

Introductions

Model N | rainmaker

What does Safe Harbor mean for Revenue Management?

Impacts to Revenue Management Operations



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Agenda

- 1 Proposed Rule Review & Timeline of Events
- 2 Current & Future State Landscape
- 3 Operational Change & Impact to Revenue Management
- 4 Additional Considerations & Closing

Proposed Rule Review & Timeline of Events

Proposed Rule Review

The Proposed Rule discusses three key changes:

Amend Discount Safe Harbor

Amends the existing discount safe harbor so that it would no longer protect rebates from manufacturers to plan sponsors under Medicare Part D or Medicaid MCOs, either directly or through PBMs acting under contract with plan sponsors under Medicare Part D or Medicaid MCOs

Point of Sale Safe Harbor

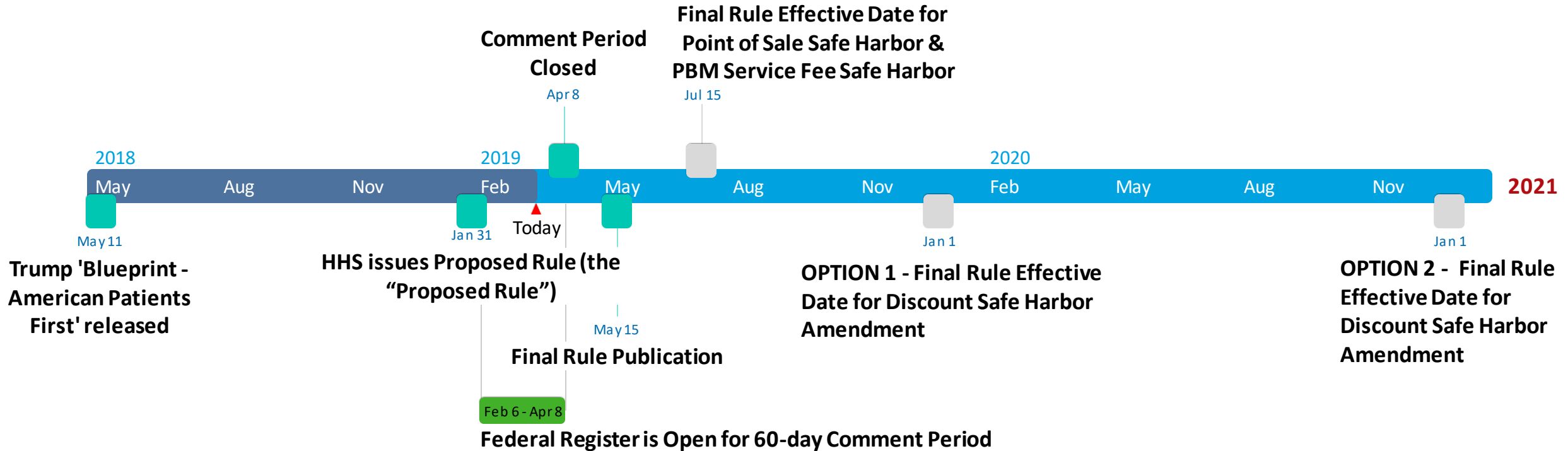
This new safe harbor would protect certain price reductions offered by manufacturers to Part D plans and Medicaid MCOs that are reflected at the point of sale to the consumer

PBM Service Fees Safe Harbor

PBM Service Fee safe harbor would protect payments pharmaceutical manufacturers make to PBMs for services the PBMs provide to the pharmaceutical manufacturers

