REIMBURSEMENT AND REBATE ISSUES

Since President George W. Bush signed the Deficit Reduction Act of 2005 (DRA) into effect, pharmaceutical manufacturers have converged on this critical event in a series of public discussions and individual preparedness initiatives. The goal of these activities is to understand the motivation and objectives behind the DRA while implementing a strategic and operational response.

As the latest in a string of federal mandates regulating the industry, DRA is proof positive that the government is taking a greater and increasingly controlling interest in pricing and rebate processes.

David Gelhar
I-many

The DRA reflects the current reality for an industry already beleaguered with many levels of regulatory compliance and a host of policy changes, according to experts at Model N Inc. As government healthcare spending grows at unprecedented rates, a host of new laws aimed at cost reduction have been brought in. The DRA reflects the intent of the federal government and states to maximize rebates from suppliers while minimizing drug reimbursement costs.

"This makes the DRA more budgetary rather than about healthcare reform," says Ali Tore, cofounder and senior director of product management at Model N. "Moreover, there is pending guidance and clarification on issues by the Centers for Medicare and Medicaid Services (CMS)."

For Mr. Tore, the DRA raises an age-old question: Is it possible to write a regulation affecting the industry's most fundamental financial processes that is simple, straightforward, and practical to implement?

"Today, manufacturer executives, as well as legal and operational experts, are concerned about the practical aspects of proposed changes to key government pricing and Medicaid-related requirements such as average manufacturer price (AMP) reporting and the lack of clarity on changes to calculation inputs such as prompt pay discounts, nominal pricing, and class of trade categorization," Mr. Tore says.

He adds: "Over the longer term, there is concern about the potential use of AMP in a cost-based system for drug reimbursement, the public availability of historically proprietary pricing data, and the overall impact on pricing strategies, systems, and organizations. These questions, in turn, drive many fundamental concerns relating to workload, compliance, and internal process, which ultimately could impact competitive and market strategies."

There is considerable uncertainty about the DRA. But this has not stopped the leading companies from moving forward. Mr. Tore says efforts to assess the potential impact and identify and address identified risks based on available information have begun.

CHOOSING TECHNOLOGY FOR DRA COMPLIANCE

For many pharmaceutical companies that currently manage government pricing requirements with internally developed and manual systems, the DRA may well represent the proverbial straw that breaks the camel's back.

"As the latest in a string of federal mandates regulating the industry, DRA is proof positive that the government is taking a greater and increasingly controlling interest in pricing and rebate processes," says David Gelhar, senior director of life sciences at I-many Inc. "Supporting this trend is the government's involve-

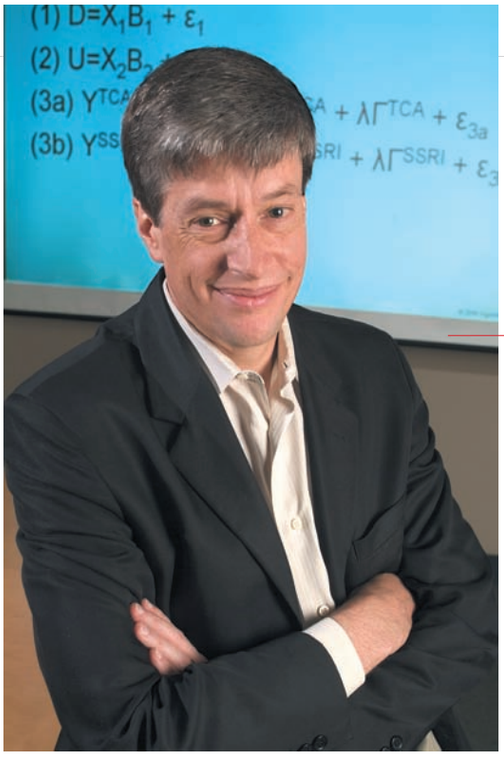
Thought Leaders

WILLIAM (BILL) H. CROWN, MA, PH.D. President, i3 Innovus, Waltham, Mass; i3 Innovus provides research solutions to support market access and reimbursement of healthcare products and delivers real-world evidence that helps products succeed in the market. For more information, visit i3innovus.com.

