Maximize the value of innovative commercial contracts

Overcome your fears of risk and compliance pitfalls

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WHITE PAPER

Traditionally, pharmaceutical manufacturers priced their drugs using a fixed cost per unit basis. As markets have become more competitive, and public and legislative scrutiny on healthcare costs has heightened, pharmaceutical companies are increasingly looking for new ways to drive demand and sales.

Innovative approaches to contracting is a growing trend, as the right mix of pricing and discounting can entice customers to purchase or cover more of your products. But these approaches also come with potential pitfalls that can impact your company's success – and land you on the front page.

This white paper will help you understand the top three things you should consider as you look to use innovation to maximize the value of your commercial contracts.

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Don't become a headline.

__12+ drug makers sued__ by 44 states for conspiring to inflate prices by 1,000%.[1]

Drug maker avoids five-year ban from federal healthcare program; __agrees to pay $24.1 million for price fixing and bid rigging.__[2]

"U.S. pharmaceutical executives have been put on notice that they __could be held criminally liable for fueling America's epidemic of opioid addiction."__[3]

Keep reading to discover how to avoid these pitfalls and put innovative contracting to work for you.

[1] "Teva and Other Generic Drugmakers Inflated Prices Up to 1,000%, State Prosecutors Say." The New York Times, May 11, 2019.

[2] "Generic Drug Maker Admits to Fixing Prices for Cholesterol Medication." The New York Times, May 7, 2020.

[3] "Opioid executive admits to 'no morals' ahead of prison term." Financial Times, January 23, 2020.

What is an innovative contract?

Simply put, an innovative commercial pharma contract includes pricing and rebate incentives that are structured in a way that influences customer behavior. These strategic offerings are used to encourage providers and payers to drive more demand for your products and/or ignore your competitors' products.

Contracts can range from basic to extremely complex arrangements that include multiple upfront discounts as well as numerous backend rebates. By creatively approaching how you structure initial pricing and discounts on the backend, you can potentially increase sales and market share. Additionally, depending on the terms and conditions you implement, you may be able to demonstrate cost-effectiveness as it relates to patient outcomes.

The benefits of innovation

Faster market access

Higher sales volumes

Faster patient access to drugs

Demonstrable patient outcomes

With such strong benefits, why wouldn't you embrace innovative contracting?

By definition "innovative" means to introduce something new or different. And doing so often comes with some level of risk. A key concern with innovative contracting strategies is how to make them feasible and profitable.

- **There's no standard format.** How do you ensure the contracts you offer can be executed efficiently, drive results, and don't eradicate your margins?
- **Calculating innovative contracts is difficult.** This challenge is especially evident with value-based contracts, which require you and your customer to agree on a clinical endpoint or financial metric for drug assessment.

- **You need accurate data to properly calculate contracts.** This challenge is two-fold. First, you need accurate sales data to understand current contract performance and profitability before you can extend new offers. Second, if you do reach an agreement on a value-based contract, data must be shared to adjudicate the findings.
- **HIPAA concerns surrounding the data must be addressed.** And of course, because you're potentially dealing with protected health information (PHI), especially in the case of value-based contracting, you must be prepared to address HIPAA compliance for data security.

Adding another layer of risk to innovative contracts is the regulatory landscape. Federal and state regulations can quickly render these contracts unprofitable or impractical. Strict guardrails and pricing rules dictate what you can charge the various government healthcare programs for drugs – and many of these rules are based on calculations resulting from price points offered to the commercial market.

Along with ensuring that you're following the rules set forth in the Office of Inspector General's Anti-Kickback Statute, you also need to pay close attention to government pricing requirements when you create your commercial contracts. Medicaid, for example, requires that drug manufacturers offer a price that is equal or less than the best-available discount price offered to the commercial market.

29%

of pharmaceutical executives stated that agreeing on metrics for evaluating drug performance and patient outcomes is a major operational hurdle to value-based contracts.[4]

Nearly

70%

of pharmaceutical executives named product "best price" concerns and other legal or regulatory issues as the biggest barriers to value-based contracts.[5]

[4] Ben Comer. "Pharmaceutical value-based contracting: Collaboration is key." PwC, September 26, 2018.

[5] Ibid.

Determine the right discount direction.

There are numerous pricing and rebating strategies. The way you use them to incentivize can be virtually endless. When determining your approach, you should always consider your drug's characteristics, the available competition, patient needs and outcomes, and your financial goals.