Timeline of Events

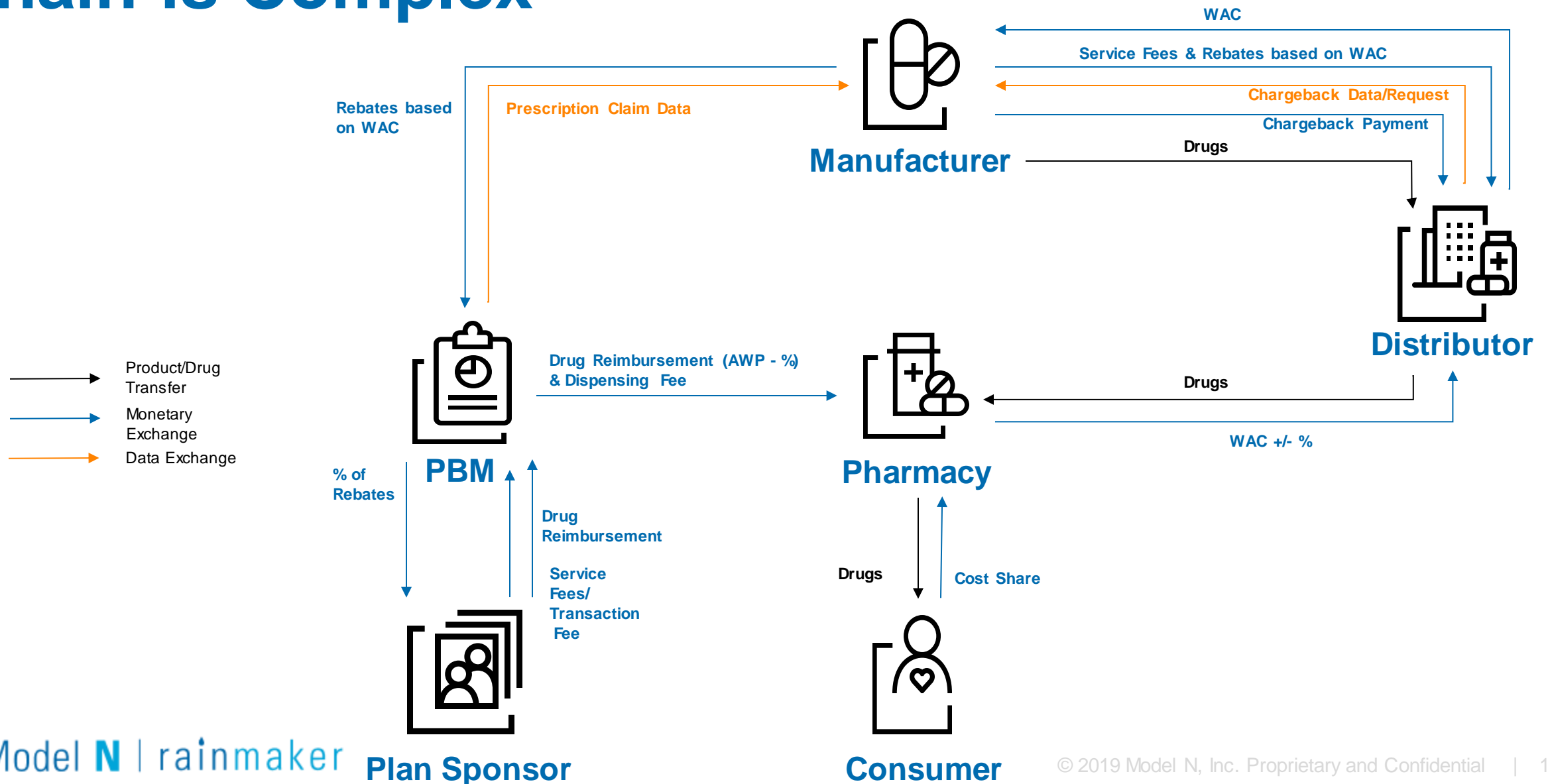
The Proposed Rule discusses implementation by January 2020, but also discusses a second option of January 2021 implementation



