Looking Ahead
The Deficit Reduction ACT

A PRESCRIPTION TO ADOPT FORWARD-LOOKING STRATEGIES
and ensure corporate and regulatory compliance excellence


Gopkiran Rao

As government healthcare spending increases, Congress, states, and agencies will continue to put cost management and containment on their agendas. Given this reality, it is important to build nimble manufacturer organizations, processes, and systems strategies to anticipate and accommodate changes in a timely fashion.

Today, pharma and biotech managers overseeing government programs, as well as their financial and legal counterparts, are focused on implementing the key provisions of the Deficit Reduction Act (DRA 2005). The DRA is a wake-up call for companies to look back on the history of how public policy has interacted with industry growth and evaluate their response to the evolution of federal and state program policies because these directly affect revenue strategy and execution. The DRA again highlights that regulatory compliance is a moving target at best; keeping abreast of government pricing and reimbursement requirements is one of the most challenging issues facing pharmaceutical manufacturers today.

"For example, even with the release of the much anticipated CMS ruling on Dec. 15, 2006, details of several key requirements are still missing," says Gopkiran Rao, director, industry marketing, at Model N. "As government healthcare spending increases, Congress, states, and agencies will continue to put cost management and containment on their agendas. Given this reality, it is important to build nimble manufacturer organizations, processes, and systems strategies to anticipate and accommodate changes in a timely fashion."

As manufacturers look to understand and digest the impact of the latest DRA pronouncements, they must begin to address not just the tactical requirements but drive executive education and internal readiness initiatives to deliver an overarching compliance roadmap extending well beyond March 2, 2007, the earliest date that manufacturers must first start implementing some of the DRA's key provisions.

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ANTICIPATE THE FINANCIAL TRICKLE DOWN

Over time, DRA provisions relating to the key components of the Medicaid rebate calculation AMP may increase claim amounts from states.

"For manufacturers with certain patient populations, this may mean an uptick in outgoing rebates," Mr. Rao says. "Every participating drug manufacturer should regularly examine and revise their government rebate accruals policy to anticipate and cover any changes in the underlying Medicaid drug rebate policies and factors. Working with outside experts or acquiring in-house capabilities to conduct what-if analyses and/or financial modeling exercises to project expected dollar amount increases is certainly a best practice to consider."

ADAPT PRICING AND CONTRACTING STRATEGIES

Manufacturers, already coping with reimbursement pressures, are likely to see changes, such as narrower definitions of "nominal" type pricing as roadblocks to extending lower prices to certain "qualified" customers without increasing other liabilities, thus lowering revenue.

"Manufacturers need to be prepared to constantly monitor and adapt pricing and contracting strategies and to assess the impact of different scenarios," Mr. Rao says. "This might include adjusting or extending specific price points and incentives to customer segments or examining the impact of decreased reimbursement limits for measuring the effect on medium- and long-term revenue projections."

BUILD A FLEXIBLE, KNOWLEDGEABLE ORGANIZATION

According to Mr. Rao, many of the changes brought by the DRA will impact the organizational structure of pharmaceutical manufacturers. For example, the introduction of monthly price reporting and an explosion in the number of potential prices to be reported to various agencies will likely increase the workload on already stretched government contracting and rebate organizations.

"Typically, the IT functions supporting

these resources will also be impacted," he says. "Manufacturers must evaluate and test organizational readiness while investing in better systems to ensure they are reporting their numbers in an accurate fashion."

ASSESS SYSTEMS CAPABILITIES AND ARCHITECTURE

Many of the DRA changes affecting pricing calculations and submissions involve the need to source, validate, and process additional data from multiple systems as part of accurate and timely reporting requirements.

"In many sophisticated companies, knowledge sits in the heads of one or two key individuals," Mr. Rao says. "This is not a scalable proposition. With DRA, the importance of financial data from enterprise resource systems (ERP) that permits monthly calculations, as well as still unclear requirements for manufacturers to include external pricing data — authorized generics — will require substantial, new integration between heterogeneous systems and IT environments. Not only do manufacturers need to assess whether their current financial systems can provide transactional data at the necessary granular level, but they also need to review the current capabilities of their government pricing and Medicaid claims systems to handle increased information volume."

BRING IN EXPERTS AND ASSESS READINESS

Noncompliance, intentional or accidental, is not an option in today's climate. With the wide ranging statutory changes introduced with the DRA, the effort of managing compliance is likely to intensify for pharmaceutical manufacturers. Making changes to key reporting requirements should require the knowledge and insight of internal resources but may also demand external expertise, including legal counsel, regulatory consultants, or systems integrators.

"Companies should make it a corporate mandate to regularly evaluate and update their pricing policies and standard operating procedures as an integral part of their compliance strategy," Mr. Rao says.

IN CONCLUSION

"The passage of the Deficit Reduction Act of 2005 has once again put the spotlight on the industry's pricing and contract strategies in the context of government pricing and Medicaid requirements," Mr. Rao says. "While executives and managers alike must comprehend and interpret changes to the legislative environment, it is equally important for their counterparts in IT, finance, and operations to help them anticipate and implement appropriate responses to these evolving requirements. The DRA has undoubtedly created anxiety, but it also presents an opportunity to invest in a forward-looking strategy that starts with the building blocks of process, data, people, and policies."

Manufacturers need to build the framework to assess, interact, and respond to market and regulatory dynamics. Only then will they minimize the negative impact on revenue and profitability and eliminate the risk of regulatory noncompliance. ✦

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10 BASIC DRA QUESTIONS TO ASK IN YOUR COMPANY

AWARENESS

1. Is there executive visibility and commitment to this important issue and will that permit a comprehensive review of investments in people, systems, and process?
2. Has your organization formally studied the implications of DRA on your company?
3. Has your organization chartered a DRA implementation project?

PREPAREDNESS

4. Do you understand the unique challenges of each provision?
5. Do you feel confident that you know what the key changes are and have a plan to address their impact?
6. Are you evaluating your authorized generics deals and nominal price contracts pending additional clarification?
7. Which functions in your organization will feel the impact of DRA the most and what is your plan to support them?

ACTION PLAN

8. Are you hiring more resources to help execute your DRA plan?
9. What types of system investments are you making or planning to make?
10. How will you be better prepared in time for the final regulations due this year?

TIPS FOR DRA COMPLIANCE

EDUCATE EXECUTIVES

- Develop executive visibility and understanding of regulatory programs, contracts, and potential for business impact/risk.
- Develop a long-term investment plan to build a world-class organization, systems infrastructure, and reporting systems.
- Empower specific individuals with developing best practices and change management tools.
- Charter specific what-if style projects with outside experts if necessary to test for inflexibility in processes and tools.

EVALUATE

- Understand the unique challenges of each government agency and its pricing calculation and reporting requirements.
- Evaluate commercial contracts and incentives: are they negotiated to ensure compliance with your regulatory policies and SOPs?
- Invest in educating the organization about what the key regulatory or legislative changes are.
- Build an organizational structure that is flexible to withstand the impact of a major regulatory overhaul or business change.
- Build capability to meet reporting deadlines in a timely and proactive mode.

TAKE ACTION

- Consider hiring and training more resources starting now to help execute your compliance strategy.
- Build a long-term system improvement and investment plan.
- Create or actively participate in an ongoing dialogue with your industry peers and the regulatory bodies before the next DRA hits.