



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

SIXTH ANNUAL PHARMACEUTICAL REGULATORY AND COMPLIANCE CONGRESS AND BEST PRACTICES FORUM

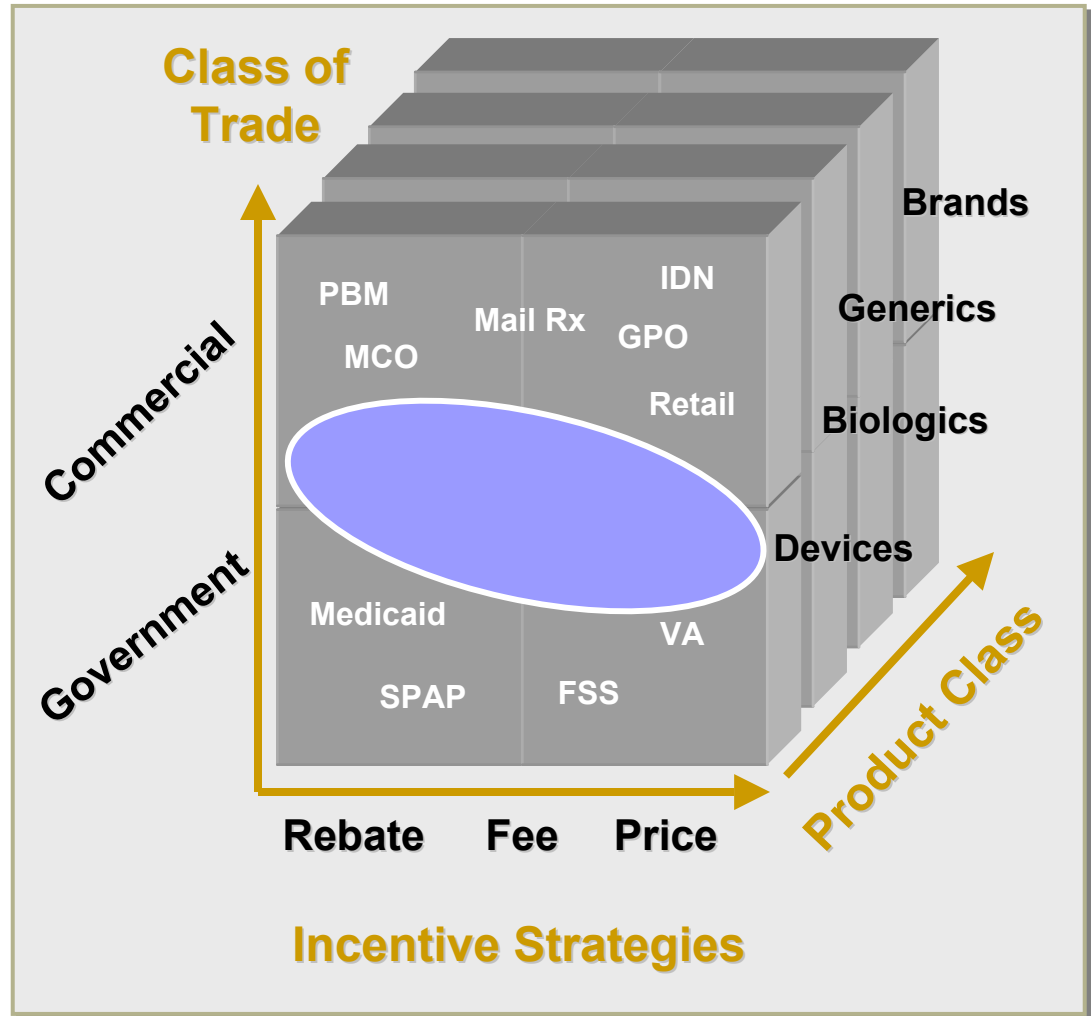
David Weiss
Solutions Director
Model N, Inc.

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...