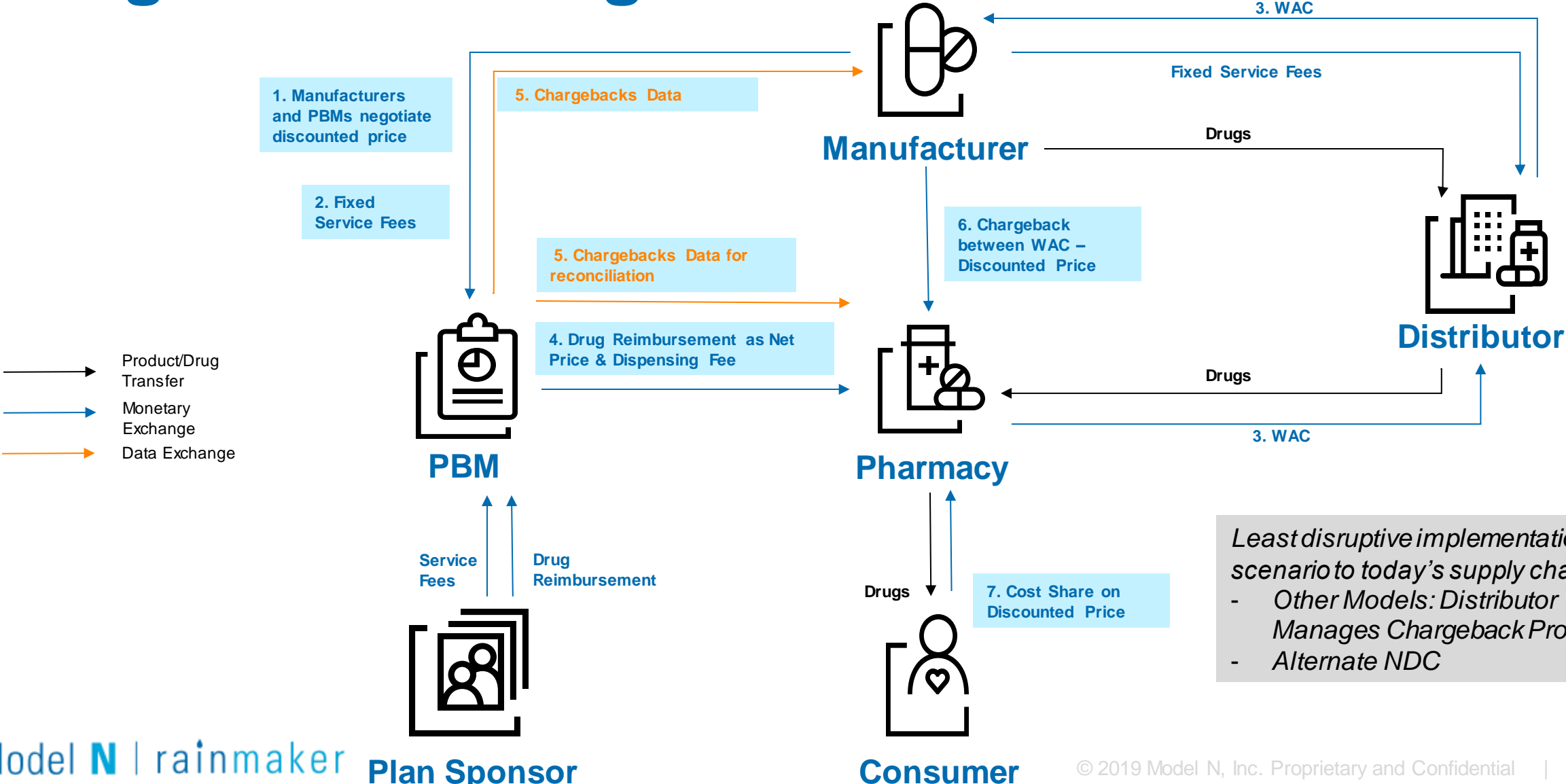
The HHS proposal would remove the existing safe harbor protection on Jan 1 2020 with the two new safe harbors effective 60-days after publication of the final rule, assuming an immediate publication post the comment period would point to June or July 2019, (an aggressive assumption, mid-May is more likely).

