GROSS-TO-NET: CHALLENGES AND BEST PRACTICES

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The application of clinical pathways and their enforcement through quality metric benchmark setting and appropriate use criteria is needed to guard against perverse financial incentives that encourage overutilization and underutilization. Moving forward, the more diligent payers and integrated delivery networks can be in evaluating and incorporating utilization criteria when establishing clinical pathways, the better off our system will be.

Due to current market dynamics and existing policies, payers and at-risk providers have their own financial incentives that may be contrary to that of society, as well as patients, in terms of clinical outcomes. Clinical pathways are typically built to guide clinicians to prescribe the most appropriate treatment to optimize clinical and financial outcomes.[1-3] However, clinical pathways can also be used to ensure provider and payer incentives are aligned and reinforce what is best for patients and members via the lens of population health.

This article will explore different payer policies and market dynamics that can result in the overutilization or underutilization of healthcare treatments (Table 1). It also explores opportunities to mitigate the unintended consequences of previous policies, both through new Centers for Medicare & Medicaid Services (CMS) policy efforts and clinical pathway application. Because most spending in healthcare is funded by the government, CMS policies determine how most of healthcare funding is spent.

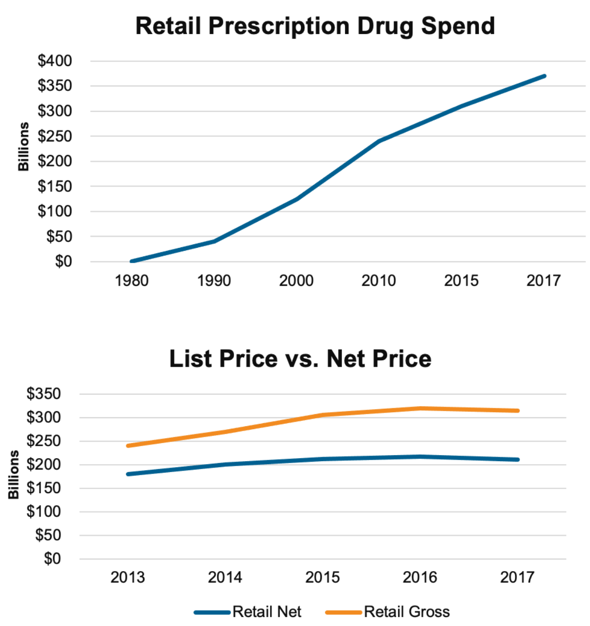


Figure 1: The charts above show how prescription spending has risen dramatically the past several decades, while an increasingly wider divide develops between gross and net retail prices for drugs[2]

Rather than continuing forward with traditional market access strategies, this changing dynamic implores manufacturers to consider revenue management in new ways. Instead of simply confining gross-to-net activity to the pragmatic exercises of forecasting and accrual, manufacturers can expand its scope to include a strategic analysis of how liabilities can be prospectively reduced. In broadening the focus of financial planning from the perfunctory to the proactive, expenses can be viewed more as mitigatable variables and less as immutable assets. Accounting then becomes a valuable tool in the effort to reduce revenue leakage.

Understanding the complicated interplay between product costs, commercial contracting and government pricing is a difficult task for gross-to-net analysis, even in the traditional sense. Integrating those concepts into a comprehensive revenue enhancement plan across an organization is exponentially more challenging. However, by assessing proposed contracting strategies, manufacturers can moderate potential risks while confirming the operational capabilities necessary for success.

Industry Outlook

Pharmaceutical pricing and contracting are highly self-referential and interconnected, even across different lines of business. Understanding the interaction of these elements is crucial to gaining a broader perspective of the challenges in gross-to-net management and ways in which these obstacles can be overcome. The following section provides an example of how contracted discounts can have interdependent elements that complicate gross-to-net management for manufacturers.

COMMERCIAL CONTRACTS

A common measure of cost control within commercial payer agreements is the inclusion of a price protection clause. In these deal structures, price increases to the contracted product are negated after a predetermined threshold is breached — any amount in excess at this point is remitted to the customer as a price protection rebate. For example, if a manufacturer sets price protection at 6% per year for a product, then any WAC expansion over 6% within that time frame is given back as an additional discount for invoiced claims. Further price increases only enlarge the overall discount without yielding any gains in net revenue. A particularly exorbitant breach, combined with other contracted discounts, may set a new best price, which directly affects rebates paid under Medicaid.