DAVID GELHAR. Senior Director of Life Sciences, I-many Inc., Edison, N.J.; I-many is a provider of advanced contract life-cycle management solutions for managing corporate commitments. For more information, visit i-many.com.

RUSSELL LAMONTAGNE. President, Corinth Group Communications, New York; Corinth Group is a healthcare consulting company. For more information, visit corinthgroup.com.

ALI TORE. Cofounder and Senior Director of Product Management, Model N Inc., Redwood Shores, Calif.; Model N provides revenue management solutions, offering an integrated suite of applications for pricing, contracts compliance, rebates, fees, and chargebacks optimized for the industry practices of life-sciences companies. For more information, visit modeln.com.



ment in the pharmaceutical industry, with spending growing almost 123% over the five-year period ending 2006, and Medicare's share of this spending spiraling by a factor of 10."

According to I-many experts, against this backdrop, it has become increasingly difficult and time-consuming to keep homegrown and manual systems current, let alone flexible enough to deal with a continuous barrage of regulatory changes and the complex calculations and transaction filtering that the DRA will likely require.

The magnitude of the DRA impact will not be known until final rulings are made by the CMS. But according to an I-many-sponsored survey, produced by PharmaVOICE, 96.3% of respondents believe that the CMS regulations should include information about a change to the base AMP and 92.5% believe that retail class of trade should include retail pharmacies. And yet, the majority of manufacturers participating in the survey say they will wait for official CMS guidance before making any changes to their pricing and rebate systems.

"This wait-and-see approach may be problematic for several reasons," Mr. Gelhar says. "First, CMS may provide an implementation interval, but it may not be long enough for all manufacturers to make the necessary changes. Second, existing homegrown and manual systems may not be adaptable to the changes that are finally mandated."

MEDICARE PART D UPDATE

The expansion of prescription drug coverage to the elderly under the Medicare Part D program represents a significant change to the program since it was enacted in 1965.

"For most enrollees, this design involves an annual $250 deductible; 25% cost sharing for drug expenditures between $250 and $2,250; 100% cost sharing for drug expenditures between $2,250 and $5,100 — the so-called donut hole; and, finally, a minimal 5% copayment for enrollees with catastrophic drug costs above $5,100," says William Crown, Ph.D., president of i3 Innovus. "But it is important to recognize that for enrollees who are also eligible for Medicaid or who meet low-income eligibility guidelines, copays are minimal, often just a few dollars or waived completely. In addition, many Part D providers offer programs that have a zero deductible, and several cover generic drugs or even brand name drugs in the donut hole, typically, with a higher premium for the plan.

There were at least two major unknowns before the enactment of Part D, Dr. Crown says: first, would the program have the intended effect of expanding prescription drug coverage for the older population; and second, what effect would its complicated benefit design have on medication adherence for patients being treated for chronic conditions?

"We now have preliminary but incomplete evidence on both of these questions," he says. "The Medicare Part D program does appear to have expanded prescription drug coverage for the elderly. Similarly, there are discernable changes in medication refill rates as people pass through the various copay thresholds, particularly into the donut hole, and all the way through the donut hole to the catastrophic coverage portion."

But, Dr. Crown says, the observed patterns of medication refills, switching, and discontinuation are complex and need to be better understood.

"For example, do patients who enter the donut hole, but who do not expect to pass through to the catastrophic phase behave differently from those who expect to quickly pass through to catastrophic coverage," he asks.

We now have preliminary but incomplete evidence on both of these questions. The Medicare Part D program does, indeed, appear to have expanded prescription drug coverage for the elderly. Similarly, there are discernable changes in medication refill rates as people pass through the various copay thresholds, particularly into the donut hole, and all the way through the donut hole to the catastrophic coverage portion.

Dr. William Crown, i3 Innovus

FIVE SIGNPOSTS ALL PRICING EXECUTIVES SHOULD KNOW

Signpost 1: Arm Pricing Departments with Industry Leading Budgets — Top companies support their global, U.S., and European affiliate-level pricing departments with budgets large enough to support pricing analysis during each stage of product development.

Signpost 2: Assign Adequate Pricing Staff to Brands at Each Development Stage Based on Projected Sales Levels and Innovator/Me-Too Status — Strategic pricing headcounts assigned to individual products vary significantly from preclinical development through late-stage clinical trials, launch, and post-marketing.

