

PHARMACEUTICAL COMMERCE

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Challenges in Contract Strategy and Operations for Pharmaceutical Manufacturers

Effective integration of a company's contract strategy with operations can have a big impact on financial performance

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OVER THE PAST 20 YEARS, pharmaceutical contracting has been transformed from being a small incremental part of the typical pharmaceutical manufacturer's business to one that is integral to almost every market segment. In many cases, filling a conventional prescription invokes multiple contractual agreements between the manufacturer and other parties. For example, sales within the institutional segment of the business can require a manufacturer to honor its fee-for-service contracts with wholesalers, the payment of administration fees to group purchasing organizations (GPOs), and submission of performance-based rebates to individual hospitals.

For retail managed-care sales, manufacturers will still need to honor those same wholesaler fee-for-service agreements and likely pay rebates to pharmacy benefit managers (PBMs) or other managed care plans. Government-funded programs including the Federal Supply Schedule (FSS) program, Medicare Part D, and State Medicaid have only served to further complicate the contracting landscape. Despite the amount of discounts currently being paid, which can exceed 90% of list price, there still remains significant challenges within the industry to better manage contracting from both a strategic and operational perspective.

The benefits of both improved pricing and improved operations are highly significant when you consider that the vast majority of sales within the industry are impacted by one or more contracts. From a strategic perspective, offering discounts that are too low can result in the loss of a contract and subsequent revenue erosion of greater than 50% compared to being "on contract." On the other hand companies can offer steep discounts to customers that have little ability to control business. The result is a direct

CONTRACT CHALLENGES

- **Effective Process Integration Between Strategy and Operations**
- **Accurate Forecasting of "Contract" vs. "No Contract" Sales Scenarios**
- **Effective and Efficient Contract Development**
- **Efficient Administration and Payments**

negative impact on the product's gross profit without any increase in sales.

Let's take as an example a retail-based product with sales of \$250 million per year that competes in a therapeutic class with three other competitors. In today's environment, let's also assume 80% of sales involves some sort of contract in which discounts are required to be on formulary. If \$50 million of sales (25% of the contracted total) are discounted too aggressively by 10%, then there is already a \$5-million opportunity for improvement. On the other hand, if the product could have received favorable formulary placement but did not at high control accounts with additional volume of just \$10 million, the revenue opportunity lost could be \$5 million. The challenge for manufacturers is to develop more quantitative methods to forecast these benefits and risks so the trade-off between sales and gross profit is managed optimally.

From an operational perspective, it is not uncommon to identify a number of factors affecting contract performance, including the following:

Challenges in Contract Strategy and Operations for Pharmaceutical Manufacturers

- **Poor compliance management:** The inability of Contract Operations personnel to have the time and/or technology tools to monitor how closely contract customers are complying with their contractual obligations.
- **Overpayment of contractual obligations:** The overpayment of rebates, administrative fees, and chargebacks due to, among other things, the inability to effectively track group membership eligibility, duplicate claim submissions, and automated analytics to identify outliers in claims submissions.
- **Operational inefficiencies:** These inefficiencies include manual workarounds due to poor processes and a lack of automated tools to more efficiently manage key administrative processes.

Within the industry, it is common to identify improvement opportunities that represent 1-4% of a product's contracted sales. Using the example of the \$250 million product above, there could be an opportunity to decrease operational revenue leakage by \$2-\$8 million.

The next sections provide more detail regarding the challenges in improving both strategic and operational revenue leakage, and discuss some industry practices being adopted to address them.

Challenge #1: Effective Process Integration Between Strategy and Operations

One of the most important challenges is the effective integration of contract strategy with contract operations. It is one thing to be able to think creatively about contract strategy that drive business goals, however, the ability to effectively and efficiently administer these contracts can be overly burdensome. For example, one strategy could be to implement performance-incentive contracts with customers based on a market share baseline that is adjusted quarterly as measured by actual performance. At the end of the year, certain total dollar volumes will trigger another rebate based on the dollar volume tier. For instance, a customer who achieves a higher market share in the first quarter is then eligible for a higher rebate in subsequent quarters. The dollar volume from each contract is then mapped to an overall dollar volume tier and an additional yearly rebate is paid.

While such contracts may achieve the business objectives of preferred formulary placement, the operational implications are significant since it will be difficult to automate such complex calculations for rebate purposes.

Therefore, manual intervention will be required and will be extremely labor intensive. To the extent such complex strategies are executed across both the institutional and retail managed care markets where potentially hundreds to thousands of individual contracts will have to be administered, the effort to manage these contracts will potentially be overwhelming. What other types of contract structures could achieve the same business objectives without such complexity?

