Navigating the U.S. Government Market

Top 5 Factors Every Biotech and Pharmaceutical Company Should Keep in Mind

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Introduction

Are you ready to launch your drug in the U.S. government market? It’s important to get it right the first time.

Biotechnology and pharmaceutical manufacturers are developing novel therapies and bringing innovation that is saving and improving lives across the globe. Bringing these products to the U.S. market increasingly means reimbursement through government payers and providers, such as Medicaid and Medicare, with approximately half of the U.S. population receiving a drug benefit through a publicly funded program. The challenge for emerging companies is that the program requirements are very complex and noncompliance can expose companies to significant risks.

In talking to many CFOs and Commercial leaders at emerging companies, their greatest concern about Government Programs is the fear that they “don’t know what they don’t know.” There is certainly a recognition of the importance of the government market in the United States, but there is also a growing awareness of the importance of compliance from day one and getting it right the first time.

Here are five top questions that deserve your priority attention to help you protect your business.
1. How will the various government payers and providers utilize, purchase, or cover my products?

— To understand how your products may be utilized by various government payers and providers, it is important to understand the programs and the populations they serve. The Medicaid Drug Rebate Program, for example, is retail based, providing an outpatient benefit to the Medicaid eligible individuals, primarily low-income Americans. Although Medicaid is a Federal Program, each state administers the program at the state level, reimbursing retail pharmacies for Medicaid utilization at the unit level, such as tablets, capsules, and milligrams, as this is how the drugs are dispensed. The state then invoices the manufacturer for a quarterly Medicaid Rebate. Therefore manufacturers with a drug that is distributed primarily through the retail channel tend to have higher Medicaid utilization.

— Other programs, such as the VA Federal Supply Schedule and the 340B program, which is primarily a safety net program through nonprofit clinics, are purchase based, with entities generally purchasing product from a wholesaler at the package level for their inventory. Injectable products that are administered in a physician’s office or clinic are generally subject to Medicare Part B average sales price (ASP) reimbursement when the clinic administers product from their inventory to the Medicare eligible patient. These “ASP Products” tend to have lower Medicaid utilization as they are not generally distributed through the retail channel. So in summary, evaluating how applicable your drug may be for each program is highly dependent upon the nature of the drug and its distribution.

<table>
<thead>
<tr>
<th>Programs</th>
<th>Outpatient Benefit (primary population each program serves)</th>
<th>Physician’s Office/Clinic</th>
<th>Purchase Inventory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicaid Fee For Service (FFS)</td>
<td>Medicaid Managed Care Organization (MMCO)</td>
<td>Medicare Part D plans</td>
<td>340B Program</td>
</tr>
<tr>
<td>Medicaid Supplemental Rebates</td>
<td>State Pharmaceutical Assistance Programs (SPAPs)</td>
<td>Medicare Part B Physician Administered Drugs</td>
<td>VA/FSS Federal Supply Schedule</td>
</tr>
<tr>
<td>Low Income Americans (approximately 70 million)</td>
<td>State Plans for Specific Populations not covered by Medicaid or Medicare</td>
<td>Part D Coverage Gap</td>
<td></td>
</tr>
<tr>
<td>Payment</td>
<td>Low Income Americans (approximately 70 million)</td>
<td>Primarily Elderly</td>
<td>Patients of 340B Entities Generally</td>
</tr>
<tr>
<td></td>
<td>Quarterly Rebate, Invoice Submitted to the Manufacturer Submitted and Paid After the Fact</td>
<td>Elderly</td>
<td>underinsured populations</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Federal Government Agencies</td>
</tr>
</tbody>
</table>

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2. What are the ongoing requirements that manufacturers have to meet when they participate in Government Programs?

— **Medicaid, Medicare, the VA, and PHS each have very specific statutory reporting requirements**, such as monthly and quarterly price reporting, which the government uses to establish pricing and reimbursement under each of the programs. Collectively the calculations are referred to as Government Pricing.