	Tiered / volume-based	Outcomes / value-based	Subscription models
Examples	**Volume thresholds, spend thresholds, market share, product purchasing history**	**Financial risk-based, health outcomes-based, adherence-based, indication-specific**	**"All you can treat" or "Netflix" model[6]**
Benefits	• Incentivizes larger volume purchasing commitments • Provides customers with significant savings annually • Is ideal for situations where large quantities of drugs are needed (i.e., preventive therapies)	• Links reimbursement to patient outcomes • Helps manufacturers accelerate coverage decisions • Enables payers to balance access and affordability	• Establishes a set price for unlimited patient access for a predetermined time period • Enables greater patient access to curative therapies • Improves therapy compliance
Challenges	• Gaining visibility into actual purchases compared with estimated volumes defined on a contract • Ensuring contract compliance	• Requires a complicated calculation based on measuring value on expected results, other available treatments, cost, and manufacturer accountability • Has a high administrative burden to monitor data and ensure results match contract requirements	• Need to clearly define the patient population that will receive access to avoid extreme fluctuations in population size

[6] Through one of these arrangements, the customer pays a flat fee for an unlimited supply. The Louisiana Department of Health and Department of Corrections entered into one such agreement with Asegua Therapeutics, whereby Asegua provides patients who are enrolled in Medicaid or incarcerated with unrestricted access to its hepatitis C medication over the next five years.

For innovative incentives that are right on the money, turn to Model N.

Maximize contract potential with the optimal mix of targeted incentives. Model N gives you tools to perform the complex calculations necessary to execute traditional and innovative contracts, as well as conduct analyses to ensure those contracts pay off.

Make better decisions that lead to more profitable contracts.

With Model N Validata, you can be confident you're paying only the right claims, at the right time, for the right amount. Visibility into competitive insights and the effectiveness of your programs helps you ensure every deal is beneficial.

Automatically calculate accurate rebates and reimbursements.

An advanced functionality in Model N Revenue Cloud, Strategy Designer uses key data (prescription, sales, clinical, etc.) to build strategies for creating and implementing pricing, rebates, and accurate calculations that meet your specific needs.

Consume accurate data from different sources.

Through relationships with data providers, Model N helps you understand and execute value- and outcomes-based pricing. Electronic data interchanges (EDIs) link your sales data, so you can ensure indirect sales were sold at the right price and execute contracts against your data sets.

"Companies will need a scalable, repeatable and efficient capabilities system to manage dozens of different types of emerging pricing models across a diverse portfolio and pipeline of products."[7]

[7] PwC. "Creating a stable drug pricing strategy in an unstable global market." https://www.pwc.com/us/en/industries/health-industries/health-research-institute/creating-a-stable-drug-pricing-strategy.html

Protect your profitability.

Building profitable contracts requires understanding the motivations behind your customers. This insight will enable you to incentivize in different ways, based on their goals. It will also ensure you aren't offering discounts that won't pay off.

Provider	Payer	Government
Who: Hospitals, pharmacies, health systems, doctors' offices	**Who:** Health plans, pharmacy benefit managers	**Who:** Medicaid, Medicare, veterans' administration, military
Goal: Buy products at a low price with a high rebate	**Goal:** Want rebates to defray their cost of putting your drug on formulary and paying for members to access the drug	**Goal:** Control costs paid for by the taxpayer through legal mandates that ensure the lowest possible price

Providers physically take possession of your drugs and dispense them to the patient. That means you want your initial price to be as enticing as possible. For generic manufacturers, incentivizing the providers to bring your drugs into their facilities is key to increasing your sales and revenue. You'll want to focus heavily on discounting upfront prices and couple those with backend rebates.

Payers are reimbursed for your product, so you'll want to give discounts that incentivize better product positioning against competitors for when a prescription is filled. This market is where branded pharmaceutical manufacturers will want to focus. You should aim to create the right level rebates and backend discounts that incentivize better coverage and higher placement on formularies.

While the greatest room for innovation falls within the commercial contracting realm, you should never ignore the government. In addition to the legally required, mandated discounts you must provide, you can consider supplementary agreements that may help you reach a preferred level of coverage.

Regardless of the type of customer you're working with, always take a strategic approach to discounting and rebating.

The key to profitability is a good line of sight into the deals you make.

For innovative contracts to work, they must benefit all parties. Ensuring contract compliance is critical. You need to know with certainty that a customer adhered to all purchasing commitments, including volume, market share, and timeframe. On the flip side, you must provide the agreed-upon rebates and discounts in a timely and accurate manner.

Post-deal analytics help you understand whether you've given the right deal to the right customer and what adjustments to make in the next contract.

- Get information that will help you articulate why you are or aren't offering a customer a certain contract.
- Evaluate what types of contracts are positively impacting your business and eliminate the ones that aren't.
- Access key insights into contract performance so you can better negotiate and avoid revenue leakage on future deals.

For pharma profitability that's right on the money, turn to Model N.

