KPMG

The Evolution of Government Programs in the US

Balancing Opportunity and Risk to Bring Your Drug to This Important Market

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Introduction

In the words of Billy Joel, *"get it right the first time that's the main thing."*

For late stage biotech and pharma companies getting ready to launch products in the US and sell through Government payers and providers, this is an important message.

In my 20 years of working in this highly specialized space, Government Programs (GPs) has evolved from a mainly administrative and operational company function to the largest market in the US and a vital market for emerging companies. In a market such as this, you only get one shot at your initial launch, and even more importantly, your company will have to live with those results for as long as the drug is on the market.

Modern pharmaceutical and biotech drug development is bringing life-saving and life-enhancing products to people across the world. In the US, access to these products is increasingly available through Government payers and providers. With over 70 million Americans eligible for Medicaid[1] and over 39 million eligible for Medicare, a third of the United States population is covered by just two programs.[2] Add in the 340B program, with an annual drug spend of $16 billion, and the VA program which provides benefits through the VA hospital system and the Department of Defense, and you have a significant, growing market primed to cover a larger and larger population share.

However, with that market opportunity comes ***challenge*** and ***risk***.

The Government market is highly regulated and the price paid for your products in that market are, for the most part, defined by regulation. If you overcharge the government, with or without intent, you run the risk of a potential False Claims Act investigation by the Office of Inspector General (OIG), as well as the Department of Justice and State Attorney Generals. There is no statute of limitations and these agencies give little room for leniency; what you do on day one will stay with you, potentially becoming an issue down the line. Therefore, a key challenge is making sure you know what needs to be done and how to implement your program effectively and, more importantly, in a compliant manner.

Source: [1]Kaiser Family Foundation (http://kff.org/health-reform/issue-brief/medicaid-moving-forward/)
Source: [2]Kaiser Family Foundation (http://kff.org/medicare/fact-sheet/the-medicare-prescription-drug-benefit-fact-sheet/)

What are the risks of getting it wrong? Non-compliant actions can lead to long-lasting financial exposure born from a lack of understanding into the mechanics of government pricing and to compliance exposure through potential False Claims Act and/or Anti-Kickback actions, which can cripple a company with fines, penalties or a possible Corporate Integrity Agreement (CIA), not to mention disbarment from sales to GP customers.

When I speak with emerging companies about GPs and ask about their biggest fears and concerns, what I often hear is that they "don't know what they don't know." I end up spending a good deal of my time with companies educating them on the program requirements and options, which, as a 20-year experienced GP Geek, I actually find very refreshing. 20 years ago my audience for GP training was primarily the GP company professional, who was tasked with the responsibility of performing the required calculations and processing government rebates. These days there is an eagerness across the entire organization to learn the ins and outs of GPs. The stakes, if not the entire game, have changed completely.

When emerging companies are about a year out and feel positive about their drugs' FDA approval, they begin to rewire themselves from a drug development organization to a commercial organization. During this time, we see the establishment of a Commercial team and the hiring of Managed Markets and Commercial leads. We also see the -Finance team trying to get an understanding of forecasting, gross-to-net and accruals, as well as the operational aspects of the transactional data that feeds into the calculations. In addition, of course, there is interest from the Legal & Compliance teams to better understand the programs' compliance requirements. With the risks of non-compliance being quite steep, organizations will typically engage with experienced third-parties who can help them navigate their journey towards launch as effectively and efficiently as possible.

Due to all of these different factors, as companies build new teams and hire new professionals, they are faced with a major learning curve. While these professionals may have perhaps known that there was a GP function in their previous employers (and that it was important), they often don't come in having a very deep understanding of GPs' requirements. As a result, these newly assembled teams are eager to learn, and seek to build an integrated Commercial and Market Access approach. A growing interest in GPs is, of course, a good thing but it's not sufficient; strong knowledge in this area is an absolute must for companies.

