



Model **N**

Operational Excellence and Process Efficiency Strategies for Government Pricing

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Session Topics

Government Pricing Landscape

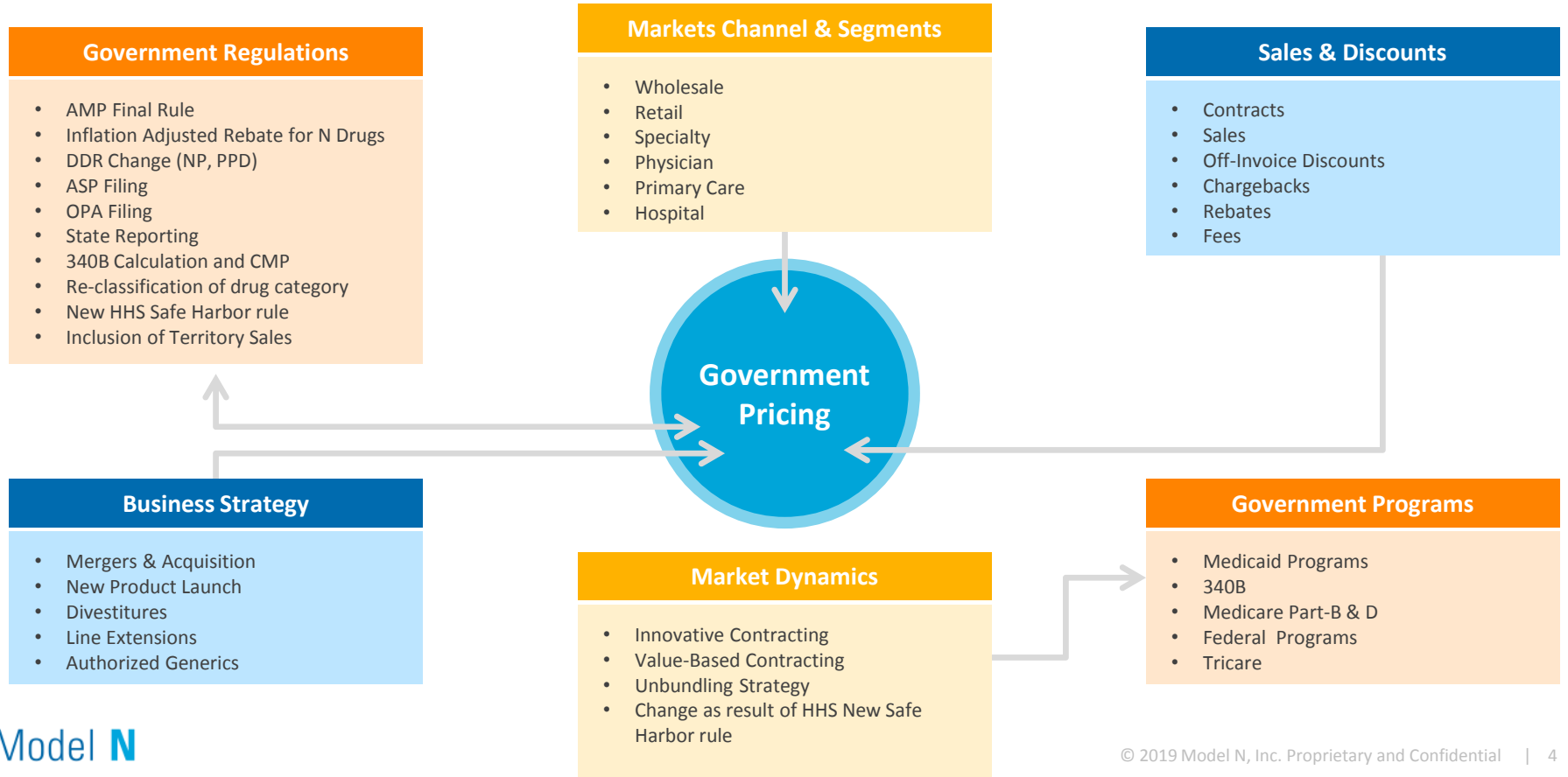
GP Operations

GP Fundamentals and Design

HHS Safe Harbor rule

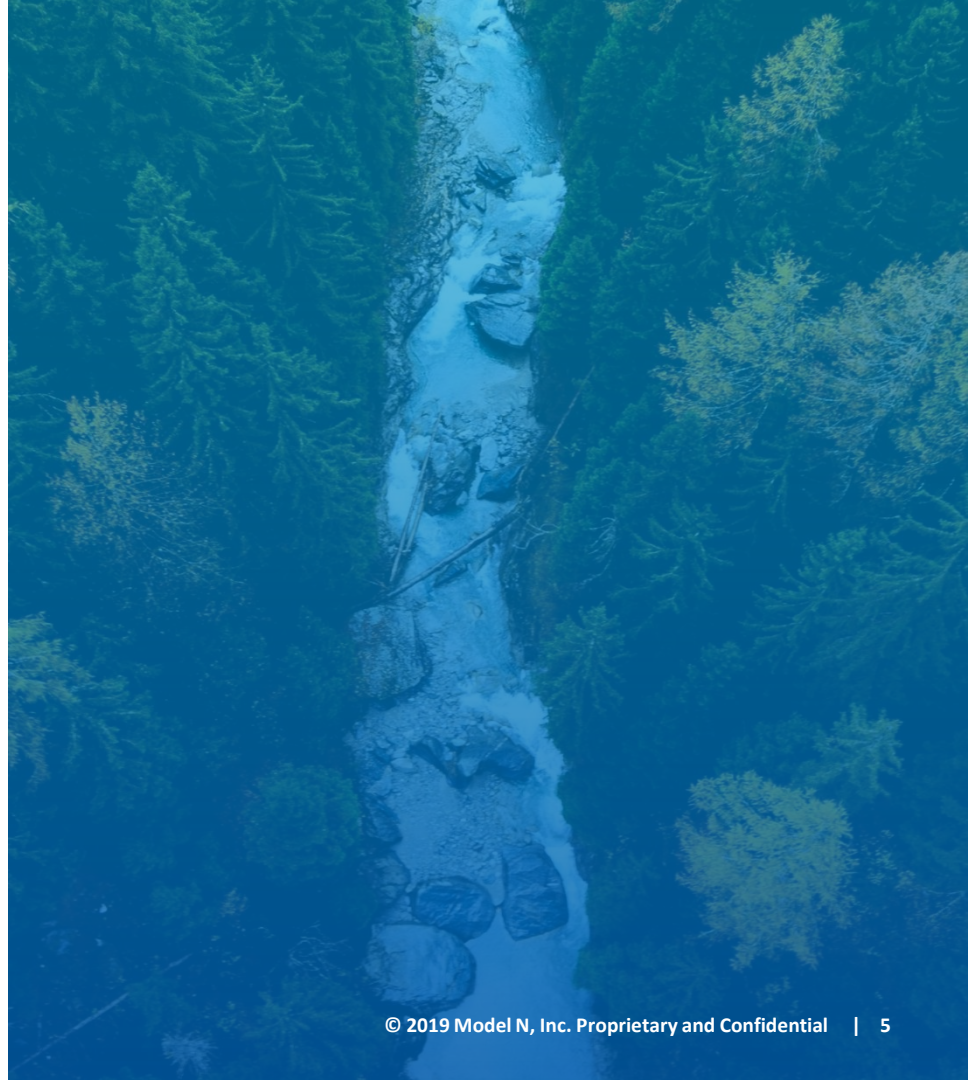
Q & A

Government Pricing Landscape



GP Operations

- Constant vigilance with government regulations and communications
- Adapt to market dynamics
- Incorporate changes in market channels and segments
- Acquaint with upstream processes and data
- Define and manage policies
- GP calculations & reporting
- Evaluate down-stream impacts and liabilities
- Support Audits!



GP Operations- Managing Class of Trade

- COT Assignment
 - COT Change
 - Change in a historical period
 - Who owns and manage COT
 - COT review
 - Impact on Contracts
 - Sales Validations
 - GP Policy Impacts
- Consider effective dating COT
 - Define a reconciliation process based on COT
 - Ensure your GP system supports reproducibility with respect to COT effectivity and changing classes of trade

GP Operations- Key Processes

- Bona Fide Service Fees
- Patient Support Programs
- Returns
- Bundled Sales Arrangements
- Stacking
- Blending
- Inner & Outer Packs

Implement a system and process where the policy can easily be changed and analyzed

GP Operations- Price Reporting

- **Standard Reporting**

- Monthly AMP
- Quarterly AMP, BP
- ASP (Product & Price), Addendums
- 340B Price
- Quarterly and Annual VA Reporting