Transparency is critical, as you need accurate data to ensure the most advantageous contracts and avoid price floor violations. Model N provides a single system of record for handling all aspects of pricing, contracts, chargebacks, and compliance.

Interact seamlessly with providers.

Model N Provider Management gives you real-time visibility and insights into the institutional contracting process, including all pertinent contract details and customer purchasing activities, so you can make better business decisions, ensure contract compliance, and reduce revenue leakage.

Take a comprehensive approach to payer management.

Model N Payer Management helps reduce risk with the payer and pharmacy benefit manager (PBM) contracting processes. With increased visibility and control, you can easily reject invalid claims and decrease rebate overpayments.

Make better business decisions.

Use Model N Intelligence Cloud to derive insights from data in the Model N Revenue Cloud, your ERP systems, and syndicated data resources. By answering what-if questions, running models and scenario analyses, and measuring post-deal success, you can optimize pricing to increase the probability of deal success.

Facilitate contracts flawlessly.

Innovative contracting success demands effective reconciliation of the financial impact on your revenue, compliance with government regulations, and accurate data analysis, so can be confident you're maximizing value.

See and understand what will result from your commercial contracts.

Commercial contracts can impact your ability to adhere to regulatory compliance. The more innovative a contract is – and thus, its higher level of complexity – the harder it will be to ensure you're addressing government requirements. Unpacking your strategies to accurately calculate your government price can become burdensome and risky if you don't have the right capabilities. Offering the wrong customer a discount that you think will increase their purchases could actually cause you to have to offer a discount to the entire government. For example: If you discount the wrong customer(s) too much, you could trigger a price reduction clause that means you now have to subsequently and proportionally discount the Federal Supply Schedule.

Without good visibility into your contracting processes, you could inadvertently reduce your government prices – and ultimately, the revenue from your largest customer. You need tools that will enable you to accurately calculate on both sides – commercial and government – so you can be innovative and strategic with complex offers that drive demand commercially, while ensuring compliance with government pricing.

Establish processes to ensure commercial contracts are executable and profitable.

Before you begin to offer innovative contracts, you should establish a solid methodology that details the types of contracts you will implement, how they will be structured, and what assessment criteria you will use to measure their success. Using preapproved templates will enable your contract marketing team or sales reps to mix and match programs for rebates and discounts. Most importantly, with these preapproved templates, you can be confident you have the ability to support what's offered – from administration, to payment, to compliance – significantly reducing your overall risk.

Effectively handle nuanced and country-specific discounting requirements.

The challenges of giving the right rebate and the right price to the right customer also exist outside the U.S. In fact, in many cases there is more regulation on how products are discounted and how you can go to market overseas.

If you're like many pharmaceutical companies, managing global pricing and discounting is handled with manual processes, which heightens your risk of noncompliance and revenue leakage. Of particular concern with manual processes is the lack of transparency and real-time visibility into global contracts. Without a clear line of sight into the contracts you execute, you could inadvertently cause price erosion when you discount to a country that price references another.

For contract administration that's right on the money, turn to Model N.

Model N helps you manage the regulatory repercussions of your contracts – from pricing calculations to the contracts themselves.

Streamline your contract process.

By transforming contracting from a mostly manual, back-office process into a key component of a faster, digitally enabled sales strategy, you can accelerate approvals, reduce errors, and simplify administration of even the most complex agreements.

Improve governance and mitigate risk.

Through standardized and preapproved templates, a clause and term library, and automated version control and audit trail, you can reduce errors, eliminate rogue contracts, and be confident that all agreements are not only feasible, but profitable.

Execute innovative pricing strategies more effectively and globally.

Model N Global Pricing Management enables you to continuously adjust pricing by region and increase visibility and data sharing across your organization. Along with effectively executing innovative pricing strategies, you can ensure the prices you set reflect countries that price reference each other.

Ensure your commercial contracts are right on the money – with Model N.

“Broader engagement in innovative arrangements will require the ability to identify the most appropriate contracting opportunities, build deeper relationships with partners, execute strong contracts, and manage ongoing risk.”[8] –McKinsey & Company

Model N helps you leverage innovation to maximize the value of your commercial contracts, while enabling you to avoid the pitfalls that could put your revenue and your brand at risk.

Trusted by 48 out of the top 50 global pharmaceutical companies, Model N reduces the risk of noncompliance, streamlines revenue management, and stops revenue leakage in payer and provider contracting and rebate processes.

Get started today by scheduling a 15-minute introduction call to gain insight into:

- How your processes compare with industry best practices
- Areas that offer the biggest opportunity to improve profitability
- How you can streamline discounting, compliance, and contract administration across your organization

SCHEDULE A MEETING

[8] Mckinsey & Company. “Innovative pharma contracts: When do value-based arrangements work?” October 19, 2017.