

Initial drug product launch considerations when participating in US government pricing programs

Government Contract Services
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Now, next and beyond

Now:

understand your product and market

Review your product, its target patient population, possible patient gains and market share analysis. Is participation in the government markets required for proper coverage and pull-through of your patient population?

Next:

build, buy or outsource

Has the decision to participate already been made? What steps have you taken to source skilled staff, implement systems or issue RFPs for outsourcing vendors?

Beyond:

impact on pipeline products

How will future pipeline products change the need or desire to participate? Will your portfolio be diverse and require participation later?

Weighing the merits of participation

One of the most exciting and tense moments for a pharmaceutical manufacturer is nearing the conclusion of your products' successful clinical trials or readying for U.S. Food and Drug Administration (FDA) approval submission.

Your organization has spent many years and significant financial resources to be this close to launch. So now begins the next chapter that will help define success, the commercialization of your products. Activities such as readying contracts with suppliers and end customers, organizing logistics and the need to hire sales staff demand your time. This is a critical time to determine where the multitude of government programs fits into your overall strategy.

Government programs can influence your organization, so analyzing how the programs can impact your product is imperative. In general, a manufacturer's participation in the primary government pricing programs is voluntary. Before deciding whether to participate, it is important for your organization to better understand the overall market for your prescription drug product, your patient population, how your product will be distributed to the patient and your competition's approach. Fully understanding each element is necessary to properly evaluate the potential benefits likely to be gained from participation in government programs.

Participation offers many benefits but there are risks, compliance and gross-to-net considerations that must be considered. And while participation is voluntary, it almost always represents an all-or-nothing proposition. For instance, to have your drugs covered under Medicare, you must participate in the Medicaid Drug Rebate Program (MDRP). If you participate in the MDRP, you must also participate in the Public Health Service 340B (PHS) and Veterans Affairs Federal Supply Schedule programs (to the extent that you have covered drugs under these programs). Each government pricing program contains unique and complex requirements for calculating and reporting product pricing to the applicable government agencies. The requirements are based on myriad statutes, rules and regulations applicable to these government programs, as well as authoritative guidance issued by government agencies. While these programs reach a wide audience, there are administrative, compliance and bureaucratic hurdles involved.

Proper analysis will help you better determine if you need to participate in the various government programs to have a successful product launch, or product in general. Robust analysis will help visualize the full value of participating in government pricing programs - or passing on this route. Properly vetting and strategizing for these and many other concerns are exactly what your company should be addressing at this stage. Establishing the proper people, processes, policies and partners to navigate this space will make the execution and management of the government programs that much more effective and efficient.

Steps to take now

1 Conduct an assessment of products and patient population to determine potential patients covered under the government programs

2 Review the impact to gross-to-net for applicable government programs to set appropriate expectations with senior leadership and finance

3 Confirm that all stakeholders understand, and are prepared to support, government program participation

Questions leadership need to ask

- 1. Do we need to participate** in the various government programs to have a successful product launch, or product in general?
- 2. What are the benefits** from participating in government pricing programs?
- 3. Do we have the in-house capabilities** to address government mandates, guidelines and orders?
- 4. Does the multitude of government programs fit** into our overall strategy?

Key government programs

MDRP: MDRP is designed to offset the overall cost of prescription drugs under the Medicaid Program, where manufacturers are required to pay quarterly rebates to states on those drugs for which payment are made under each state plan.

PHS 340B Program: The 340B Program enables covered entities (e.g., disproportionate share hospitals) to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services, through discounted drug prices given by participating manufacturers.

Department of Veterans Affairs Federal Supply Schedule: The manufacturer agrees to provide discounted prices for prescription drugs to federal purchasers via VA schedule contracts based on disclosed commercial practices and negotiated pricing relationships with commercial customers.

Medicare Part B: Medicare Part B (medical insurance) covers a limited number of outpatient prescription drugs that are generally provided at a doctor's office or a hospital outpatient setting, with providers reimbursed based on the average sales price reported by manufacturers for their covered physician-administered drug products

Tricare Retail Refund Program: Tricare was established by the U.S. Department of Defense (DOD) in an effort to provide health services for military personnel and their dependents for prescription drugs through local retail pharmacies, and the program provides the DOD with a rebate based on the pricing agreed upon by the manufacturer and the Government.

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