Ensure your system is able to produce and reproduce necessary output for respective agencies in a timely manner

- **State Reporting**

- AMP, BP, ASP, URA, WAC
- WAC increases*
 - Advance Price increases
 - Justification of increases
 - Increase threshold
 - Essential Diabetes drug list

- Define a configurable process as more states are requiring similar pricing report
- Work with your finance/strategy team to ensure WAC changes are reported

GP Operations- 340B

- 340B Calculation
 - Restatement
 - 340B Refund in case of overcharge
 - Price Reporting to HRSA
 - Duplicate Discount
 - Medicaid, Commercial
 - GPO Prohibition
 - Audit
- Consider defining a process for 340B restatement and refund
 - Prepare for HRSA Audit
 - Closely monitor 340B program developments

GP Operations- Federal Operations

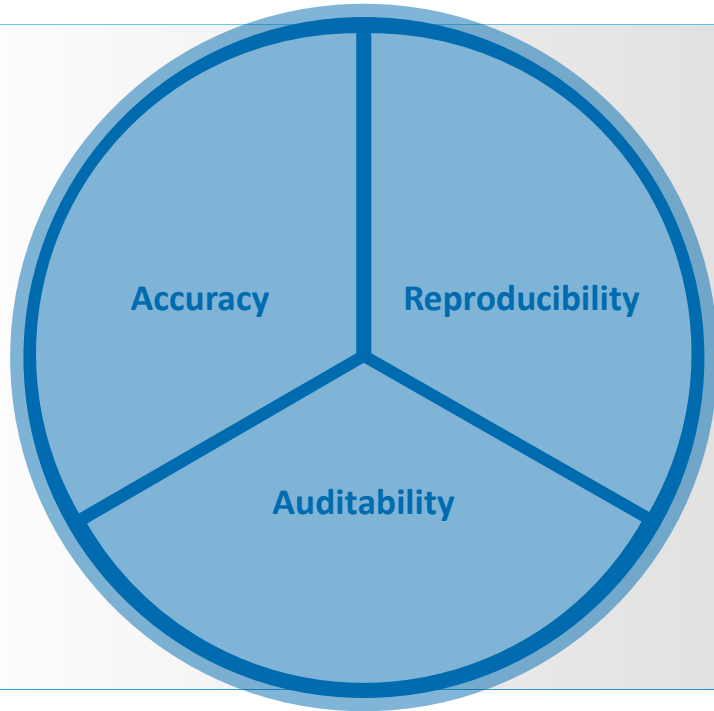
- NFAMP Calculation
 - FCP Calculation
 - FSS Compliance Monitoring
 - New FSS contract and existing contract renewal
 - Product and contract expirations
 - Tricare Rebate Payment
 - Support Audit
- Ensure GP system supports all VA price calculation
 - Establish a system to monitor FSS compliance and a process to support RFM
 - Work with IT team or system provider to prepare necessary data such as CSP in case contract renewal and negotiation
 - Establish a system to Pay Tricare Rebate and utilize on NFAMP calculation

HHS – Safe Harbor Rule

- Excludes Medicare Part D and Medicaid MCO rebates from AKS discount safe harbor protection
- The new safe harbor protects certain discounts such as POS price reduction and PBM service fees
- Target effective date:1/1/2020
- Over 25000 comments has been submitted to HHS

- Analyze potential COT impact on GP filters
 - As new chargeback/rebate model evolve in the industry, ensure transactions are qualified by key attributes that can be easily utilized in GP
 - **Do the new chargebacks contain enough data?**
 - Evaluate potential bundle arrangement, i.e payer/patient arrangement
 - Evaluate potential change to GP formula
 - Work with legal advisor to review the impact
-
- Adopt a system that has all framework already established
 - Able to change GP policy, verify and operationalized in a timely manner before deadline

Fundamental Tenets of Government Pricing



Consistent and solid maintenance is key:

- Master Data
- Direct Sales
- Commercial Contracts
- Government Contracts
- Chargeback Process
- Rebate Process
- Discount Reallocation
- Medicaid Contracts and Rebates

GP Design Considerations

GP POLICY AND PRICE TYPES

Master Data

Customers (wholesalers, GPO/IDNs, PBM/HMOs, States)

Products (ID/NDCs, Strengths, Forms/5i, Dates, S/N/I, UPP)

