Government Price Reporting Issues: Mitigating Compliance Risk with Automation and Best Practices

SIXTH ANNUAL PHARMACEUTICAL REGULATORY AND COMPLIANCE CONGRESS AND BEST PRACTICES FORUM

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Solutions Director
Model N, Inc.
Today’s Agenda

» Explore Government Price Reporting operational challenges and issues from Solutions Providers perspective

» What are the key learnings and best practices related to?
  » Policy and documentation
  » Data and process
    » Calculations and filings
  » Reporting and analytics

» How can automation and systems tangibly mitigate compliance risk from a business process/controls and data validation perspective?
Market Trends and Regulations Impacting Pricing…

» Convergence:
  » Classes of Trade
  » Incentive Strategies
  » Product Portfolios
  » Regions or Countries
  » Federal & State

» Compliance:
  » Robinson-Patman
  » MMA 2003
  » OBRA 1990 & 1993
    » CMS Advisory (70+)
  » VHCA 1992
    » VA Advisory (37+)
  » SOX 404
Operational Challenges
Visibility to Net Pricing and Net Revenue

*Linking together Net Pricing is a monumental challenge for many reasons…*

**Which Price is the Right Price?**

- **List Price**: $100, -10% = $90
- **Contract Price**: $90, -12% = $78.8
- **PPD**: $78.8, -2% = $77.31
- **Rebate**: $77.31, -5% = $73.15
- **Fees**: $73.15, -2% = $71.49
- **Net Price**: $71.49, -19% = $59.13

**Infrastructure:**
- Fragmented process & systems
- Data in many systems, spreadsheets or on paper
- Process crosses departmental boundaries
  - Customer Service
  - Finance
  - Sales and Account Management
  - Contracts and Pricing
  - Legal

**Other Priorities:**
- New programs increasing contract volumes
- Audit and field support
- Strained resources and SMEs
Government Pricing Reporting
Massive Amounts of Data Are Required

- **Transactional Data**
  - Direct sales
  - Returns
  - Free goods
  - Terms
  - Indirect sales
  - Chargebacks payments (forecast, actual)
  - Rebates (forecast, actual)
  - Admin and service fees (forecast, actual)
  - Adjustments
  - Allocations
  - Sales and marketing expenses

- **Dimension Data**
  - Product (NDC and hierarchies)
  - Class of Trade
  - Customer
  - Contracts
  - Dates (Transaction, invoice, paid, etc.)

- **Historical Prices**
  - WAC
  - AWP
  - Baseline AMP
  - Federal Medicaid URA
  - Prior period filings

- **Miscellaneous**
  - Consumer Price Index – Urban (CPI-U)
  - Assumed Prompt Pay Discount (APPD)
  - Nominal Price Factor (NPF)
  - Industrial Funding Fee (IFF)
Government Pricing Solutions
How Can Automation Help?

- Robust tools to manage “imperfect data”
- Ability to handle time-lags and historical adjustments

• Enforces top-down polices
• Consistent price reporting methodologies

• Integrate new programs flexibly and painlessly
• Easy for laymen to understand and to use

• Audit trail on calculation, notes and signoffs
• Balances with financial systems of record
What Level of Controls and Auditability is Required?

Hint…Much More than Record Logging!

**FDA Batch/Lot Tracking**
- Finished Goods
- Ingredients
- Recipes

**Government Price Reporting**
- Calculations
- Transactions
- Policies
Best Practices: Systems
Links Policy, Data, Calculation, Filings and Reporting Together

- Policies
  - Document of price policy and methodology
  - Defines smoothing and allocations

- Calculations
  - Exceptions management
  - Drill down and Analytics
  - Workflows

- Reports
  - Archive of filings & restatements

Workflows & Alerts
Reporting & Embedded Analytics
Data Management, Integration and Control
Best Practices: Systems
Integrated Price / Rebate Models for Accuracy and Control

→ Integrated
   → Price and Rebate Calculations share a common framework
   → Automated price changes and alerts

→ Extensible
   → New programs, calculations and reports can be added painlessly

→ Benefits
   → Real-time monitoring
   → Responsive to changes
   → Detection of input changes
Best Practices: Systems
Net Price Monitoring

- Monitors net effective price fluctuations of all contracts
- Alerts against price floor violations
- Alerts against price adjustments to tracking customers
  - FSS Price Alerts
  - Tracking customer
- Special Handling for Amendments
  - Scans all active contracts for violations due to “external” changes
**Best Practices: Data Information Architecture**

**Internal Data**
- Direct Sales
- Accruals and Estimates
- Indirect Sales
- Chargeback Payments
- Managed Care Rebates
- Sales Rebates & Fees
- Credit, Return & Allowances
- Marketing Expenses
- Pricing Policies
- Calculation Methodologies

**External Data**
- T-Bill and CPI-U Rates
- Drug Distribution Data
- Customer/Product Master Data
- Utilization Data

**Integration Services**
- Channel
- Format
- Frequency
- Message Delivery
- Validations
- Preprocessing
- Consolidations
- Allocations
- Alerts / Escalations

**Data Mart**
- Allocations
- Master Data
- Transactions Details
- Info-Cubes

**Analytics**
- Compliance
- Settlement
- Operational Reports
- Management Reports

CPI-U Rates
### Best Practices: Policies

**Understand How Your Incentives Effect Pricing Compliance**

<table>
<thead>
<tr>
<th>Markets</th>
<th>Incentive Strategy Type</th>
<th>Pricing</th>
<th>Rebates</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>PPD</td>
<td>Direct</td>
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<tr>
<td>Retail</td>
<td>Wholesalers / Distributors</td>
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<td>Retail Chain &amp; Independent</td>
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<td>Staff HMOs</td>
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<td>Regulated Market</td>
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<td>PHS Covered Entities</td>
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<td>Prescription Drug Plan</td>
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Best Practices: Policies
Document Calculation Methodologies

