Auditing a Key Customer

Managed Care Audits that Meet Business Goals and Maintain Successful Relationships

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Results from a Recent Poll - Greatest Financial Impact

- Competitor advantage vs. contracted products
- Co-pay or deductible higher than anticipated
- Customer's plan rollups include ineligible benefit designs
- Concerned about double dipping regarding 340B related purchases with submitted rebate claims
- Rebate process incorporates ineligible prescription claims
Meet the Experts

Terri Bernacchi
Strategic Consultant, Audit & Risk Assurance

Tim Krzeminski
Director, Audit & Risk Assurance

Disclaimer

• This presentation is being made by specific presenters, and reflects their industry experience on the topics at hand
• The information expressed in this presentation does not necessarily reflect the advice of CIS
• This presentation does not constitute legal advice, does not reflect interpretation of guidance or agency perspective, and is meant for discussion purposes only

Contact us to request a copy of the recent CIS whitepaper, Managed Markets and the Pharmaceutical Manufacturer.
About CIS’ Audit Team

CIS has an experienced staff 100% focused on compliance & ethics

- Staff consists of CPAs, CFEs, CIA’s and industry experts
- CIS is 100% focused on Life Science Compliance

Subject Matter Expertise in Managed Care Audits and Desktop Reviews

- Currently engaged with several Pharma Manufacturers to execute Managed Care Contract Administration, perform desktop audits of PBM contracts on their behalf, and execute PBM on-site audits
- Conducted multiple Conference Speaking Sessions, Webinars, and Blogs on Managed Care Topics including Managed Care Audits
- Active participants in NCPDP

Independent audit organization

- No conflict of interest with PBMs or MCOs
- Dedicated adherence to HIPAA and HITECH compliance
Objectives

Evaluate how the audit process has changed over the past 20 years

Identify best practices in managing the contractual “audit clause” with trading partners

List the benefits to both parties of an audit conducted using best practices

Discuss how the post-audit debrief process can yield greater contract value or a shift in strategy

Managed Care Audit case studies
The importance of MCO/PBM contract compliance

- Rebates and discounts paid to PBMs, health plans and end users of the manufacturer’s products are some of the largest expenses for a pharmaceutical manufacturer.
- The lack of visibility into price concessions has become a great concern for the industry as these greatly impact profitability and Sarbanes-Oxley compliance, as well as directly impacting price reporting under Government pricing and rebate programs.
- Manufacturers place significant reliance on managed market entities to accurately adjudicate prescription claims, manage product formularies, and accurately invoice for rebates and fees pursuant to agreed upon terms.
- Consistent monitoring of MCO/PBM operations is essential to increase compliance, curtail revenue leakage, improve operational efficiencies, and mitigate risk due to incorrect government pricing functions.
Summary Statement

Audits are a necessary tool to assure that contract terms are being honored and the financial payments have been earned.

Although they interrupt daily activities, audits do not need to be antagonistic, even if there are findings of concern to either party.
Technology of Benefit Management (POS processing, Cost Savings)

Technology has become “commodity” in Benefit Mgt

Generic dominance (now ~85% of Rxs), coupled with reduced competition due to CER will drive different patterns

Creative benefit designs have greater focus / impact than Formulary alone

Technology of Disease /Risk Management, EMR, EHR, Erx Processing

Rise of the Accountable Care Organization and post-ACA health care provider / payer Models

Smarter, more nimble pharma deal makers (Specialty, Bio Tech, Coupons)

Tsunami of Branded, Innovative Products within Competitive Therapeutic Categories (70-80% of Rxs)

Formulary as a New Concept

Technology of Benefit Management (POS processing, Cost Savings)

Rise of the Pharmacy Benefit Manager Business Model

Unsophisticated pharma deal makers matched against PBM powerhouses

An Abbreviated “History of Rx Rebates”

1986-2014 The Key Drivers (Then & Now)
Related Contract Terms

The Audit Clause:

Customer shall at all times maintain access to accurate records and systems with respect to eligible participating plans, members, participating pharmacies, and all pertinent information relating to the dispensing and sale of contracted products by participating pharmacies to Members.

