited resources but smart design.
- Provides valuable input into any ERM to proactively identify and quantify risk.

Takeaways

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- Supporting risk assessment with IRO-type reviews.
- Health care trends: More sophistication...
 - Risk assessment
 - Enterprise wide-risk assessment
 - Data analysis
 - Data mining

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Takeaways

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- Benefits and Objectives:
 - Supports compliance program transparency.
 - Provides tools to demonstrate compliance program effectiveness from various perspectives.
 - ✕ Design/process
 - ✕ Output/results
 - ✕ Answers two of the three questions any prosecutor would ask to determine whether a CP is effective (Federal Sentencing Guidelines)
 - Is the corporation's compliance program well designed?
 - Is the program being applied earnestly and in good faith? (new)
 - Does the corporation's compliance program work?
 - Prevents and / or assists in successfully passing government audits.

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Examples and Applications

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- **Systems Review: Conflict of Interest (COI) process.**
 - Consider:
 - ✦ Conducting a walkthrough of an entire COI process, including policies as written, collection process, completeness of lists of persons to participate, process owner, follow-up or enforcement if no cooperation is present.
- **Transactions Review: COI on file.**
 - Consider:
 - ✦ Conducting a review of a sample of contracts or personnel and their COI information on file; verify by interviewing appropriate individuals and conducting a document review to determine the accuracy of COI statements and to determine if they are current.

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Examples and Applications

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- **Systems Review: Sanction Screening Process.**
 - Consider:
 - ✦ Conducting a walkthrough of an entire sanction screening process. Who is tasked within the organization? What data exchange are necessary? Is there a vendor currently in use that accommodates the organization's needs? Is there an effective resolution process?
- **Transactions Review: New Hire Sample.**
 - Consider:
 - ✦ Conducting a review of a sample of new hires and test whether the sample got prescreened before hire and are screened again within a set timeframe (90 days, monthly or at most a year after hire).

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Examples and Applications

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- **Systems Review: Compliance Training Program Development and Maintenance.**
 - Consider:
 - ✘ Conducting a walkthrough of the entire process. Determine how compliance training content, mode, and frequency are determined? Who approves content update? Does it reflect industry trends? Is there a test? Are there sufficiently detailed written policies and are these followed or inadequate? Is content development ad hoc or does a process exist?
- **Transactions Review: Compliance Training Completion.**
 - Consider:
 - ✘ Conducting a review of a sample of new hires or current employees and test if they have completed mandatory compliance training and if not, whether there was any follow up or corrective action plan.

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Examples and Applications

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- **Systems Review: Plan or Product Development.**
 - Consider:
 - ✘ Conducting a walkthrough of a complete product development process of a new product or plan offering including signoffs and appropriate State and Federal certifications.
- **Transactions Review: Marketing Practices.**
 - Consider:
 - ✘ Conducting a review of marketing practices to ensure that there is no adverse selection of members (i.e., selecting or denying beneficiaries based on their illness profile or other discriminating factors). Conduct analysis and review of both enrollment and disenrollment data. Determine if all marketing items are appropriately utilized for enrollment. Did the MCO violate the Medicare marketing guidelines, or other Federal or State laws, rules, and regulations to improperly enroll beneficiaries? Study a sample of marketing representatives and marketing activities. Review training processes to ensure policies and procedures are routinely reinforced.

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Examples and Applications

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- **Systems Review: Failure to provide medically necessary services.**
 - Consider:
 - ✘ Conduct a walkthrough of approval / coverage processes. Did the MCO provide the plan enrollee all medically necessary items / services that the MCO is required to provide (under law or under the contract)?
- **Transactions Review: Incorrect calculation of TrOOP.**
 - Consider:
 - ✘ Collect a sample beneficiaries. Review how sampled beneficiaries' TrOOP calculation is determined and identify any output errors from the system. Determine if the MCO miscalculated beneficiaries' TrOOP that resulted in improper payments by CMS or beneficiaries.

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Examples and Applications

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- **Transaction Review: Payments for excluded drugs.**
 - Consider:
 - ✘ MCOs must ensure that they only provide coverage for drugs listed in their approved formularies and in accord with section 1860D-2(e)(2). Identify a sample and determine whether the MCO's billing system is current. Review a sample of enrollees and prescribed drugs to assess if coverage was appropriately billed.
- **Transaction Review: Multiple billing.**
 - Consider:
 - ✘ MCOs must ensure that prescriptions are appropriately billed. Select a sample and review whether the same prescription is being covered and paid for under Medicare Part A or Part B, and then a second time under Part D, and/or possibly Medicaid.

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Examples and Applications

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- **Transaction Review: Inappropriate Enrollment/Disenrollment Reporting Data.**
 - Consider:
 - ✘ Review whether the organization is properly reporting enrollment and disenrollment data to CMS to ensure appropriate prospective payments are received. For example, Part D Sponsor fails to effect timely disenrollment of beneficiary from CMS systems upon beneficiary's request. Select a sample of beneficiary requests and determine if disenrollment was timely. Develop universe of disenrolled beneficiaries and assess if disenrollment was implemented in accordance with written procedures and policies.
- **Systems Review: Appeals Process.**
 - Consider:
 - ✘ Conduct a walkthrough of the appeals process. Review whether the organization is ensuring the appropriate appeals processes have been implemented and handled appropriately. This will ensure that Medicare beneficiaries are not denied their right to an appeal or denied a timely appeal.

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Examples and Applications

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- **Systems Review: Handling Customer Complaints or Hotline Calls.**
 - Consider:
 - ✘ Conducting a walk through of what happens when a call comes in and step by step processes of handling the call to completion or resolution. Who are the participants in the investigation and resolution process? What are the timelines? What is reported back? How are results integrated into training and reported to oversight committees and board?
- **Transactions Review: Call Center.**
 - Consider:
 - ✘ Selecting a sample of calls or call takers and analyze how they handle customer. Review how protocols are implemented such as, gathering enrollment information, registering a complaint, collecting customer satisfaction data. Analyze call handling, routing, etc.

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