**Example: Average Manufacturer Price**

Net Sales = (Direct Sales – Indirect Sales) – (Chargebacks + Rebate + Adjustment)

Net Units = (Direct Units – Indirect Units)

AMP = Net Sales / Net Units

<table>
<thead>
<tr>
<th>Buckets</th>
<th>Description</th>
<th>$</th>
<th>Units</th>
<th>Operation</th>
<th>Smooth Allowed</th>
<th>Date Type</th>
<th>Precision</th>
<th>Product Dimension</th>
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<tbody>
<tr>
<td>Direct Sales  (DS)</td>
<td>Eligible sales and units shipped directly by Customer (e.g. sales to wholesalers and retail pharmacies)</td>
<td>$</td>
<td>Units</td>
<td>Add</td>
<td>Invoice Date</td>
<td>Actual</td>
<td>NDC11</td>
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<tr>
<td>Indirect Sales (IS)</td>
<td>Ineligible sales and units derived from Chargebacks (e.g. federal sales or non-retail chargebacks for AMP)</td>
<td>$</td>
<td>Units</td>
<td>Subtract</td>
<td>Paid Date</td>
<td>Actual</td>
<td>NDC11</td>
<td></td>
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<tr>
<td>Chargebacks (CB)</td>
<td>Chargeback dollars paid for eligible classes and contracts</td>
<td>$</td>
<td>Units</td>
<td>Subtract</td>
<td>Yes</td>
<td>Paid Date</td>
<td>Actual Smoothed 12 mo</td>
<td>NDC11</td>
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<tr>
<td>Rebates (RB)</td>
<td>Rebate dollars paid for eligible classes and contracts</td>
<td>$</td>
<td>Units</td>
<td>Subtract</td>
<td>Yes</td>
<td>Earned Period</td>
<td>Accrual</td>
<td>NDC9</td>
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<tr>
<td>Adjustment (FA)</td>
<td>Any other eligible sales offset or discount that are not counted as a chargeback or rebate (e.g. trade allowance)</td>
<td>$</td>
<td>Units</td>
<td>Subtract</td>
<td>Yes</td>
<td>Earned Period</td>
<td>Allocation</td>
<td>Product Group</td>
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</table>

**May Vary with Price Type**

**Will Vary with Price Type**

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Best Practices: Business Process Automation
Workflow Enhances Control, Communication and Efficiency

Business Process

1. Calculate and Report Base Prices
2. Manage Contract Life Cycle
3. Load and Scrub Claim Data
4. Validate Rebates
5. Generate Payment
6. Financial Approval
7. Mail to Account Manager
8. Present To Customer

Role-based Portal

Claims / All Claims / By Period / 2004 / Q1

Claim Activities
- Create a new claim
- Import a claim from file
- Adjust an existing claim
- View claims flagged as a price adjustment
- View open disputes
- View existing claims by folder
- Search for existing claims
- Search for existing payments

Alerts
- Claim is Approaching Due Date
- New AMP Price List Revision is Available
- Inputs to UPA Price List has Changed
- Inputs to URA Price List has Changed

Reference
- CA2004Q2MED1-12345-001
- AMP
- 421502454
- 839589618

Date Sent
- 10/15/2004
- 10/14/2004
- 10/13/2004
- 10/13/2004

My Recent "In Process" Claims

200401 AZ Medicaid was created
200401 MN Medicaid was created
200401 MN Medicaid was created
200401 NY Medicaid was created
200401 VA Medicaid was created
200401 VT Medicaid was created

Sent
- Tue, 6/22/2004
- Tue, 6/22/2004
- Tue, 6/22/2004
- Tue, 6/22/2004
- Tue, 6/22/2004
- Tue, 6/22/2004

Reporting Activities
- Current Quarter Claim Status Report
- UPA Trending Analysis
- Monthly Interest Projections
- Quarterly Claim Summary
- Annual Claim Summary
Best Practices: Reporting
Need to Track By State, By Program and By Product

Unified reporting across multiple dimensions:
- Programs
- Pricing
- Rebate components

Highlights rebate and risk drivers

More accurate forecasts and accruals

<table>
<thead>
<tr>
<th>NDC</th>
<th>PERIOD</th>
<th>AMP</th>
<th>BP</th>
<th>URA Basic</th>
<th>URA Penalty</th>
<th>URA Supp</th>
<th>Total URA</th>
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<td>1.34</td>
<td>1.34</td>
<td>12,300</td>
<td>854</td>
<td>$ 1,310</td>
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</table>
Many firms recognize that “Gross to Net Revenue” as a whole needs to be as an end-to-end business process, supported by a unique toolset...
Who is Model N?

- Pioneer of solution category “Revenue Management”
  - Integration of Pricing, Contracts, Settlements and Regulatory Compliance
  - Founded in 1999

- Fast Adoption by Pharmas and Biotechs since 2004
  - Leveraging Medical Technology install base

- Leader in Web Technology
  - Next generation platform - $50M invested and 5 patents pending

- Recognized by Analysts Firms
  - Featured as leader by AMR and Gartner
  - Red Herring Top 100 Finalist

- Stellar Financial Results
  - Profitable growth while investing in the business at same time
  - 5X License Revenue of closest competitor in Q3
Thank You…Questions!

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