Customer shall, upon 30 days written request, allow Company or its authorized representative to inspect, at reasonable times, all such information and shall furnish such information to Company as it relates to Customer’s performance under this Agreement. Audits shall not exceed X per year and are limited to a look back period not to exceed X quarters. Company shall pay costs associated with Audit.

Dispute Clause:

Both parties shall use best efforts to resolve disputes in a timely way, in good faith. Any disputes relating to the administration of this agreement or to the eligibility of rebates submitted by Customer that are not resolved through negotiation between the parties shall be submitted to binding arbitration pursuant to the Federal Arbitration Act, 9, USC.

Company shall pay amounts that are not otherwise in dispute within the timely payment provisions of this agreement.
“Not All Relationships Require a Contract”

~ a very wise CFO

Is there a clear “mutual interest”? 

Does the mutual interest sustain itself over the proposed timeframe (term) of the agreement?

Are the requirements for each party infeasible? 
For example:

- Does a discount expectation go beyond company pricing standards or financial policies?
- Is data expected easily collected or does the cost for collection exceed contract value proposition?

Does either party lack the ability to actually administer the terms and conditions?

Does the cost to manage the contract exceed the value of the arrangement?

Does legal counsel believe the contract introduces untenable risk?
Best Practice: Audit Rules in Seven Easy Steps

1. Establish an Audit Program Rather Than Just One-Off Audits
2. Consider the Practical Needs of the Trading Partner
3. Consider Participating in the Audit Process
4. Good Communications to the Auditee
5. Don’t Overstate Findings
6. Seek a Better Understanding of the Future Business Context and Relevant Concerns with the Trading Partner
7. Create Rational Internal Expectations of the “Return on Audit”
Develop a Program, not a Patch

1. **Establish an Audit Program Rather Than Just One-Off Audits**

Planning audits in advance reserves budget funding to maintain audit as an reassurance that rebates, discounts, and admin fees are legitimately earned.

Removes the concern that audits are forensic in nature.

Keeps internal staff & customers on an “even keel” when an intent to audit is announced.

Advance planning balances time & personnel workload.

Can incorporate different kinds of customers and rotations (wholesaler/distributor, PBM/Payer, specialty).

“Our company allocates a portion of the budget every year to assure we conduct at least 3 customer audits. Over a 3 year period, we audit most key accounts, keeping customer disruption to a minimum. This process also signals an expectation of accountability to our Account Managers.”

~ Senior Director, Finance, Midsize Branded Manufacturer
Work with the Partner

2. Consider the Practical Needs of the Trading Partner.

Calendar and communication management represents a challenge for everyone.

If you show flexibility with the audit schedule, it may make the auditee more willing to work with you on other issues.

Efficient, agenda driven meetings or calls.

Lay out and agree upon timing and data needs early in process.
Communicate & Document


It’s a stamp of approval – signaling interest at the executive level

Representative should have authority to resolve minor conflicts and negotiate settlement as audit is wrapped

Helps expand internal understanding of the audit process and results

4. Good Communications to the Auditee.

Mitigate the “worry” about findings

Departure memorandum

Documentation of the “requested” and “supplied” elements of the audit help organize both sides

Your audit is not the only they are working on; understanding WHY something is needed and what priorities are help get to the wrap up
Maintain Perspective!

5. **Don’t Overstate Findings.**

Extrapolation methodologies are flawed in most audit processes and a limited sample size (typical to most managed care agreements) compounds this.

Dispute resolution requires an understanding of the details of the contracts, the data, and the sample used to support a finding.

Internal politics get messy if there are large findings expected for recovery that could disrupt the relationship with an active customer.
Learn and Adapt


Audits are by nature *retrospective*

- What has changed since the “audit timeframe”?  
- What does it mean to the future?  
- Is it worth the dispute process?

Does the organization have process improvements in place that could mitigate any findings for the future?

What are the key strategic initiatives that might enhance the value of the contract or modify the concerns identified during the audit and contract review process?