Current & Future State Landscape

The Current Branded Pharmaceutical Supply Chain is Complex



Potential Implementation Scenario: PBM Manages New Chargeback Process



Least disruptive implementation scenario to today's supply chain

- Other Models: Distributor Manages Chargeback Process
- Alternate NDC

Operational Change & Impact to Revenue Management

Revenue Management Impacts

Government Pricing

	COT	Assign filterable data attributes to Part D data and modify GP filters to accommodate such attributes
	AMP / BP	Modify GP calculations to include or exclude discounts.
	Unbundling	Possible elimination of need for managing bundles and reallocating rebates
	BPI	Possible elimination of need to calculate Best Price Initial/Estimated

Sales/Chargebacks

	Data	Configure new Sale Type flag to identify new prescription plan chargebacks
	Data	Update indirect sales to consume additional data points on the chargeback line
	Validations	Possible new validations required for script scrubbing
	Interfaces	Potential new interface for new indirect sales



Master Data

	Membership	No impact
	Product	Additional UOM conversions required
	Customer	Populate customer records with additional information (i.e. Class of Trade, IDs)

Payments

	Interfaces	Modify payment interfaces/SAP to consume Credit Memo requests and generate payment to PBMs
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Contracts

	Strategies	Configure new contract strategies; re-design PBM contracts with updated strategies
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Operational Impact – Commercial

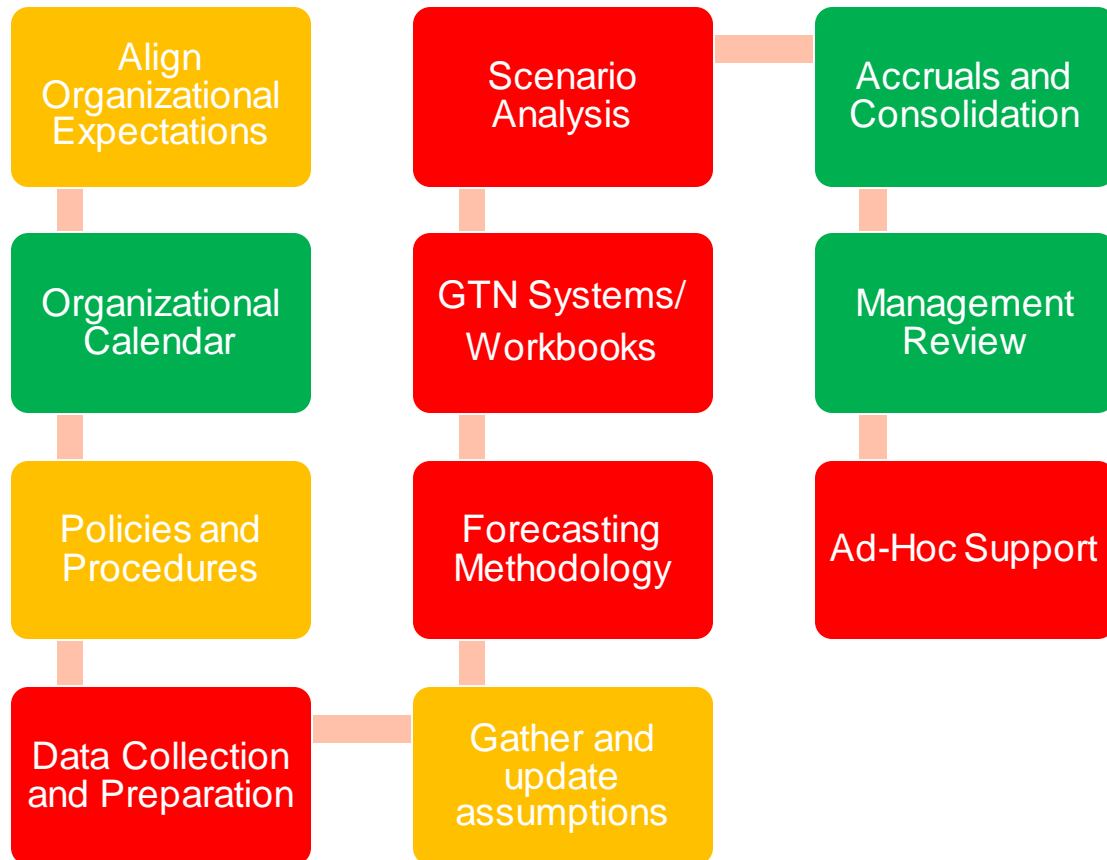
	Process / Data	People	Revenue Management Technology
Retroactive Rebates Structures move to Point of Sale Discounts	Contracting moves to an institutional model	Workload Reduction on Contract Adjudication with elimination of rebates	Strategy Designer / Formula Builder Implications
New Master Data Elements	Manage new types of data including additional plan information and data points required for contracting and sales validation	Workload expected to stay the same	Minimal Master Data Configuration Changes
New Plan Specific Chargeback Adjudication	New Chargeback Validation and Adjudication Process required on new sales data type	Increased Workload to scrub data and pay chargebacks in a timely manner	New data points & New validations required that fuse script and chargeback validations

