

Compliance in an Environment of Change

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Susan Sisskind Dunne, Esq.

Director, Life Sciences Advisory Services, Huron Consulting Group,

Joseph J. Skupen, CPA

Senior Director, US Corporate Compliance, sanofi-aventis US

LIFE SCIENCES ADVISORY SERVICES



Overview – Government Programs

Program	Obligations	Frequency of Calculation
Medicaid Drug Rebate Program	Average Manufacturer's Price ("AMP")	Submitted to CMS monthly (within 30 days of close of month and quarter)
	Best Price ("BP")	Submitted to CMS quarterly (within 30 days of close of quarter)
	Unit Rebate Amount ("URA")	Calculated quarterly by manufacturer to confirm CMS calculation – not actually submitted.
Public Health Service ("PHS") / 340B Program	PHS Ceiling Price (AMP - URA)	Calculated quarterly by manufacturer and submitted to Wholesalers to load into their contract pricing systems.
Medicare Part B	Average Sales Price ("ASP")	Submitted to CMS quarterly (within 30 days of close of quarter)
Federal Supply Schedule	Quarterly and Annual Non-Federal Average Manufacturer's Price ("Non-FAMP") Federal Ceiling Price ("FCP")	Submitted to VA quarterly (within 45 days of close of quarter) Annual Non-FAMP/FCP submitted to VA annually 45 days after the close of the 3 rd quarter (11/15)

The Challenges of Pricing Compliance

- Net price:
 - Not clear what constitutes a price concession
 - Data not always available at necessary level of detail
- Inclusion and Exclusion: COT, contract, transaction type reason codes and price/unit
- Due Within 30 or 45 Days
- Lagged Transactions
- Variation across programs
- Nature of programs impairs ability to be conservative
- Guidance is often incomplete, unclear, and constantly evolving

Focus Areas for Risk Evaluation

- Reconciliation of Government Pricing transaction data to General Ledger
 - Accounting for commercial rebates
 - Rebates paid match chargeback utilization
 - Medicaid rebate payments
 - Unit of measure issues
 - Archive of legacy system data

Focus Areas for Risk Evaluation

- Establishing Accurate Pool of Baseline Data
 - Customer Master
 - Product Master
 - Robust Class of Trade Schema and assignment rules
 - Robust Transaction Type and Order Reason Code Schema and assignment rules
 - PHS / 340B Eligibility monitoring
 - Baseline AMP calculations
 - Obtaining accurate CPI-U data
 - Federal contract membership management

Focus Areas for Risk Evaluation-Adjusting to Change

- Adjusting to Organizational Change:
 - Policy and SOP comparison
 - Data Integration
 - Systems Integration
 - Personnel Realignment
 - Archiving of Legacy System Data

Focus Areas for Risk Evaluation-Adjusting to Change

Obstacle Course of Recent Statutory Changes

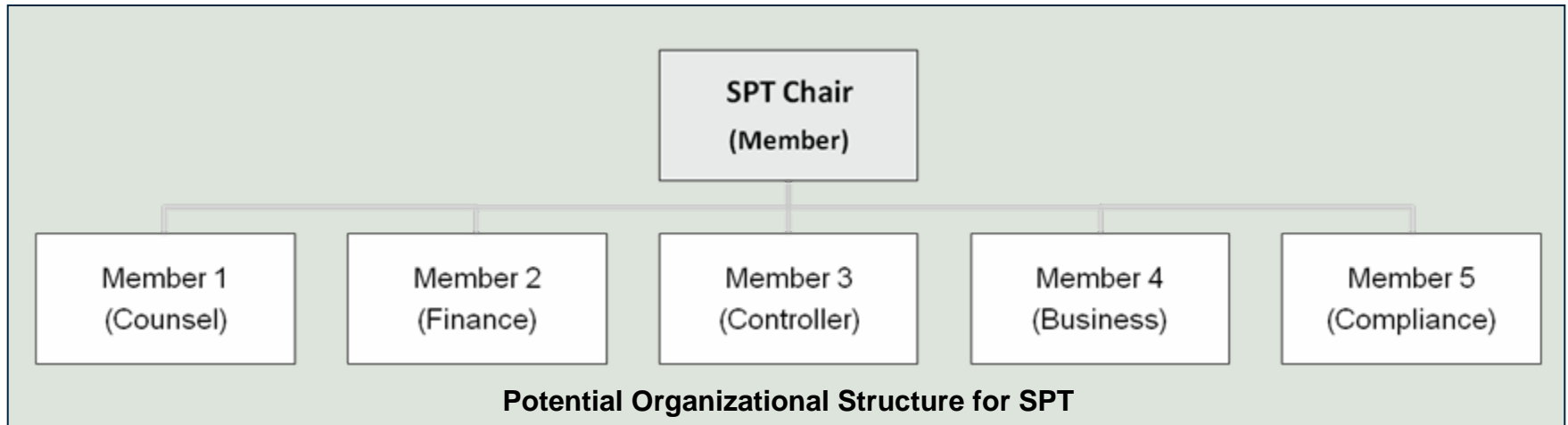
- MMA
 - ASP and reimbursement rates
- DRA
 - Definitions and reporting obligations
- PPACA
 - Medicaid
 - Changes to AMP eligible customers
 - Rebate amount
 - Sub categories with further changes
 - Medicaid Managed care
 - Changes to 340b
- Environment of Change Must be Absorbed into Auditing Compliance