— Each program was established by legislation, such as OBRA ’90 for the Medicaid Drug Rebate Program, and the Veteran’s Healthcare Act of 1992 for the VA Federal Supply Schedule (FSS). The agencies that administer the programs, such as CMS (The Centers for Medicare and Medicaid Services) provide authoritative guidance through formal regulation and other means which detail the operational requirements, including specific calculation requirements. The key required reporting calculations include:

<table>
<thead>
<tr>
<th>Program</th>
<th>Calculation</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Medicaid Drug Rebate Program</td>
<td>Monthly and Quarterly Average Manufacturer Price (AMP)</td>
</tr>
<tr>
<td></td>
<td>Quarterly Best Price (BP)</td>
</tr>
<tr>
<td>Medicare Part B</td>
<td>Quarterly Average Sales Price (ASP)</td>
</tr>
<tr>
<td>VA/FSS</td>
<td>Quarterly and Annual Non-Federal Average Manufacturer Price (Non-FAMP)</td>
</tr>
<tr>
<td>340B Drug Pricing Program</td>
<td>Quarterly PHS Price</td>
</tr>
</tbody>
</table>
3. What goes into establishing the Government price?

— Each of the calculations are based upon commercial transactions to certain categories of direct and indirect customers (referred to as Class of Trade, or COT), such as calculating the Medicaid Retail AMP on the average price paid by retail customers, or calculating the VA Non-FAMP on prices paid by nongovernment customers.

— Manufacturers develop calculation methodologies that are based upon current guidance. The methodologies include various reasonable assumptions on how the company has applied guidance to their particular business and commercial activity, contracting, definitions of COTs, and what constitutes a discount or an administrative fee. All of the required data, including direct sales, indirect sales (contracted sales that were sold through a distributor), or rebates, are mapped to the methodologies and used on a monthly and quarterly basis to perform the calculations according to the methodologies.
4. What is required to enter into the various government programs?

- Each program—Medicaid, Medicare, VA, PHS, and Tricare—has its own unique requirements in order to have your drugs covered on day one of your launch. The administrative process can take up to six months. The process and requirements vary, from the simple signing of an agreement for the 340B program, to the complex process of entering into a VA Master agreement and negotiating FSS pricing.

- A key thing to consider is the accuracy of information that is provided to the government and is entered up front into their systems (back to the theme of get it right the first time!). CMS, for example, maintains the Drug Data Reporting (DDR) system. If product information, such as drug classification and unit of measure, is entered into the system incorrectly, the errors could cause calculations and/or rebates to be incorrect and subject the manufacturer to potential False Claims Act action, meaning that the data or information provided to the government resulted in the government paying more than they should have for the drug.
5. What are the compliance requirements of government programs and the risks of noncompliance?

— **Under programs such as Medicaid and Medicare, CMS requires C-Level certification of the accuracy of the pricing calculations that are submitted to the government.** This requirement has really raised the visibility of GP Compliance in companies, as CEOs and CFOs need to have reliance and confidence that the calculations they certify are accurate.

— One of the more significant areas of compliance requirements today is the CMS 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 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 in raising or lowering the price. A key challenge is that CMS does not define FMV in their guidance, and the evaluation can be fairly subjective depending on available data. Where each agency establishes its own compliance requirements, such as certification for Medicaid pricing data, the Office of Inspector General’s (OIG) mandate is to “protect the integrity of the programs.” The OIG fills that mandate through audit and investigation (the OIG publishes an annual work plan outlining their priorities for the year). The OIG published a document in 2003 called Compliance Program Guidance for Pharmaceutical Manufacturers, where the accuracy and integrity data reported to the federal government was identified as one of the three key risk areas in the pharmaceutical industry. Inaccurate pricing reported to the government, regardless of intent, can result in potential False Claims Act violations, where the government can seek recovery and penalties if they find that they may have overpaid for pharmaceutical products.

With the significant market opportunity of the U.S. government market, come significant compliance and operational requirements. Emerging manufacturers often struggle to understand the requirements of the various government programs and are constrained in their ability to build the costly and necessary internal systems and infrastructure. Given the opportunity, the complexities, and the operational requirements, many companies choose to outsource the function.

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How KPMG can help

At KPMG we understand the journey of emerging manufacturers. We bring the value of the KPMG firm, with broad experience across life sciences, with a high-touch boutique feeling to help companies through the complexities of product launch and entering the government programs to enhance your opportunities and build a sustainable compliance program. KPMG has a GP Launch toolkit to accelerate your program enrollment with a strong value proposition that allows you to decrease your infrastructure cost and reduce your initial investment.

KPMG provides reliance and confidence in the company’s compliance with government program requirements, with one of the most experienced and dedicated GP teams in the industry. Our professionals have over 25 years of performing calculations and claims support services. KPMG also provides internal proprietary systems managed by our government programs experts. We become your government programs team, providing support to establish a sustainable compliance program every step of the way.
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