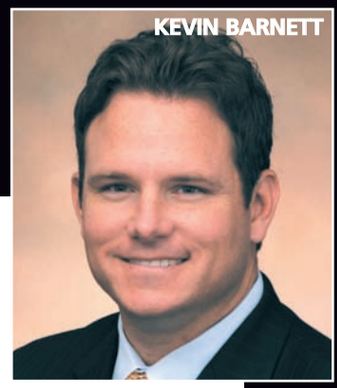
Contributed by Kevin Barnett



MEDICARE PART D IT'S CRUNCH TIME ... AGAIN

Manufacturers are facing déjà vu with Part D. While the 2006 Part D year recently came to a close and the 2007 Part D year is nascent, crucial decisions related to 2008 Part D are right around the corner. The Centers for Medicare and Medicaid Services (CMS) requires that managed care organizations (MCOs) and pharmacy benefit managers (PBMs) that are interested in serving as Part D sponsors for 2008 submit their formularies and bids to CMS by April 16, 2007, and June 4, 2007, respectively. This means MCOs and PBMs will be engaging in product-specific, contracting-related discussions with manufacturers during the first few months of 2007.

For the most part, contracting interactions between manufacturers and Part D sponsors for 2007 Part D (which took place at the beginning of 2006) were uneventful. Part D sponsors were focused on making sure that the new program was operational within their organizations. Further, there was a very narrow window of time and a dearth of data for making formulary decisions. As a result, the contracting process for 2007 was primarily a "check-the-box" exercise, with most sponsors leaving their 2007 Part D formularies very similar to their 2006 formularies. But there are a confluence of factors that suggest Part D formulary decision making and contracting for 2008 could be substantially different.

DIFFERENCES FOR 2008 PART D

There are strong indications that Part D sponsors will manage their formularies much more tightly and push aggressively for rebate and price concessions in 2008. Consider the following variables:

- Plans and manufacturers now have a year's worth of experience and data from the program. These data and experiences will serve as key input to formulary decision making and contracting for 2008.
- In 2008, Part D sponsors will face additional financial risk because of a reduced safety net from CMS against losses (created by a narrowing of the risk corridors CMS uses). This provides a clear incentive for Part D sponsors to tightly manage their Part D business.
- The leading Part D sponsors are now known. In 2006, the top-eight Part D sponsors represented more than two-thirds of the lives enrolled in Part D. These leading plans clearly have more bargaining power now and are likely to exert this power more when interacting with manufacturers regarding Part D contracting for 2008.
- The patents on many high-profile drugs are either recently expired or will soon be expired. The resulting new generic alternatives that Part D sponsors have at their disposal are likely to change formulary and contracting dynamics for Part D.

WHAT LEADING PART D SPONSORS ARE SAYING

- Leading Part D sponsors are well aware of the narrowing of the risk corridors that will take place for 2008 Part D. While this does present some concern, most are confident that they are taking appropriate steps to compete successfully vis-à-vis the narrowed safety net.
- Categories of particular interest and importance for Part D sponsors in 2008 include: cardiovascular, diabetes, gastrointestinal, insomnia, mental health, oncology, and osteoporosis.
- Most plans will be conducting reviews of key drug categories and intend to go through a formal bidding process with manufacturers — similar to what was done in 2005 for 2006 Part D formularies.
- Many plans are focused on better managing specialty products in Part D, with some indicating they are considering narrowing the number of specialty products covered on their formularies.
- Plans now have more interest in/willingness to consider performance-based contracts with manufacturers.

THE PATH FORWARD FOR MANUFACTURERS

The warning flare has been fired. For manufacturers, a lot of research and analysis needs to be done over the next few months to support informed decisions regarding Part D contracting for 2008, and several critical questions need to be addressed, including:

- How is the Medicare Part D landscape likely to evolve over the next few years?
- From a formulary perspective, how are leading Part D sponsors managing the categories in which they compete, and how is this likely to change in the future?
- What are the contracting objectives for each of their key products?
- What are the key issues and opportunities for their products vis-à-vis the evolving Part D environment?
- What are the strengths and limitations of their current approach to contracting in Part D? What have been the results of their current Part D contracting strategy, and what are the largest opportunities for improvement?
- How has the formulary positioning of their products affected their use in Part D? On average, what is the benefit of being on formulary? On average, to what degree is use negatively affected with disadvantaged or nonformulary positioning?
- How should they approach contracting for Part D in light of the evolving market?
- How can they effectively segment and prioritize accounts and regions to ensure appropriate strategies are pursued and resources are deployed appropriately?
- What is the projected financial impact of the selected Part D contracting strategy for each of their products? What is the projected aggregate financial impact on their organization?

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