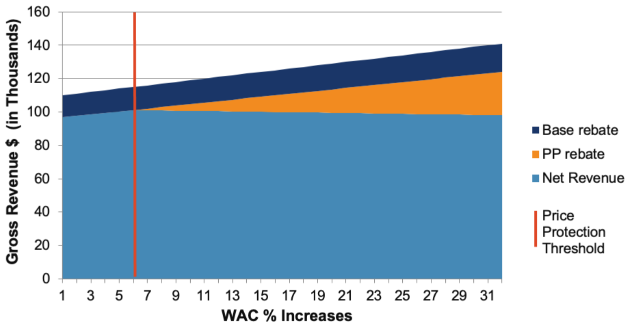


Figure 2: The graph above illustrates how raising the WAC beyond a certain point can trigger Price Protection rebates, which contribute to proporionately smaller net revenue from affected customers

MEDICAID CONTRACTS

In the Medicaid Drug Rebate Program, there are several controls that have been implemented to curb price hikes. Through an agreement with CMS, manufacturers are required to offer discounted prices to states in exchange for their inclusion in the program. For branded drugs, the rebate offered is either 23.1% of the Average Manufacturer Price (AMP) or the AMP minus the best price offered among commercial institutions in the private sector, whichever is the larger of the two options.

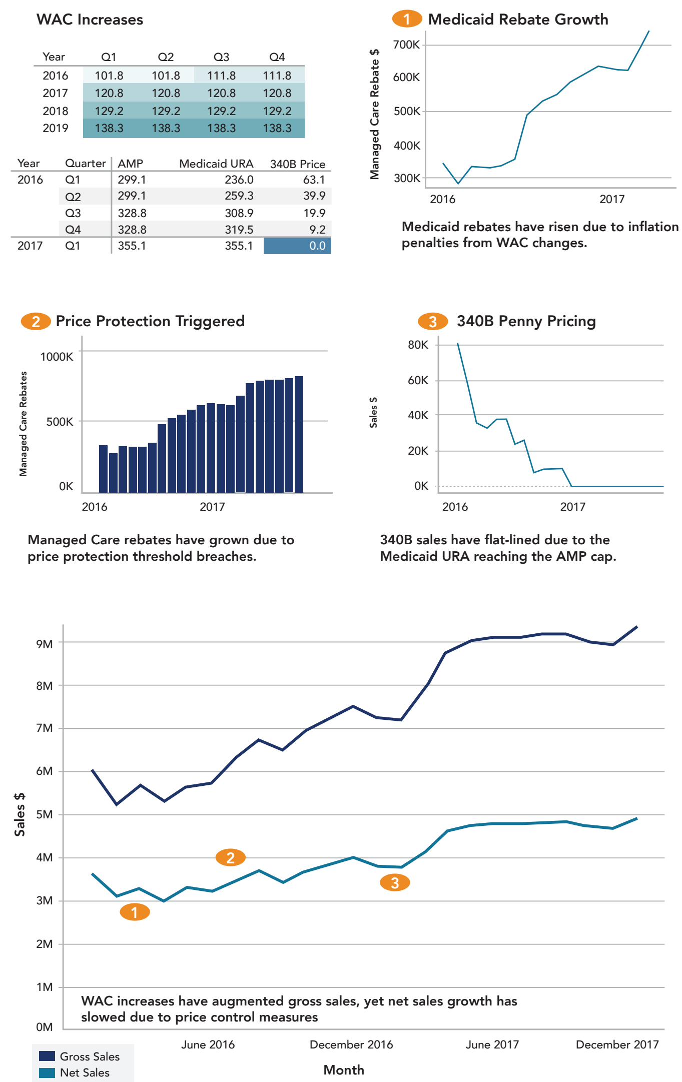
Consequently, if the total commercial discounts described in the previous section surpass the standard Medicaid deduction, the rebate paid to states increases. Simultaneously, the program stipulates that if the current product AMP has increased from the time of its launch faster than the rate of inflation, measured by the Consumer Price Index-Urban (CPI-U), then an additional rebate must be paid. If the combined rebates are higher than the current AMP, then they are reduced to equal AMP. This scenario directly impacts another line of business, as the Medicaid rebate amount is referenced in determining the price of drugs in the 340B Drug Pricing Program.

1	Basic Rebate = (> of AMP * (23.1%) or AMP - BP)
2	Adjusted Baseline = (Baseline AMP / Baseline CPI-U) * Quarterly CPI-U
3	Total Rebate = Basic Rebate + Additional Rebate
4	If Total Rebate > AMP, then Total Rebate reduced to = AMP

Figure 3: The table above shows the standard Medicaid URA calculation and how best price can be used to set the reimbursement amount for Medicaid rebates

340B DRUG PRICING PROGRAM

In cases where a product's prices have risen substantially, the Medicaid Unit Rebate Amount (URA) can grow to equal AMP, at which point the URA is capped. Consequently, the 340B Drug Pricing Program sets product purchasing rates by subtracting the URA from AMP. In instances when the price points equal one another, the calculation nets a price of zero, and manufacturers default to "penny pricing," wherein they must charge $0.01 for the product under the 340B program. This can be particularly impactful for organizations whose products are utilized heavily in the covered entities of this channel.



