



# Monitoring and Auditing Around Government Pricing

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# Session Agenda

- Definition and Purpose of Compliance Monitoring and Auditing over Government Pricing Calculations
- Government Pricing Monitoring Controls
- Designing Auditing Plans for Government Pricing Calculations
- Example
- Q&A

# Compliance Monitoring and Auditing: *Regulatory Basis*

“An effective compliance program should incorporate thorough monitoring of its implementation and an ongoing evaluation process”

- OIG Compliance Guidance

# Monitoring and Auditing

## *Definitions*

- Monitoring Controls – those procedures performed on a day-to-day basis by operating management to ensure compliance with policies.
- Auditing – those procedures performed by an objective party to test whether the monitoring controls are operating effectively and whether the company has complied with its policies.

# Monitoring and Auditing: *Government Emphasis*

- “Perhaps the best evidence that a provider's compliance program is operating effectively occurs when the provider, through its compliance program, identifies problematic conduct, takes appropriate steps to remedy the conduct and prevent it from recurring, and makes a full and timely disclosure of the misconduct to appropriate authorities.” – IG Brown, March 2000
- “...one of the precepts of an effective compliance program is the early detection of billing errors and other problems through a system of internal audits and by empowering employees to do the right thing.” – AIG Morris, July 2001
- The government’s emphasis on auditing carries over to CIAs, which require extensive transaction-based audit-type work.



# Government Pricing Monitoring Controls

# Government Pricing Monitoring Controls

Monitoring controls should be established to ensure the:

- ✓ **Completeness** of the data used in the calculation.
- ✓ **Accuracy** of the data used and of the calculation itself.
- ✓ **Validity** of the data used for the calculation
- ✓ **Restricted access** to the data sources and the calculation system.



# Government Pricing Monitoring Controls

## *It's all about Addressing Risk*

- Identify the risks/process breakdowns that could result in the price reporting calculations being incorrect.
  - Map the process, including all source systems and external data feeds
  - Apply CAVR to each element of the process to address inherent and control risk.
- What needs to be done to achieve CAVR in total?
- Breakdowns often occur during periods of change.



# Government Pricing Monitoring Controls

## *It's all about Addressing Risk*

Sample risks to be considered:

- Sales, chargeback or rebate information imported into system is not complete.
- Maximum allowable rebates are not accurately calculated.
- Classes of trade are incorrect or improperly aggregated
- Pricing calculations don't consider whether company owns NDA or ANDA.
- Mathematical errors in spreadsheets
- Chargebacks are unnecessarily paid
- Discounts are offered that are not included in calculations

# Government Pricing Monitoring Controls

## *It's all about Addressing Risk*

Sample control types:

- Reconciliations (C)
- Review and approval (A, V)
- Keeping current procedures (C, A, V)
- Source document review (C,A,V)
- Validated interfaces (C, A, V)
- User Access Controls/Password protection (R)

# Government Pricing Monitoring Controls *Exercise*

Match the control activity to the applicable risk.

You have 10 minutes.

We will discuss afterwards.

# Compliance Auditing

## *Key Considerations in establishing Plan*

- Frequency (annual, bi-annual)
- Scope (policy, calculation, data flows, systems, rotation)
- Approach (transaction testing, process review, policy review, reperformance/examination)
- Skill set of auditors (can normal auditors be used)
- Use of privilege (evidence of compliance auditing vs. protecting findings)
- Approach for addressing findings (remediation plan, refilings)
- Decisions based on inherent risk of monitoring controls.

# Compliance Auditing

## *Sample Audit Areas*

- Review pricing methodologies and templates, and compare to current business practices, recent guidance and industry better practice. (C, A, V)
- Test sales data reconciliation process (C).
- Test MAR calculation process (A)
- Review class of trade assignment process and controls over edits to classes of trade. (C, A, V)
- Based on policies, reperform a sample calculation and assess reasons for variance from original result. (C, A, V)
- Review process for information flows to government pricing personnel. (C, V)

# Compliance Monitoring and Auditing

## *Pulling it all together*

<b>Risk</b>	<b>Control</b>	<b>C</b>	<b>A</b>	<b>V</b>	<b>R</b>	<b>Auditing</b>
Sales, chargeback, rebate information is incomplete	Information used in calculations reconciled to source systems and general ledger. Supervisor reviews and approves reconciliations.	X	(X)	(X)		On an annual basis, select 2 quarters and review reconciliations for existence, timely completion, reasonableness of reconciling items, and evidence of approval
Discounts in the calculations do not include off-invoice credits issued subsequent to the sale.	Pricing personnel receive copies of any transactions not processed through chargeback or rebate systems, and review for appropriate treatment.	X	X	X		On an annual basis, select 30 payments made to customers and assess for proper inclusion/exclusion from the government pricing calculations.

# Compliance Monitoring and Auditing

## *Pulling it all together*

<b>Risk</b>	<b>Control</b>	<b>C</b>	<b>A</b>	<b>V</b>	<b>R</b>	<b>Auditing</b>
Spreadsheets used for calculations reflect methodology	Supervisor periodically reviews the calculation for compliance. Changes in policy are incorporated into the next month's calculation.		X			On a bi-annual basis, compare the calculations to the approved methodology and assess whether the calculations accurately reflect the methodology.
Sales transactions in the government pricing are valid sales for government pricing purposes	Review the sales data relied upon for ASP, AMP, BP to verify that all sales are to eligible classes of trade and only to domestic customers.	X	X	X		On an annual basis, review the COT assignments for 30 sales transactions and assess whether the COT assignment is reasonable. Review COT table and assess whether required COTs are included.



# Compliance Monitoring and Auditing

## *Pulling it all together*

<b>Risk</b>	<b>Control</b>	<b>C</b>	<b>A</b>	<b>V</b>	<b>R</b>	<b>Auditing</b>
Credit/returns are valued at the correct amounts and are valid transactions for inclusion in AMP calculation	Review the credit/returns data relied upon for AMP to verify that only credits to the retail class of trade and to domestic customers are included.	X	X	X		On an annual basis, select 30 credits and test for proper inclusion/exclusion in the AMP calculation. Review data feeds for ASP and BP to assess whether returns are excluded.
Access to government pricing systems is restricted to appropriate personnel	Relevant spreadsheets and data sources are password protected.				X	On a bi-annual basis, review access controls over government pricing systems and data sources.

# Recap

- Monitoring controls are designed to ensure that the price calculations are based on complete, accurate and valid data sets, to which the right methodology is correctly applied.
- Monitoring controls are the responsibility of the department responsible for the calculations.
- Map your processes from source data systems to submission—do you have CAVR?
- Once controls are in place, subject them to periodic compliance audits by qualified personnel to test effective operation.
- Automated processes can allow for more efficient monitoring and auditing due to reduced inherent risk.



# Question and Answer

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