Focus Areas for Risk Evaluation-Adjusting to Change

- Adjusting to Statutory/Regulatory Change:
 - Policy and SOP amendment
 - Altering class of trade and/or transaction type/order reason code schemas to reflect changes in regulation
 - Altering existing systems to account for methodological changes and/or implementation of new system
 - Communication mechanism that is reactive to change to pull in appropriate stakeholders
 - IT
 - Finance & Contracts
 - Sales & Marketing
 - Compliance
 - Legal

Potential Structure of a Strategic Pricing Team

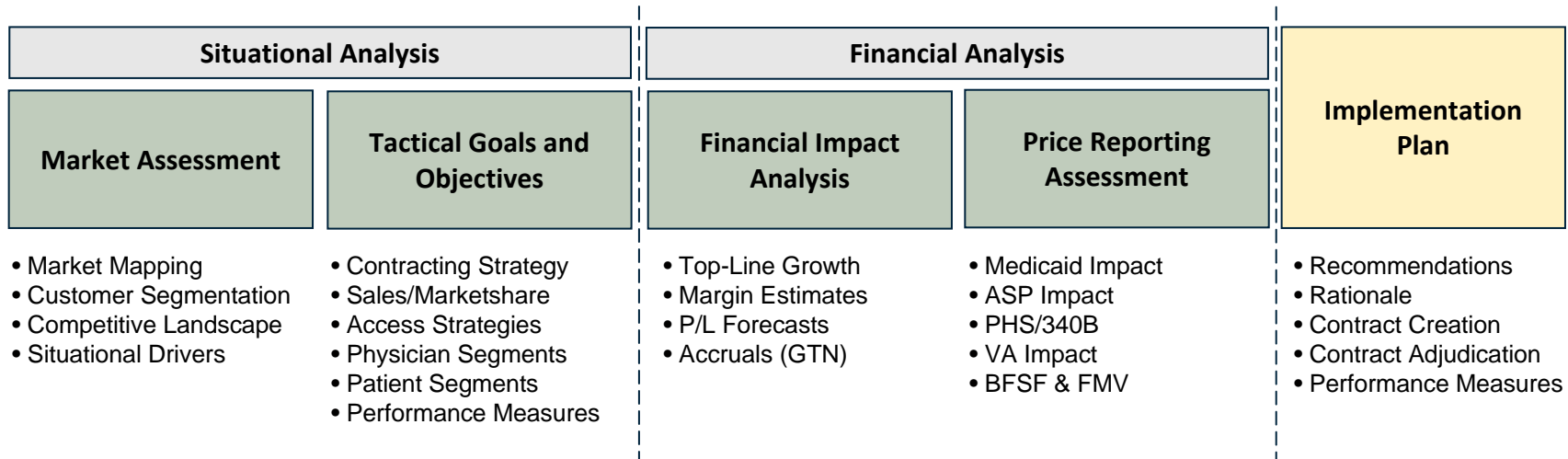
Developing a Cross-Functional Team to Develop Consensus



- Larger organizations may have 7 to 9 members while smaller organizations may structure a team with 5 members and allow for a consensus with at least 3 members present.
- Typically, the SPT would be chaired by someone with strategic pricing oversight and functional responsibility for employees in pricing and contracting functions.
- The SPT chair would also be a member with additional participants from various finance, business, and operational functions.
- In some organizations, someone from legal may be a member while in others, legal may act in an oversight and advisory capacity.

Guidelines for Strategic Pricing Team Review

Standardizing the Submission and Review Process



- Most organizations typically require that sales/marketing/national accounts make a formal presentation for review and approval by the SPT. The presentation will generally include a situational analysis, a financial review, and an implementation plan.
- The level of formality of the presentation or the “package” that is submitted to the SPT can be adjusted based on the needs of the organization.
- However, the basic elements, as described on this slide, are likely to be needed by a cross-functional team to provide an adequate level of review and approval for any pricing strategy that has a substantive impact either to the market or the brand P/L.