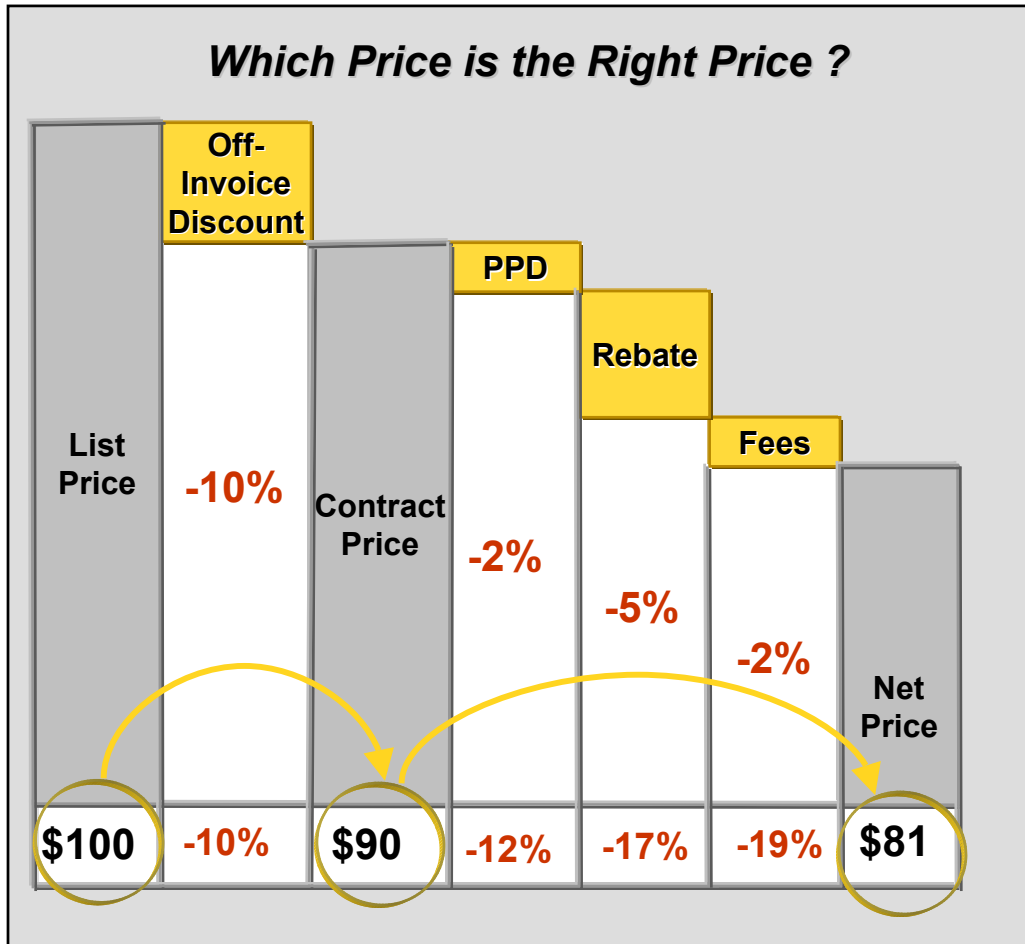
- **Convergence:**
 - Classes of Trade
 - Incentive Strategies
 - Product Portfolios
 - Regions or Countries
 - Federal & State
- **Compliance:**
 - Robinson-Patman
 - MMA 2003
 - OBRA 1990 & 1993
 - CMS Advisory (70+)
 - VHCA 1992
 - VA Advisory (37+)
 - SOX 404



Operational Challenges

Visibility to Net Pricing and Net Revenue

Linking together Net Pricing is a monumental challenge for many reasons...



→ 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

→ Miscellaneous

- Consumer Price Index – Urban (CPI-U)
- Assumed Prompt Pay Discount (APPD)
- Nominal Price Factor (NPF)
- Industrial Funding Fee (IFF)

→ 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

Government Pricing Solutions

How Can Automation Help?

