



FEBRUARY 2007

### **Medicare Part D: Deal with Pricing “What If’s” Now**

Launched in October 2005, Medicare Part D is still very much a work in progress, making pricing a challenge for pharmaceutical companies. With just a year’s worth of data, drug companies now are submitting bids to insurance companies that they hope position their drugs to be selected as preferred agents in 2008 formularies. In doing so, they have had to take some measured risk in terms of how deeply they discount their drugs.

A lot of “what ifs” went into that number crunching, but there is a potentially bigger “what if” brewing in Washington that could dramatically affect drug pricing, and maybe even impact the contracts you are writing today. What if Congress passes legislation that takes pricing negotiations away from the pharmaceutical producers and the insurance companies that offer Part D benefits?

There are a number of ideas floating around Congress. One would require drug makers to provide “best price” rebates, as they have been required to do for Medicaid since 1991. Another proposal, the Medicare Prescription Drug Price Negotiation Act of 2007, calls for the federal government to negotiate prices with pharmaceutical manufacturers.

Let’s add another “what if”: If any legislation is enacted, what if changes are made retroactive? The government has done it before and could do it again. When the Medicaid best price rebate agreement was enacted March 1, 1991, it was made retroactive to January 1. And remember Clinton’s retroactive tax increase in 1993?

Of course, there is always the possibility that Bush will veto any such legislation that lands on his desk, but the smart players aren’t counting on that and aren’t waiting to see what happens. They are looking at what they can do *now* to protect themselves.

If Congress passes legislation that mandates Medicaid pricing or otherwise gives the government more control over Part D drug pricing, how would you frame a contract so you could be sure your company would not be penalized — or at least not penalized for a significant period of time?

For example, let's say your company is negotiating a contract to supply a drug that is commonly prescribed to patients covered by Medicare Part D, as well as younger patients? How do you determine the opportunity cost of the business you would gain from that contract, in light of the possibility that the pricing for the portion supplied under Medicare Part D could change? How could you craft contract language or pricing to minimize the impact on your profits? What metrics would you use?

There are no easy answers, but the pharmaceutical companies that are attempting to answer these questions now will be in better shape if and when Congress acts.

**If you would like to share your experience in these issues, or discuss how you can ensure a successful product launch, send an email to [rkeefe@tcgbiopharma.com](mailto:rkeefe@tcgbiopharma.com).**

Pulse is published by TCG LLC of Research Triangle Park, NC.  
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