WAC Increases

Year	Q1	Q2	Q3	Q4
2016	101.8	101.8	111.8	111.8
2017	120.8	120.8	120.8	120.8
2018	129.2	129.2	129.2	129.2
2019	138.3	138.3	138.3	138.3

Year	Quarter	AMP	Medicaid URA	340B Price
2016	Q1	299.1	236.0	63.1
	Q2	299.1	259.3	39.9
	Q3	328.8	308.9	19.9
	Q4	328.8	319.5	9.2
2017	Q1	355.1	355.1	0.0

Figure 4: The set of tables above illustrate how commercial and government discounts have overlapping influences that affect the divide between gross and net revenues

Operational Challenges

DATA ACCESS, STANDARDIZATION AND USAGE

Financial operations often incorporate data from a multitude of sources that require extraction and integration to fold into models. Compiling contract, pricing and transactional data in a consistent and reliable manner can prove challenging when information is sourced from different platforms. Since the retrieval of this information is often done manually, timing differences can mean these datasets get out of sync with one another.

Transactional datasets vary across lines of business, requiring adjustments and conversions to calculate gross-to-net values properly. The various sales and price concessions offered for a product occur in different datasets that need to be standardized to compare and measure values accurately. For example, discounts provided across different lines of business often track the same product in different units of measure.

Given the vast operational variables between organizations, there are few software solutions equipped to handle gross-to-net calculations, at least without heavy configuration or customization. In most cases, companies choose to manage their forecasting and accruals manually, risking human error in favor of retaining more control over their methodology.

CONTRACT COMPLEXITY

Contracted deal structures are evolving in more intricate arrangements, which can pose a risk to accurate forecasting if miscalculated. Achieving a consistent methodology in forecasting and accruals becomes more difficult when deal structures become more sophisticated, reducing the certainty of predictions. Varied payment schedules and performance thresholds make forecasting difficult to maintain predictably and consistently. Contracts can have significantly different payment timing and achievement criteria, making it more challenging to properly accrue and make accurate forecasts for these arrangements.

Next Steps

RECOMMENDATIONS

As the industry continues to observe rising gross revenues and steeper discounts, examining gross-to-net strategy becomes increasingly more important. Companies should consider these practices as a means of not just reporting but informing the health of their commercial operations. Exploring gross-to-net operations in coordination with contract communication, transaction processing and government pricing can help mitigate unnecessary liabilities on a proactive basis.

FORECASTING AND ACCRUAL DATA

Manufacturers should first determine the methodologies used to support their gross-to-net needs. Many of these decisions have no right answer but may be guided by business model, customer base, product portfolio and organizational capabilities, among other factors. For example, these deliberations might include choosing whether records should be aligned based on the period in which the transactions occurred or the time frame in which they were reimbursed. Another decision might be whether to handle managed care rebate tracking at the channel level or specifically to each payer. Companies might examine whether forecasts are driven solely off historical data or managed in a more predictive manner. An additional decision could be made regarding whether financial models should use only payments themselves or include the contracts they were based on as well. Finally, organizations may consider the amount of historical data necessary to drive predictions. There is no right or wrong choice in most cases, but aligning with other stakeholders will ensure the methodologies employed are appropriate for a specific organization.

Once the guiding framework has been established, manufacturers should focus on acquiring the information needed for their models. Since forecasting and accruals are more accurate and reliable when predicated on solid data, companies should access, collect and organize as much supporting information as possible to drive their financial analysis. As datasets often contain areas of overlap, aggregated information should distill the sales and rebate data down to its unique elements and make meaningful connections between them. A standard update schedule should then be established to coincide with payment provisions and database refresh schedules. As this process evolves, procedures can be streamlined to realize efficiencies and focus on more important datasets.

CONTRACTING COMMUNICATION

Gross-to-net operations can be a critical tool in monitoring the success of an agreement throughout the contract life cycle. Rather than merely tracking liabilities, the data collected can be an important barometer of the health of a specific arrangement, deal structure or brand. By comparing actual performance to initial expectations, forecasts and historical data, gross-to-net activities can help inform prospective market strategies. This can be supported by implementing communication plans and monthly review meetings to align expectations to operations and collaborate on challenges. Establishing standardized contract summary templates can align contracts and finance teams on the meaning, setup and execution of terms and conditions. When expectations are aligned on a contract's purpose, it becomes easier to measure and track overall performance.

TRANSACTION PROCESSING

Gross-to-net margins can be measured by financial analysis, but these analyses do not actively create change. In contrast, efficient revenue management operations can actively prevent revenue leakage, ensuring liabilities are kept to the minimum amount required by contract or statue. Every transactional domain has preventive measures that can be employed to reduce unnecessary expenditures, varying in the level of effort and complexity needed to realize their benefits.

