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Disclosure Summit
Transactions Reviews for
Non-CIA Companies

Gus Papandrikos, Daiichi Sankyo
Jack Tanselle, Navigant Consulting, Inc.

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Quiz



» What is riskier?

- › Inaccurate and incomplete Sunshine reports, or...
- › Indefensible or unjustified activities represented by reports

Answer Key



» What is riskier?

- › Inaccurate and incomplete Sunshine reports, or...
 - Potential Outcome = Fines and Questions
- › Indefensible or unjustified activities represented by reports
 - Potential Outcome = Bigger Fines and Settlements (after more Questions!)
- › Neither scenario is desired, but balancing resources to appropriately assess and manage both risks is important

The HCP Management Process



The HCP Management Cycle



Example Tests for **Accuracy and Completeness**:

- › Does report data align to payment data? Complete and accurate?
- › Do internal cost center codes and designations of activity types align?
- › How well does payment data move between source systems and the agg spend system?
- › What inconsistencies exist in the amounts and categorizations of payments made?
 - › Many others anchored around accuracy and completeness of numbers.

The HCP Management Cycle



Example Tests for **Justification and Control of Spend**:

- › Is their confirmation the activity was actually conducted/service provided?
 - › Was a signed contract in place prior to the activity, if applicable?
 - › Does report data align to what was agreed to in the contract?
 - › Does payment data align to what was agreed to in the contract?
- › Was rationale provided/activity approved per internal policies and procedures?
- › Is volume of HCPs contracted with justifiable against need and internal resources?

Transactions Reviews



- » “Control Documents” include all documents or electronic records associated with each Payment reflected in the Physician Payments Listing for a sampled physician and/or Related Entity. For example, the term “Control Documents” includes, but is not limited to:
- › documents relating to the nature, purpose, and amount of all Payments reflected in the Listing
 - › contracts relating to the Payment(s) reflected in the Listing
 - › documents relating to the occurrence of Payment(s) reflected in the Listing
 - › documents reflecting any work product generated in connection with the Payment(s)
 - › documents submitted by sales representatives or headquarters personnel to request approval for the Payment(s)
 - › business rationale or justification forms relating to the Payment(s).

Transactions Reviews (cont.)



- » For each physician and/or Related Entity selected as part of the sample, the IRO shall review the Control Documents identified by the IRO as necessary and sufficient to validate each Payment reflected in the Listing to evaluate the following:
- a) Whether Control Documents are available relating to each Payment reflected in the Listing for the sampled physician and/or Related Entity;
 - b) Whether the Control Documents were completed and archived in accordance with the requirements set forth in Company's policies;
 - c) Whether the aggregate value of the Payment(s) as reflected in the Listing for the sampled Physician is consistent with the value of the Payments(s) reflected in the Control Documents; and
 - d) Whether the Control Documents reflect that Company's policies were followed in connection with Payment(s) reflected in the Listing (e.g., all required written approvals for the activity were obtained in accordance with Company's policies).

Transactions Reviews (cont.)



- » A Material Error is defined as any of the following:
 - a) A situation in which all required Control Documents relating to Payments reflected in the Listing for the sampled physician and/or Related Entity do not exist and:
 - i. no corrective action was initiated prior to the selection of the sampled physicians and/or Related Entities; or
 - ii. the IRO cannot confirm that Company otherwise followed its policies and procedures relating to the entry in the Listing for the sampled physician or Related Entity, including its policies and procedures relating to any Payment(s) reflected in the Listing; or
 - b) Information or data is omitted from key fields in the Control Documents that prevents the IRO from assessing compliance with Company's policies and procedures, and the IRO cannot obtain this information or data from reviewing other Control Documents.

Transactions Reviews (cont.)



» Exceptions and Additional Review:

- › Exception: Control Document does not exist, but Company has initiated corrective action prior to the selection of the samples, or if a Control Document does not exist but the Company otherwise followed its policies and procedures with regard to each entry in those samples.
- › Additional Review: For Material Errors, the IRO shall conduct such Additional Review of the underlying Payment associated with the erroneous Control Documents as may be necessary to determine the root cause of the Material Errors.

Summary



- » Accuracy and completeness are critically important
 - › Continue ongoing auditing and monitoring
 - › Consider conducting different types of tests and analyses in a cyclical manner
- » Justification and control are perhaps even more important
 - › Leverage existing CIAs as indicators of what the authorities really want to see
- » Leverage testing results to improve your overall program
- » Don't expect perfection, or even get lost in pursuing it; instead, expect and pursue continuous improvement throughout the entire continuum of managing HCP relationships