Information
Availability
& Quality

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

Variable
Business
Process

- Enforces top-down policies
- Consistent price reporting methodologies

Complex...and
Increasing
Complexity

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

Visible, Auditable and
Reproducible
Results

- 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!

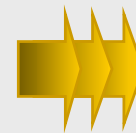
FDA Batch/Lot Tracking



Finished Goods



Ingredients

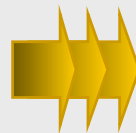


Recipes

Government Price Reporting



Calculations



Transactions



Policies

Best Practices: Systems

Links Policy, Data, Calculation, Filings and Reporting Together

→ Policies

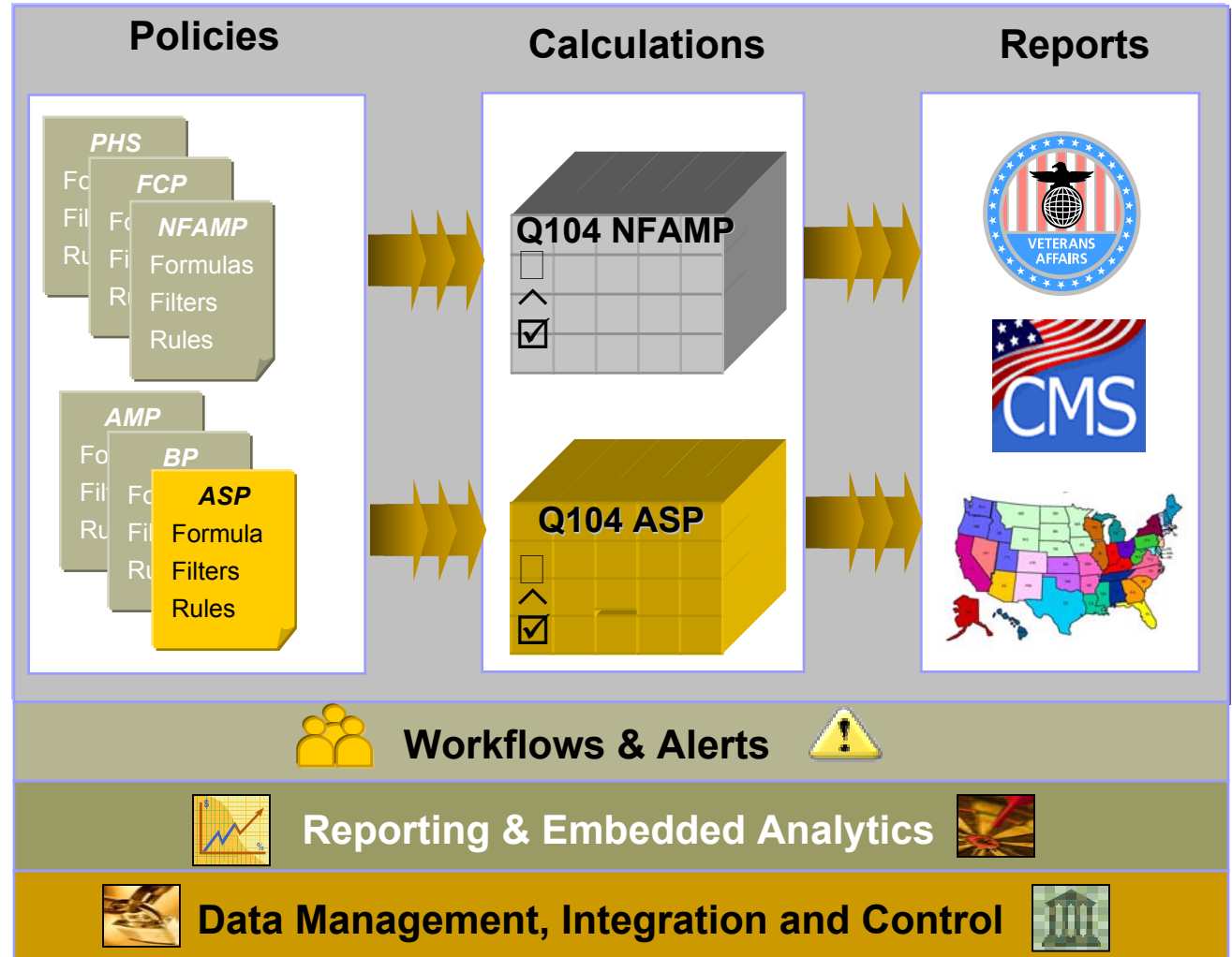
- Document of price policy and methodology
- Defines smoothing and allocations