Eight critical pre-launch company considerations

1 Government may be a significant (if not the most significant) market for your drugs

In a government-dominated market, your drug may well find an avenue to significant utilization across government purchasers and providers. It is important to look at the nature of your drug and how it is administered, as well as your distribution model. An oral dosage drug, for example, that is distributed through the retail channel may have a lot higher Medicaid utilization resulting from prescriptions to Medicaid patients than an injectable oncology drug administered in a hospital setting.

2 Commercial activity and pricing calculations are integrally related

Each calculation type is based fully on commercial activity, so you need to be able to make informed decisions in a holistic manner, such as understanding what may happen to your Medicaid pricing and rebates if you offer discounts to certain customers. The math that goes into each calculation is based upon direct sales, indirect sales through a wholesaler, and rebates. The data from transactional activity is aggregated and filtered and algorithms are run to determine net pricing for specific types and classes of customers (called Class of Trade, or COT).

Discounts to retail customers, for example, are used in your *Medicaid Retail Average Manufacturer Price (AMP)*, which is the basis for your quarterly Medicaid Rebates to the states (for Medicaid utilization in each state). What this means it that you have to evaluate, among other things, the impact of pricing, price changes, and commercial contracts across both the commercial and government markets so that you can make informed decisions and not be surprised by curveballs.

3 Contracting is changing and evolving

The industry is moving toward more evidence-based pricing models, such as Value Based Contracting. We are seeing this from a government policy standpoint, as well as from an industry lens. There are also many new and novel therapies for orphan conditions (conditions with very small populations), where there may be a very expensive course of therapy and where providers want to see evidence of drug effectiveness. The problem is that regulation happens slowly and, as a result, it cannot keep up with the pace of new contracting models. In order to mitigate the risk of non-compliance, organizations choose to engage professional services firms to evaluate how to apply current guidance to complex areas such as Value Based Contracting and Bundling arrangements.

4 You only get one shot at launch

Like I said before, what you do at launch will impact your pricing calculations for the life of the product, and once a transaction happens it cannot be taken back. There are nuances to your initial calculations that have to be understood across the Finance and Commercial departments. One example is something called *Base Average Manufacturer Price (AMP)*, which is your first full quarter's AMP. For the rest of the product's life, the *AMP* that you report on quarterly will be compared to that initial *Base AMP* and simultaneously assessed based on the rate of inflation in the US (CPI-U).

Based upon this comparison and assessment, if you were to raise your prices higher than the rate of inflation you could be running the risk of significant penalties that could practically end up with you almost giving your drugs away. Companies need to understand the nuances of this initial pricing (*Base AMP*) in order to make sure that they are managing the risks and financial exposure.

5 You are certifying the calculations

CMS (The Centers for Medicare & Medicaid Services) requires C-level certification of the monthly and quarterly calculations across Medicaid and Medicare. While one certainly wouldn't expect a CEO or CFO to be an expert on these calculations, they do need to be appropriately informed to the point where they can review the results so that they can confidently and reliably certify their accuracy. They may also choose to assign someone in the organization to perform the more detailed monthly and quarterly reviews and then go through the results with the certifier.

6 Many emerging companies outsource the function

While there are reliable professional services firms out there that can perform the aforementioned functions on a company's behalf, the company is still ultimately accountable for compliance and completion. An organization needs to be able to provide the appropriate oversight and to interact with their GP partner for things like reviews of specific transactions and the reconciliation of transactional data.

7 Companies must make reasonable assumptions in creating calculation methodologies

The agencies that run the various programs provide regulations and guidance to define the calculations with the obvious purpose of standardizing processes; nevertheless, from the company standpoint regulation needs to be evaluated, interpreted, and applied to your specific business, contracting, and distribution models. CMS has language in their regulations that states that when a rule is not clear or specific enough, manufacturers should make reasonable assumptions. A firm like KPMG can work closely with you and your legal counsel to evaluate your business to develop those reasonable assumptions, but ultimately you have to be the one that knows your business the best and you have to be comfortable with your compliance methodologies.