Operational Impact – Regulatory

	Process / Data	People	Revenue Management Technology
New Master Data Elements	COT definition of a transaction involving a 'PBM,' coding for transactions under a new type of sale and effects on GP filters	Current state remains neutral; potential new areas to be trained in	Revisions to GP filters to accommodate former rebate data in an alternate form; additional testing needed
GP Calculations (AMP and BP)	Modifications to accommodate data, review of calculation methodologies and impact to Medicaid Rebates	Potential need for temporary resources to support additional work	Revisions to GP price type filters, calculations and drill-down configurations in calculation results; additional testing needed
Unbundling	Will indirect effects lead to the elimination of bundles?	Current state remains neutral	Less system process to incorporate into quarterly processing

Operational Impact – Gross-to-Net

Typical GTN Process



Potential Immediate Impacts

- Minimal overall GTN impact if transition financially neutral
- Expectations of reduced GTN bubble/variability between actual and forecast due to lagged rebates
- Liability shift across channels (e.g. managed care to chargebacks)
- All commercial changes need to funnel down to GTN team
- Channel specific data, procedures, assumptions, models need to be reviewed
- Increased ad-hoc analysis requests

Additional Considerations & Closing

Additional Considerations

What is the opportunity cost to the manufacturer?

- Will there be more opportunities for processing errors?
- Will processing on the commercial side be daily with heavier data volumes?
- Will more dollars be left to chase based on the potential new model?
- What will daily cash flow look like?

Will the PBM Service Fees Safe Harbor drive the need for additional analysis of what's FMV – similar to the GPO safe harbor? What will be future impact of this on Government Pricing?

Has the plan for the changes in Safe Harbor and the drive of the Blueprint already started to push pricing?

- Gilead's authorized generic versions of Epclusa and Harvoni
- Eli Lilly's authorized generic version of Humalog → *Insulin Lispro*

"The significant rebates we pay on insulins do not directly benefit all patients. This needs to change."

David A. Ricks, Lilly's Chairman and CEO

What can you do today?

- Begin a dialog with other players in the supply chain about potential implementation scenarios
- Start internal cross-functional discussions across Contracting, GP and FP&A about impacts for different scenarios
- Understand impact on how you contract and negotiate
 - Financial Neutrality for key partners will be key to maintaining access; how do I model and communicate?
 - What other value added services can be offered?
- Analyze technology and data to determine changes that would be required to support the proposed rule
- Prepare a contingency plan for potential implementation in January 2020
- Stay informed of developments
- Consider submitting comments to HHS to influence the final rule

What are your perspectives?

Questions?

Visit us at Booth #5

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