→ Calculations

- Exceptions management
- Drill down and Analytics
- Workflows

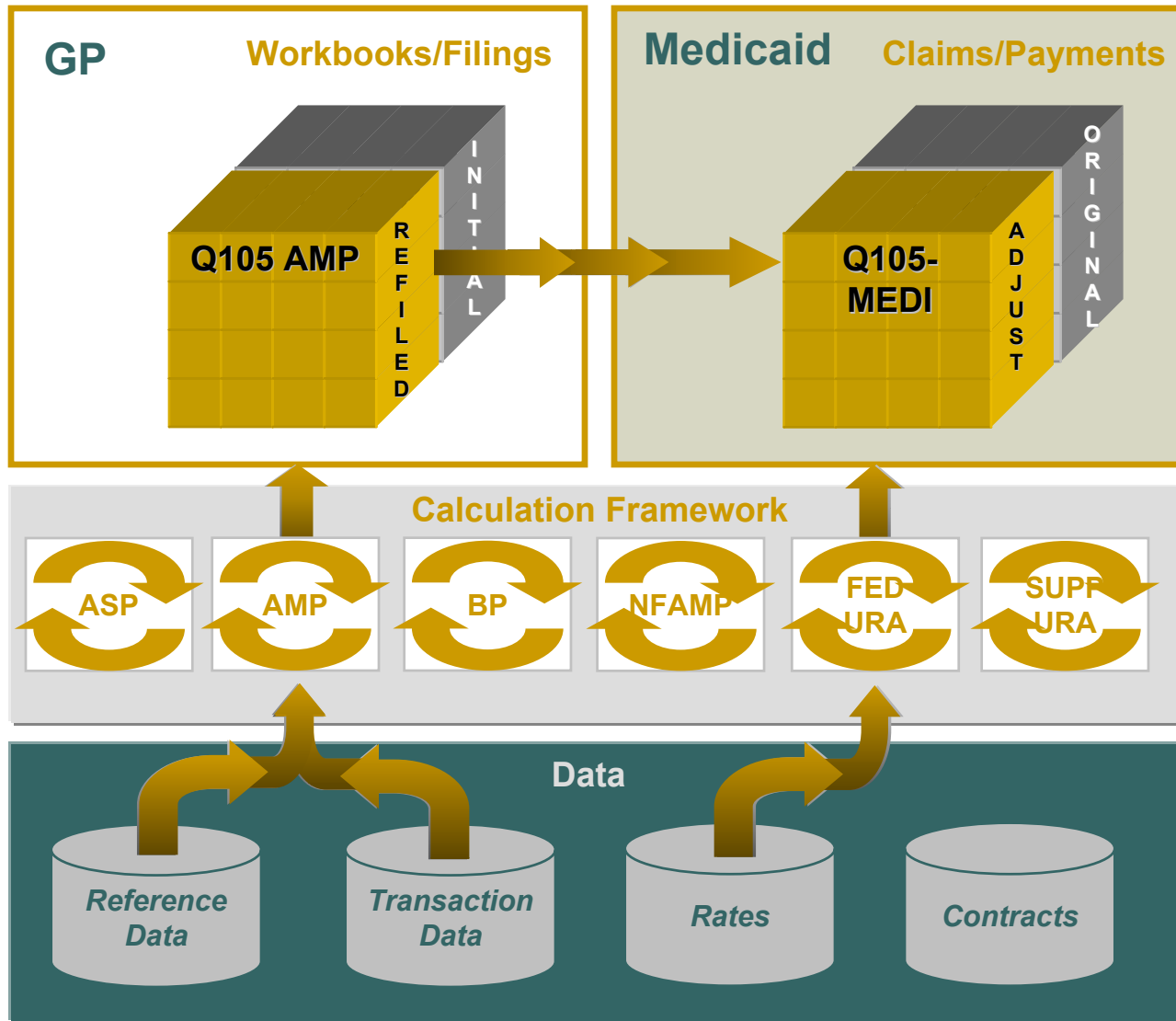
→ Reports

- Archive of filings & restatements



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

The screenshot displays the Model N Revenue Management Suite interface in Microsoft Internet Explorer. The browser title is "Model N Revenue Management Suite - DEVELOPMENT ENVIRONMENT - Microsoft