8 Some regulations are unclear or subjective

Companies have to perform an appropriate level of due diligence to make specific decisions related to Government Programs and pricing. Two key examples of this are *Class of Trade* (COT) and *Bona Fide Service Fees* (BFSF).

COT is a classification of each customer, such as chain drug store, independent pharmacy, long term care pharmacy, hospital, specialty distributer, etc. The classification given to each customer impacts how all transactions for that customer are treated in the calculations, included or excluded. COT can be considered as the building block of your government pricing. One example is a Specialty Pharmacy. There is available guidance on when a Specialty Pharmacy may or may not be considered to be a *Retail Community Pharmacy*. The decision made will impact whether all of that customer's sales and rebates are included in the *Medicaid Retail AMP* calculation, which can have a dramatic impact (negative or positive) on your AMP, and the resulting Medicaid Rebate paid to the state which is based upon the AMP.

A second key area is the Bona Fide Service Fee (BFSF) test, which includes a fair market value (FMV) evaluation. Performing the BFSF test lets the manufacturer make the determination of whether payments to third parties, such as wholesalers and Pharmaceutical Benefit Managers (PBMs), are considered a price incentive or administrative in nature. Given the materiality of these payments, the treatment of either including them or excluding them in the calculations can have a dramatic impact on price. A key challenge here is that CMS does not define FMV in their guidance, and therefore evaluation can be fairly subjective depending on available data.

So where do we go from here?

When speaking with a good industry contact of mine (let's call him John) that was hired in as the head of Commercial Operations for a pre-commercial biotech company about one year removed from launch, it was clear that he had a lot on his plate. He had to look at reimbursement strategies, pricing strategies, the competitive landscape, contracting, finding a Third Party Logistics company (3PL) for logistics and distribution, and also GPs. In addition, he had to look at his role and how to be successful from multiple perspectives, including:

- Reimbursement and evaluating how each program might cover the organization's drug
- Pricing, given the planned commercial activity, and how to model what the government's prices would be
- Base AMP, how to model the Base AMP, and how to ensure that the company was not at risk due to a very low initial Base AMP
- Gross to Net and how to establish Gross to Net models for the Government Market
- Program Enrollment and the heavy administrative burden of entering each of the programs
- Methodologies (including calculation methodologies), reasonable assumptions, COT structure, and BFSF reviews
- Operational Strategy development and decide the direction for managing the programs, insourcing or outsourcing, and if outsourcing, find the right partner

A few things really resonated with me as I discussed the journey that John and his company were on.

First, John told me up front that his greatest fear was that he didn't know enough about the programs and that he wasn't comfortable not having sufficient knowledge of the function that was falling under him.

Secondly, upon looking back, John was very grateful that he took the time to get really educated. He engaged me in order to conduct training sessions with him and the executive team, an experience which was eye-opening for the organization. As a result of this effort, the company's senior leadership gained confidence in John's credibility in the space, and an appreciation for both the potential significance of the market as well as the importance of compliance and risk management.

Third, John felt that he and the company could now focus on actively selling through this important market. They could see the opportunity, and do more than just meet the operational requirements. They could build a Market Access and Commercial team across commercial and government, establish a pricing committee, and make informed decisions across both markets.

Finally, they felt like they could manage risks. With an understanding of risks, including both risk of financial exposure, such as unknowingly developing a pricing strategy that resulted in penny pricing to 340B customers, and compliance risks born from not making sure that all steps were taken to ensure that the calculations were in compliance with current guidance and that processes were documented, John's company felt confident that they could effectively mitigate and navigate the risks of the market.

All of the above ultimately allowed the company to be as effective as possible in this vital, growing, and complicated market and to make informed decisions, while also building a sustainable framework for GP compliance. **Get informed, and get it right the first time, that's the main thing!**

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