Signpost 3: Monitor Pricing Workloads and Regularly Evaluate Pricing Department Structures to Ensure Proper Alignment with Company Needs — Frequently reevaluate pricing department structures and sizes to ensure that they adequately meet the demand for strategic pricing analysis and are organized such that they can quickly digest and adapt to changes in pricing and reimbursement environmental factors in key markets and around the globe.

Signpost 4: Begin Pricing Work Early in Development — Companies that begin pricing activities for their brands in the earliest stages — even beginning in preclinical work — see big payoffs down the road.

Signpost 5: Centralizing Pricing Budget Control Ensures Best Practice Follow Through — Companies differ greatly in terms of who pays for, and has budgetary control of, pricing activities. Sharing in the cost is not as much of a problem as sharing the decision-making process. Sharing decision power can cause friction when it comes to decisions, such as: which pricing activities should be performed, what timing is optimal, and which vendor is most effective.

Source: Cutting Edge Information, Research Triangle Park, N.C. For more information, visit cuttingedgeinfo.com.

The DRA raises an age-old question: Is it possible to write a regulation affecting the industry's most fundamental financial processes that is simple, straightforward, and practical to implement?

Ali Tore
Model N Inc.

Part D has created a major shift in the awareness and use of generic drugs, which may impact the promotion of products far more than the direct negotiation of prices by the government.

Russell LaMontagne
Corinth Group Communications

"Or if people discontinue a medication, do they drop their antihypertensive because the condition is asymptomatic, or do they forego their cancer drug because it is so expensive?"

CONSEQUENCES OF MEDICARE PART D

A popular criticism of Medicare Part D has been the inclusion of a provision that did not allow the government to directly negotiate discounts with pharmaceutical companies, says Russell LaMontagne, president of Corinth Group Communications. Advocates of the benefit design argued that competition and the ability of private plan sponsors to negotiate formulary discounts would control prices better than direct government control.

"The elements of ownership and price transparency inherent to the plan design — comparison tools combined with the exposure to out-of-pocket costs during the deductible gap — could create downward pressure on drug prices for Medicare beneficiaries and the market as a whole," Mr. LaMontagne says. "This will probably be a long-term shift that cannot be measured yet."

According to the Corinth Group, during the last three months, 3.4 million seniors entered the deductible gap of their Part D prescription drug coverage, creating a vacuum for cost-saving information and options. Within four weeks, Wal-Mart announced a plan to cover generic drugs for $4 a month, which was quickly matched by Target.

"Wal-Mart and Target were able to make this move because generic drugs are, in many cases, more profitable for retailers than branded drugs," he says. "Eventually these market forces should also close the gap between branded and generic drugs." ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

OUTLOOK: ENSURING COMPLIANCE WITH CHANGING REGULATIONS

PHARMAVOICE ASKED EXPERTS TO DISCUSS THE IMPACT OF MEDICARE PART D AND THE DEFICIT REDUCTION ACT ON THE PHARMACEUTICAL INDUSTRY.

Dr. William Crown
i3 Innovus

In 2006, the various stakeholders involved with the Medicare Part D program struggled with the immense operational challenges of getting the program up and running. In January 2007 we will have a full year of data on the experiences of enrollees. At that time, we will be able to assess what it has meant for the older population.

David Gelhar
I-many

Rather than delay and risk the consequences of noncompliance with DRA, pharmaceutical manufacturers are well-advised to act now to avoid exposure to potentially damaging outcomes in the form of substantial fines and loss of market stature. This risk avoidance and noncompliance protection can best be achieved by implementing robust government pricing and Medicaid rebate management solutions provided by vendors that have a history of quickly adapting those systems to regulatory changes.

Ali Tore
Model N

There is hope in some quarters that the DRA might be a blessing in disguise, presenting CMS with a significant opportunity to eliminate ambiguity on many fronts. Class of trade definitions, price definition clarifications, and reporting requirements are some of the issues that plagued the industry even before the DRA. Even with comprehensive guidance from CMS, there will still be variations across manufacturers on many aspects of government pricing and Medicaid claims processes. Assessing data quality, implementing organizational and operational flexibility, and engaging different parts of the organization in building a DRA compliance roadmap are all things that will dictate readiness when the next set of regulatory requirements is published.