Internet Explorer". The application title bar shows "- Price Monitoring Tiered02 - PMonTiered2-000-000 (Draft)".

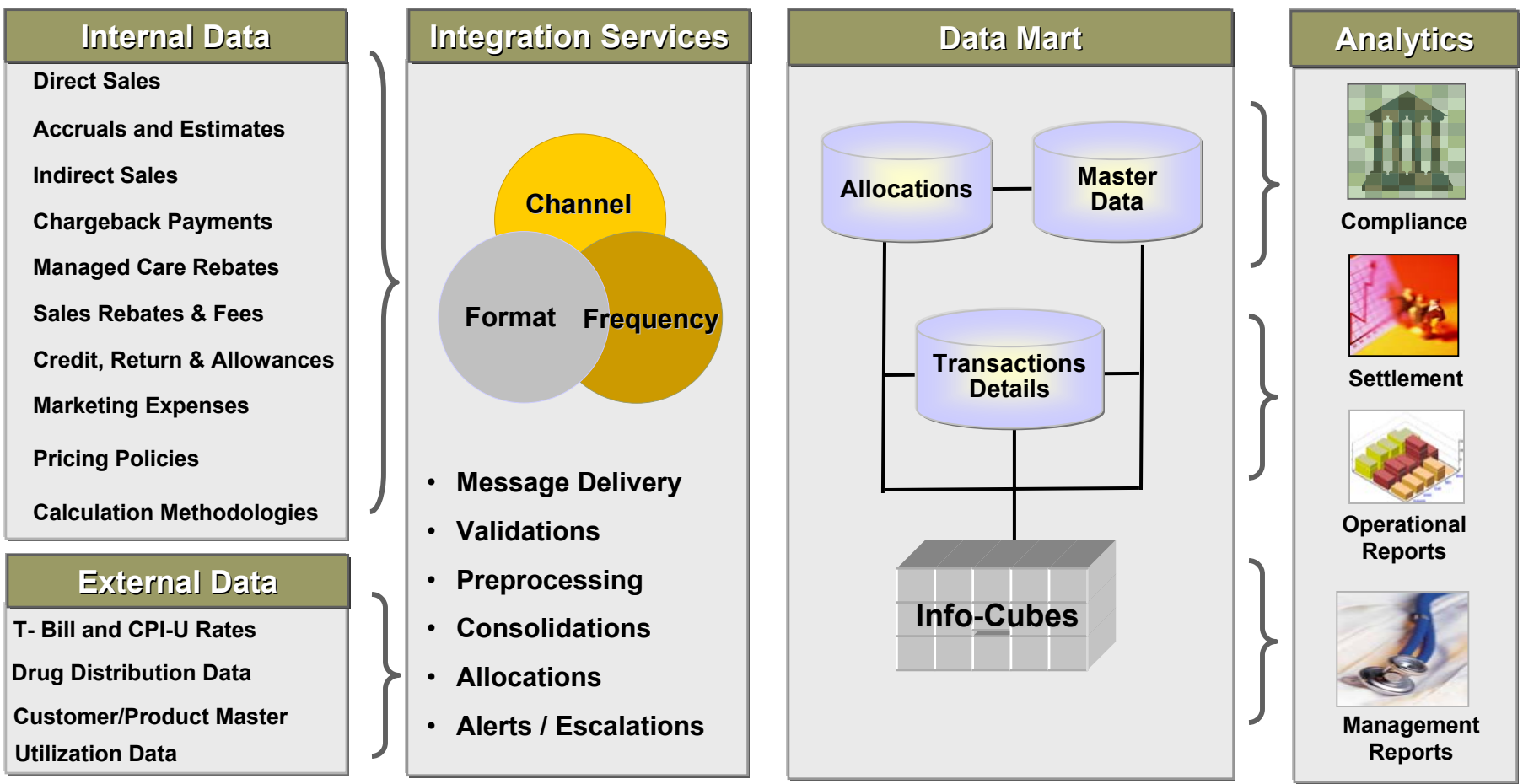
The interface includes a navigation menu on the left with sections for Tasks, Contract, and Details. The main content area is titled "Pricing Alerts" and shows a table of alerts. Below the table, there is a section for "Validation Results (No data available.)".