Pricing (WAC, AMP, BP, ASP, NFAMP, URA, FSS, PHS)

Contracts

Commercial
Government

Process

Chargebacks
Rebates
DRM

Transactions

Direct Sales
Indirect Sale/CB
Rebates

Optimization

Data Quality
Availability
Reconciliation

Data Sources
Data Filters

Complex Math
Smoothing Ratio

Validations
Monitoring

Analysis
Approval

Timely GP Calculation Requires Efficient Process

Typical 30 days reporting deadline

Additional 15 days for VA reporting

Data Readiness

Data Reconciliation

Unbundling

GP Calculation

GP Analysis

Approval

Filing and Reporting

Efficient GP Process

Increased Operational Load

Typical 30 days reporting deadline

October 1st – November 15th:
Busiest time of the year

Additional 15 days for VA reporting

Data Readiness

Data Reconciliation

Unbundling

GP Calculation

GP Analysis

Approval

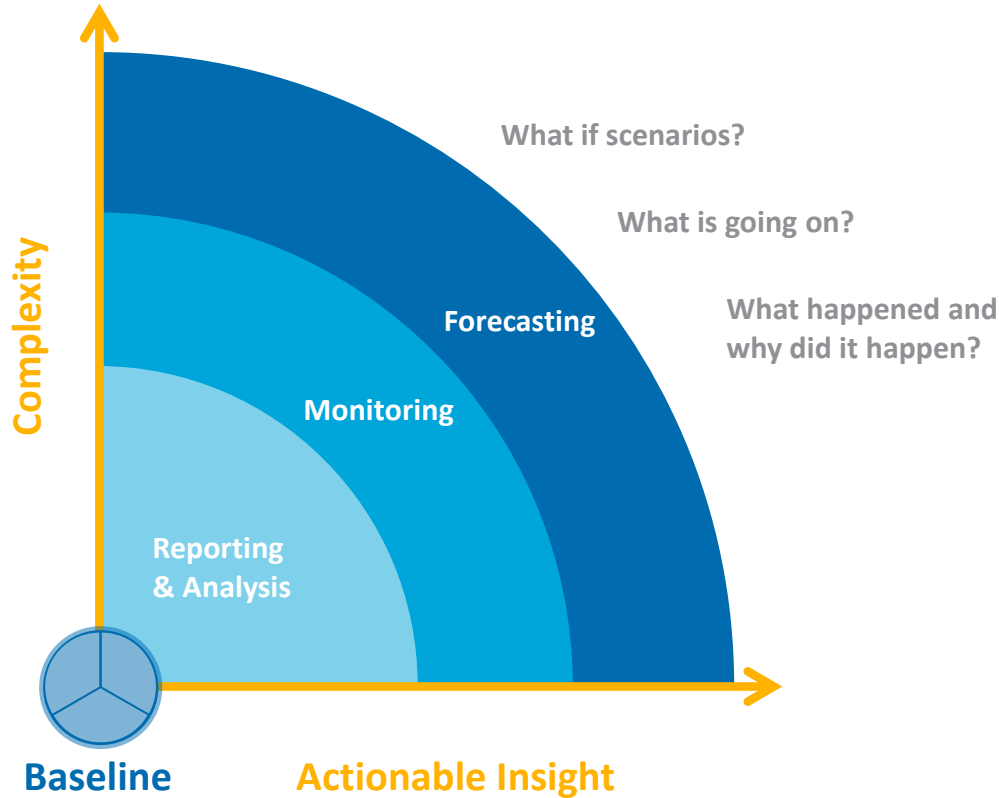
Filing and Reporting

Efficient GP Process

- Change GP Policy and analyze impact
- Support simultaneous calculations
- Support Fundamental Tenets of Government Pricing

- New contract Strategy
- Quarterly Calculation
- Annual Calculation
- Restatement
- Internal and External Audit
- Unavailability of Data

GP Analytics



Establish system that perform What-If-Analysis when any change in up-stream commercial offering or change in Policy, evaluate impact in GP and thereby forecast the liabilities such as Medicaid, 340B, Federal pricing.

A user configured tool will help to monitor the trend and determine the change in liabilities over different period based on the number calculated by GP.

GP System with "In-Built" Analytics capability provides flexibility for GP team to adopt any change in policy, analyze result and report on current scenarios.

Ability identify key factors impacting GP numbers such as WAC change, more discounts, new offering or expired contracts

Questions?

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