Are there provisions that could or should be added to the contract that maintain value but lessen anticipated risk?
7. Create Rational Internal Expectations of the “Return on Audit”

Organizations rationalize audit costs in different ways but the “return” on the cost of an audit is often hard to measure.

It should NOT be measured merely on a quantification of the findings that may still be in dispute after the audit is complete.

Audit PRICE varies by consultant but not all audits are alike; understand the scope and methodologies used.

Measure, instead, the following potential prospective financial results:

- The effect of formulary status findings on lost or gained Rxs going forward.
- Improved strategies for contract results, including modification of terms applicable to plans, benefit programs, or electronic prescribing.
- The decision to not renew a contract.
- The impact of “deterrence” and the expectation of accountability derived from the audit program.

Set Realistic and Measurable Goals
# Why Audits Will Remain Important to the Manufacturer- Trading Partner Relationship

## Traditional Managed Markets Terms Will Continue

- Rebate in exchange for formulary placement
- Rebate as a means to reduce the price for the Payer
- Sliding Scale rebate earned based on the Control over Member Benefit
- Sliding scale rebate based on volume or market share
- Price protection rebates
- Administrative fees
- Exclusion Management: especially relating to 340b Priced Dispensed units submitted under agreement

## Future Contract Terms Will Be Subject to Audits

- Proving compliance regarding the formulary placement will require more effort as Electronic Prescribing takes more prominence in the physician’s practice. Audit / Validation Language should consider this impact
- Potential exclusions relating to ineligible benefits designs. (E.g. members with High Deductible plans under which the member has paid the full amount of the drug cost or very high tier copays)
- Coupon / Copay Assistance programs that operate within or along side traditional rebate arrangements
How does CIS Approach the Audit?
We have a unique perspective.

CIS’ Approach

Experienced staff

Experience in Managed Care Audits, Wholesaler Audits, and 340B Covered Entity Audits

Expertise with government pricing compliance rules and Regulations including 340B

Expertise in commercial contracting and chargeback processing

Proprietary chargeback processing and validation systems

Value integrity of manufacturer-vendor relationship

Assistance with quantification of dispute resolution
Case Study: PBM/MCO Claims Scrub

Who?
10 Managed Care Organizations (MCOs) and Pharmacy Benefits Managers (PBMs)

What?
MCO/PBM Claims Validations

Where?
Desk audit

When/Why?
Upon Audit Committee’s Request

How?
Validated 2 quarters of claims data to verify script validity

Validation Audit Outcome

- Inconsistent data formats and data not in line with contractual obligations
- Three out of ten customers had error rates greater than 2% including duplicate claims, customer/plan not on contract, and invalid pharmacy IDs
## Case Study: PBM Audit

<table>
<thead>
<tr>
<th>Who?</th>
<th>Pharmacy Benefits Manager (PBM)</th>
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<tbody>
<tr>
<td>What?</td>
<td>Contract compliance review</td>
</tr>
<tr>
<td>Where?</td>
<td>Combined Site and Desk audit</td>
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<tr>
<td>When/Why?</td>
<td>As part of the manufacturers Audit Plan and follow-up to validation audit</td>
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<tr>
<td>How?</td>
<td>Executed audit program on-site at PBM and office after receiving transactional data</td>
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### PBM Outcome

- Identification of a significant number of duplicate claims
- Pricing issues were noted where price changes occurred however claims continued to be submitted at the ‘old’ price
- PBM plan by plan analysis of market share and co-pay distribution showing a 73% market share of client product that was paying a high rebate for “Sole and Exclusive” formulary positioning
Contact the Experts

**Terri Bernacchi**
*Strategic Consultant, Audit & Risk Assurance*
TerriBernacchi@cis-partners.com

**Tim Krzeminski**
*Director, Audit & Risk Assurance*
TimKrzeminski@cis-partners.com
Contact Information

C O M P L I A N C E
IMPLEMENTATION SERVICES

www.CIS-Partners.com
info@CIS-Partners.com