Alert Type	Approval Level / Alert Name	Product Group	Product #	Product Name	Reference Price List	Gross Price	Net Price	Reference Price
Commerical Price Floor	DIR	PMonTieredPG	Item1000	Item #1000	Price Floor List 06	\$93.00	<u>\$84.68</u>	\$94.15
Federal Supply Schedule	FSS Type 1	PMonTieredPG	Item1000	Item #1000	FSS-Q1-2004	\$93.00	<u>\$87.32</u>	\$90.00
Federal Supply Schedule	FSS Type 1	PMonTieredPG	Item1000	Item #1000	FSS-Q2-2004	\$93.00	<u>\$87.32</u>	\$110.00
Commerical Price Floor	DIR	PMonTieredPG	Item1001	Item #1001	Price Floor List 06	\$87.00	<u>\$82.65</u>	\$89.15
Federal Supply Schedule	FSS Type 1	PMonTieredPG	Item1001	Item #1001	FSS-Q1-2004	\$87.00	<u>\$85.26</u>	\$90.00
Federal Supply Schedule	FSS Type 1	PMonTieredPG	Item1001	Item #1001	FSS-Q2-2004	\$87.00	<u>\$85.26</u>	\$110.00

Validation Results (No data available.)

Best Practices: Data Information Architecture

Data Information Architecture



CPI-U Rates

Best Practices: Policies

Understand How Your Incentives Effect Pricing Compliance

Markets Class of Trade		Incentive Strategy Type			Pricing		Rebates				
		PPD	Direct	Indirect	Admin Fees	IMA Fee	Incentive Rebates	Credits	Free Goods		
Retail	Wholesalers / Distributors		X								
	Retail Chain & Independent			X				X			
	Mail Service	X	X	X	X		X				
	Long Term Care	X	X	X							
Providers	Hospitals			X	X	X	X		X		
	Medical Surgical Centers			X							
	Staff HMOs	X		X	X						
	HMO Managed Care - IPA			X							
	City/County/State Providers			X							
Regulated Market	Federal Government (FSS)		X	X							
	State Pharm. Assistance							X			
	State Medicaid Agencies						X				
	PHS Covered Entities		X	X							
	Prescription Drug Plan										

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

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

May Vary with Price Type

Will Vary with Price Type

Best Practices: Policy and SOP

Document Data Linkage to Calculation Methodologies

Example: Average Manufacturer Price

Net Sales = (Direct Sales – Indirect Sales) – (Chargebacks + Rebates + Adjustments)

Net Units = (Direct Units – Indirect Units)

AMP = Net Sales / Net Units

ModelN, Inc.