Types of Pricing Matters Typically Reviewed and Approved by an SPT

Financial Relationships Involving the Market or Customers

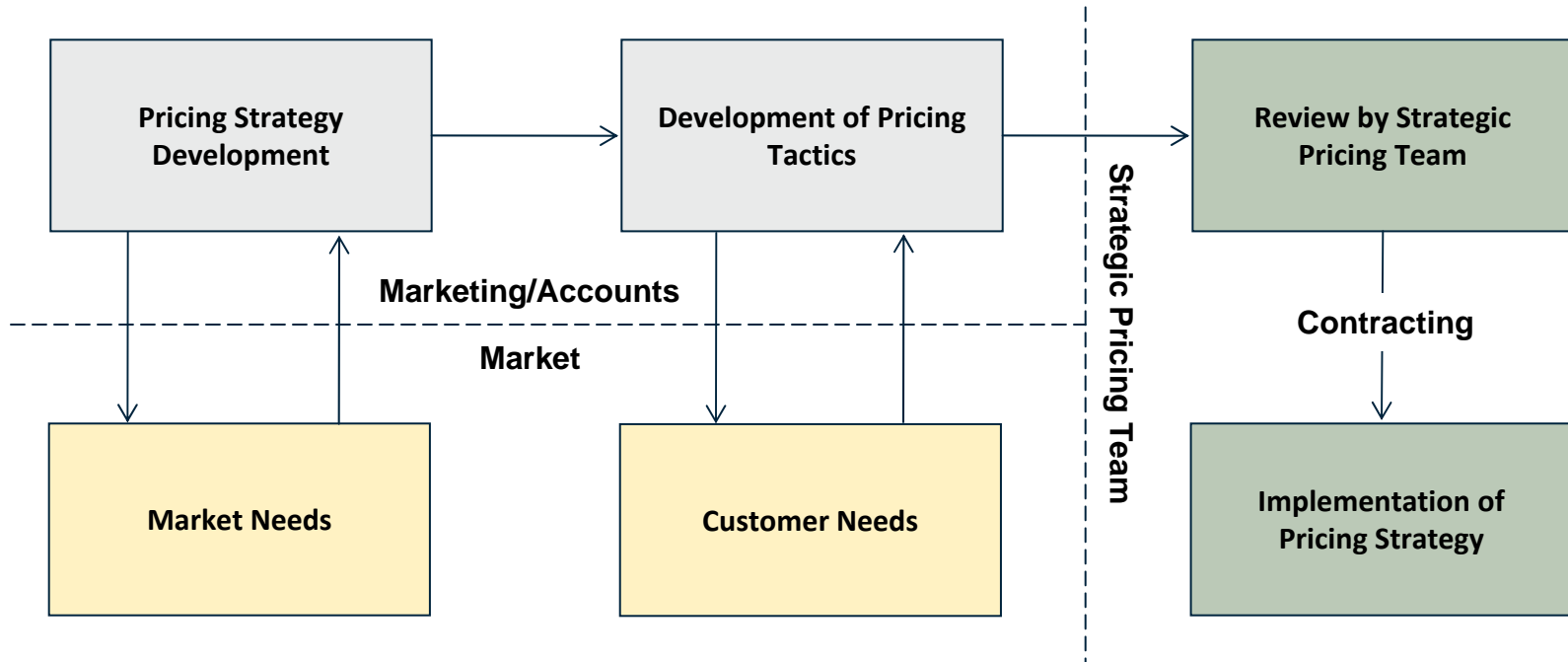
- Development and implementation of an overall corporate pricing policy
- Individual list price change recommendations
- New product pricing and in-licensed product pricing
- Approval of contracting guidelines (e.g., strategies, thresholds, customer types, etc.)
 - Discounting
 - Rebating
 - Value based pricing
- Exception review process
- Review of contract or contracting strategy performance
- Develop product lifecycle strategies
- Approval of the purchase of services from customers (e.g., data, patient support, etc.)
- Understanding of Price reporting impact (e.g., BP, CPI-U, etc.)

Enforcement

- Average settlement >\$100M
- Hundreds of cases reportedly under Seal
- Focus Areas
 - Average Wholesale Price
 - Best Price
 - Bundling
 - Nominal
 - Off-Label Promotions
 - Violations of Anti-kickbacks statute

Basic Structure of a Strategic Pricing Process

Key Objectives in Executing a Process



The basic strategic pricing process is primarily focused around supporting the needs of the market and the individual customers. Pricing strategies and tactics are developed by marketing and/or national accounts and submitted to a Strategic Pricing Team (“SPT”) for review, approval, and implementation. As contracting strategies are developed and formalized, the SPT can provide guidelines and pricing parameters by customer class for use by Marketing or National Accounts in discussions and negotiations with customers.