As a starting point, many companies have set-up cross-functional committees to set overall strategies, define business rules for approvals of pricing exceptions, and meet on an ad-hoc basis to address customer specific issues. Nevertheless, there need to be at least six key outputs from this committee to appropriately define contract strategies along with contract templates for individual contract proposals that support the Account Managers in the field who are negotiating these contracts:

1. **Goals and objectives:** Identification of the specific goals should include both financial (e.g. gross-to-net) and non-financial objectives (e.g. customer satisfaction).
2. **Customer segments and targets:** Identification of the contracted segments as well as specific customers within these segments with whom the company should contract.
3. **Brand positioning:** The appropriate positioning for the product within managed markets given the overall marketing strategy for the product or portfolio.
4. **Discount types:** Definition of whether discounts will be guaranteed, performance-based, or a combination of both as well as whether discounts will be based on market share or sales volume.
5. **Discount amounts:** Although discount types define how discounts will be offered, discount amounts define the specific percentage or dollar amount of the discount.
6. **Customer obligations:** These are the specific criteria that the contracted entity needs to fulfill to be paid the discount. They range from being relatively simple (e.g. requirement that the contracted product be one of three products on the preferred formulary, specific market share to be attained) to very complex (submission of quarterly data in NCPDP (National Council for Prescription Drug Programs) format at the plan level for both the contracted product(s) and each competitor within the market basket).

Challenges in Contract Strategy and Operations for Pharmaceutical Manufacturers

Challenge #2:

Accurate Forecasting of “Contract” vs. “No Contract” Sales Scenarios

As a part of the strategic planning process, accurate scenario analysis of being on formulary versus off is critical. For that matter, probably multiple scenarios are needed given today’s more complex pharmacy benefit designs such as those with multi-tier formularies. Too many times, upside and downside potential is inaccurately forecast leading senior executives to question the rationale for paying such high discounts—especially in the slowing market environment today. A more quantitative approach that leverages increasingly sophisticated statistical methodologies for forecasting rebates and liabilities is needed, along with better information technology tools and data to automate the process. Implicit in this approach is that not only can individual contracts be forecast more accurately, but entire books of business (e.g., Medicare Part D) can be better forecast to assess opportunities and risks in terms of sales and market share for entire customer segments over the course of quarters to years.

Some emerging practices include determining the consumer behavior to increasing co-pay differentials as a driver of share shift; multiple-regression of analysis of key customer attributes that are correlated with the ability to drive share, and customer based P&Ls. One limitation to all these approaches is data availability. For instance, accurate and comprehensive co-pay data are difficult to get in many, if not most, cases. In addition, if Company A does not have a contract with a specific customer or the customer is unable to provide it, Company A is forced to rely on third-party data versus actual contract data from its customer. In any case, leveraging a combination of third-party data and actual customer data can yield powerful insights for scenario analysis to make better contracting decisions.

Challenge #3:

Effective and Efficient Contract Development

Once the contract strategy and the supporting templates are developed, individual contracts need to be negotiated. In today’s environment, the standard tends to be simple text documents and the communication vehicle tends to be e-mail rather than paper with hard edits. To the extent there are a relatively small number of contracts that an organization writes, these tools are probably okay. As the number and complexity of contracts continue to grow, however, these tools will increasingly slow down the process. Technology can greatly help with this process through the use of automated work flow and approvals systems. As

mentioned earlier, a step in the planning process should be to establish clear policies regarding who can approve different levels of discounts and how exceptions will be managed. Some of today’s automated tools can ensure that these policies are not only followed but also maintained through electronic audit trails of changes to contracts and their subsequent approvals.

During contract development the quality of the process will also be helped by developing improved forecast models and even contract profit-and-loss scenarios. A better understanding of the customer’s ability to favorably or unfavorably influence market share will drive more rational negotiations and ultimately a more profitable contract for the manufacturer.

Challenge #4:

Efficient Administration and Payments

Once the contract is signed, it can get “thrown over the wall” to a contract administration department for execution and monitoring. To begin with, unless there’s a document management system that can be leveraged, the contract will need to be entered from scratch into a contracting system. As an improved practice, the finalized negotiated contract could be directly imported into the contracting systems for administration.

Compliance is the next challenge in contract administration. Often, the contract administration department is actively monitoring compliance with only a small subset of the volume of contracts—and sometimes not at all. Again, a number of companies offer automated solutions to manage compliance through reporting and analytics solutions. One of the primary benefits is to gain insights more quickly and be proactive in identifying potential problems in meeting contract terms. Instead of waiting for a manual report six weeks after the end of a quarter or a year, variance from expectation can be identified much more quickly and corrective actions developed to improve the situation.

Additional opportunities to improve analytics within the organization include the following:

- Payment trending reports: These reports provide longitudinal views by customer to identify outliers in rebate liabilities compared to historical norms.
- Chargeback rejection reports: These reports should provide metrics regarding percentage of line items that are processed without error, number of line items outstanding segmented by appropriate timelines (e.g., seven days versus 30+ days outstanding)
- Cycle time reports: The average total time it takes from the submission of a claim (e.g. rebate, chargeback)

Challenges in Contract Strategy and Operations for Pharmaceutical Manufacturers

Contracting increasingly continues to be a differentiator in the Managed Markets space for pharmaceutical companies as they look to increase profitability. The need for effective strategies, policies, processes, data, and technology support is stronger than ever. Contracting excellence leverages a closed-loop model that starts with strategy and drives through all aspects of contracting processes including analytics to support each area.

In an era of slow growth and weaker pipelines for many pharmaceutical companies, contracting is not only a tactic to improve profitability. It is a strategic lever that differentiates high-quality, high-performance organizations from their competition. **PC**

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