December 3, 2004

Average Manufacturer Price

Data Source	Bucket	System	Name	Value	Filter	Smooth ?
Direct Sales	DS	ERP	SalesOrders	Order_type in ('A1', 'B0', 'U8')	COT = Whlr, Splr, Rx, etc.	
	DS2	ERP	WholesaleRet		COT = Whlr	
	DS3	ERP	DirectRet		COT = Splr, Rx	
Indirect Sales	IS	Contract	TotalCot		COT = GOV, Contract = PHS001	Dollars
Rebates	RB	Contract	RebatePaid	Rebate_type = 'IR' or 'AF'	COT = Mail	
Adjustment	FA	Contract	PromptPay			
	FA2	Contract	WholesaleCr			
Chargeback	CB	Contract	Chargebacks		COT <=> GOV, Contract <=> PHS001	Dollars

Maps >

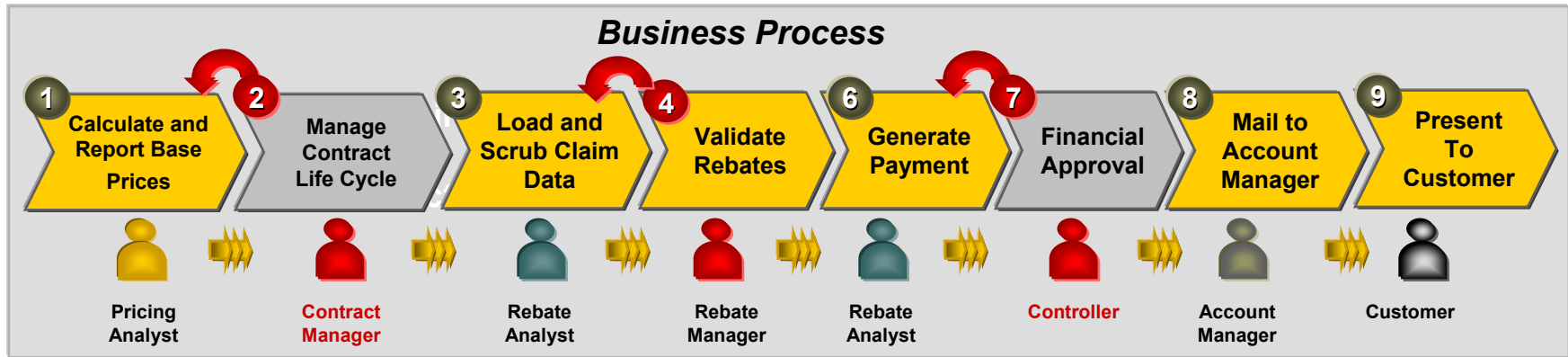
Data Source

Transactions

Policies and SOPs

Best Practices: Business Process Automation

Workflow Enhances Control, Communication and Efficiency



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](#)

Questions

- [How do I create a new claim?](#)
- [Where can I find all claims that have been flagged?](#)
- [View existing claims by folder](#)
- [Search for existing claims](#)

Alerts

Alert	Reference	Date Sent
Claim is Approaching Due Date	CA2004Q3MEDI-12345-001	10/15/2004
New AMP Price List Revision is Available	AMP	10/14/2004
Inputs to URA Price List has Changed	421562454	10/13/2004
Inputs to URA Price List has Changed	899989618	10/13/2004

My Recent "In Process" Claims

Name	Sent
2004Q1 AZ Medicaid was created.	Tue, 6/22/2004
2004Q1 MN Medicaid was created.	Tue, 6/22/2004
2004Q1 MN Medicaid was created.	Tue, 6/22/2004
2004Q1 NY Medicaid was created.	Tue, 6/22/2004
2004Q1 PA Medicaid was created.	Tue, 6/22/2004
2004Q1 VT Medicaid was created.	Tue, 6/22/2004