In chargeback processing, automated validation of submissions can prevent credits from being applied incorrectly to customer accounts. Implementing these checks and balances becomes even more advantageous when pricing is differentiated between accounts or separated by performance tiers. In these situations, performing compliance analyses to purchase commitments can ensure customers are not receiving access to price tiers for which they are not eligible.

For managed care rebates, verification that a payer's invoice is calculated correctly is a simple and effective means to safeguard against revenue leakage. Complicated terms like "price protection" can often be miscalculated by a small formula error or misunderstanding of terms, resulting in significant and unnecessary liabilities over time. Another tool for manufacturers to utilize with this data is script validation. Verifying this information can yield significant results by excluding claims that violate pre-determined thresholds in accordance with contracted terms. These vary significantly, but can include verifying the age of a script, units above a certain dosage level, invalid pharmacy types, unit of measure inconsistencies, aberrant quantities and duplicate submissions, among many other violations.

Finally, a more sophisticated level of verification comes in the form of formulary compliance audits. Most commercial agreements have stipulations about the formulary placement of a product required to secure a rebate. These commonly include being located within a certain tier, being exempt from restrictions, or not being disadvantaged compared to competitors. By comparing submitted utilization data to the associated formulary, companies can verify that the placement of their product is within the contracted standard. If restrictions from the contract are violated, such as a quantity limitation, prior authorization or step edit, manufacturers can dispute any related claims.

With Medicaid rebates, the most straightforward way to reduce incorrect billing is to review the submitted quantities on state invoices. Pharmacy and hospital data are often provided in a different unit type than what is required by CMS for price reporting and rebating. As a result, unit of measure conversions often need to be applied by state agencies or third-party providers in order to bill products correctly. Occasionally, this can result in incorrect conversions, which can affect the amount being invoiced. This is particularly true for specialty drugs, which have atypical methods of administration, or liquid form products, which are more likely to be measured in disparate ways by different institutions in the supply chain. As Medicaid data is submitted in a summary format by default, advanced verification can be employed by requesting and validating Claim Level Data (CLD), which can often uncover issues that would not be visible otherwise.

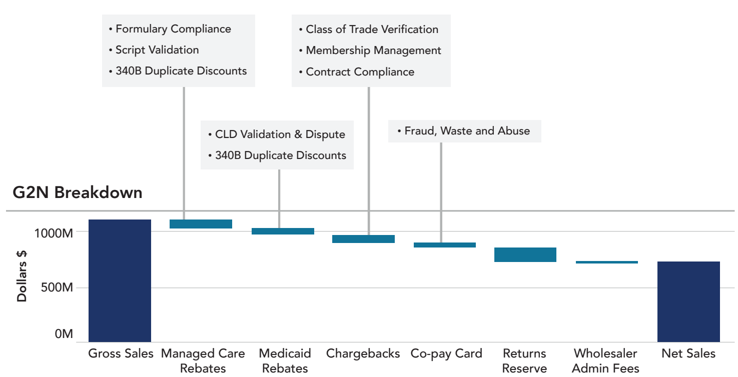


Figure 5: The chart above shows how gross-to-net management can include the active validation of liabilities incurred by manufacturers to lessen their financial impact

GOVERNMENT PRICING

Traditionally, gross-to-net activity has very little overlap with government pricing. However, the structured nature of government pricing calculations lends itself well to financial analyses used to inform commercial strategy. For example, given the impacts of setting a drug's best price, companies should take measures to prevent it from occurring unintentionally. Since Medicare utilization is excluded from best price calculations, partitioning any novel (and potentially varying) deal structures to this channel and precluding them from commercial Managed Care contracts will prevent a best price reset by default. As an additional means of control, avoiding lump-sum payments and variable payment ratios can reduce the risk of breaching the best price. In cases where these measures are not feasible, payment caps can be a reliable method for controlling price points on agreements. For example, by capping reimbursement amounts to 23.1% of WAC, the chance is reduced for the best price to outweigh AMP in the Medicaid URA calculation. Payment caps are especially useful in cases where the contracted benefit is not defined on a per-unit basis, as they help to regulate the potential best price impact, as well as providing predictable rates for best price initial calculation. Finally, the usage of "clawback" provisions, wherein reimbursed funds are recouped up to the threshold of best price, can help to mitigate financial impact when rates vary unexpectedly.

Conclusion

As companies engage in more complicated arrangements with steadily increasingly discounts, the divide between sale price and net revenue becomes even larger. Left unchecked, this trend compels manufacturers to examine gross-to-net activity not just as a financial requirement, but as a strategic tool to inform their commercial operations. Manufacturers, therefore, are encouraged to assess their strategies, systems and procedures to determine how their data can better serve them.

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