Reporting Activities

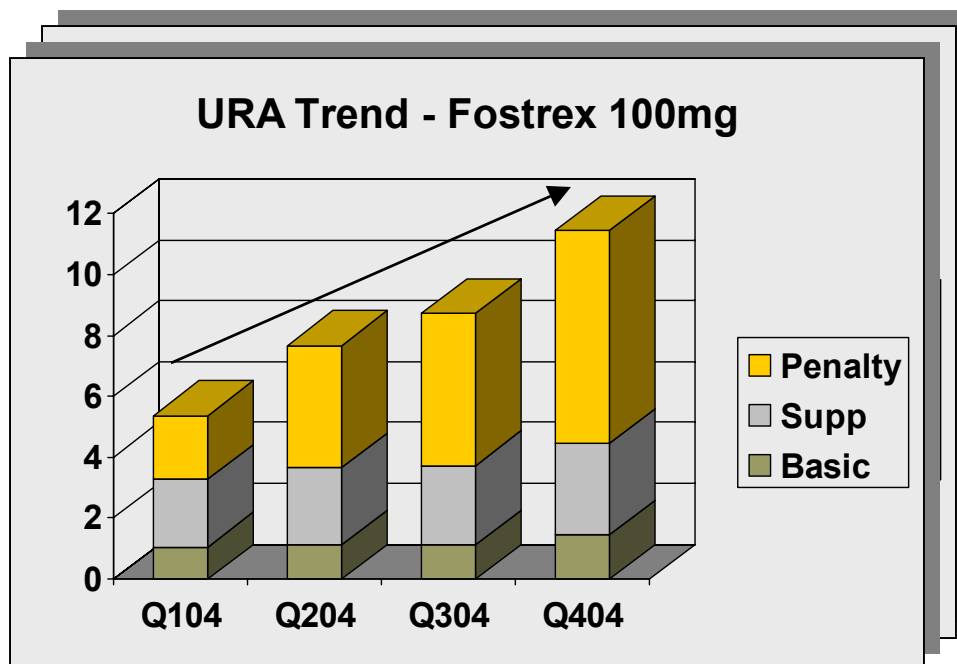
- [Current Quarter Claim Status Report](#)
- [URA Trending Analysis](#)
- [Monthly Interest Projections](#)
- [Quarterly Claim Summary](#)
- [Annual Claim Summary](#)

Best Practices: Reporting

Need to Track By State, By Program and By Product

California	NDC	PERIOD	AMP	BP	URA Basic	URA Penalty	URA Supp	Total URA	Units	Rx	Rebate
New York	NDC	PERIOD	AMP	BP	URA Basic	URA Penalty	URA Supp	Total URA	Units	Rx	Rebate
Texas	NDC	PERIOD	AMP	BP	URA Basic	URA Penalty	URA Supp	Total URA	Units	Rx	Rebate
	00001-0001-12	Q104	13.02	10.33	1.13	1.13	1.13	1.13	10,000	750	\$ 1,200
		Q204	13.05	9.87	1.20	2.20	1.20	1.20	11,000	765	\$ 1,300
		Q304	14.19	11.87	1.22	1.22	1.22	1.22	11,750	824	\$ 1,320
		Q404	14.30	11.98	1.34	1.34	1.34	1.34	12,300	854	\$ 1,310

- Unified reporting across multiple dimensions:
 - Programs
 - Pricing
 - Rebate components
- Highlights rebate and risk drivers
- More accurate forecasts and accruals



Revenue Management

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...

Pharmaceutical Revenue Management Applications

Pricing Strategy

Price Execution

Contract Mgt

Charge-backs

Institutional Rebates

Managed Care Rebates

Admin Fees

Service Fees

Gov't Pricing

Medicaid Claims Processing

Supporting Applications

Tools

Catalog

Community

Workflow

Pricing

Analysis

Technology Platform

Data

Customers

Prices

Sales

Contracts

Rebates

Chargebacks

Integration Services

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

 Bristol-Myers Squibb Company

 AMGEN®



 Boston Scientific

 MedImmune



 SCHWARZ
PHARMA



 BAIRD



 COTHERIX



 Ortho-Clinical Diagnostics
a Johnson & Johnson company



 TERUMO®



Thank You...Questions !

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