BY ELISABETH PENA VILLARROEL

Managing Marketing Under Medicare Part D

MEDICARE PART D presents many opportunities, as well as challenges, for pharmaceutical marketers. **AS THE INDUSTRY ADAPTS ITS MARKETING STRATEGIES FOR THIS EVOLVING ARENA, TRANSPARENCY IS A TOP PRIORITY.** Brand teams also need to remain flexible and stay on top of emerging information and trends to best position their products.

Compliance Concerns

With the increase in prescriptions expected as a result of Medicare Part D, pharmaceutical manufacturers should begin to expect heightened scrutiny of their rebate and discounting programs designed for large purchasers. Since none of the regulatory safe harbors to the antikickback statute were drafted under Part D, it is unclear exactly how many of these rules will be adopted under the new program. Manufacturers can prepare and protect themselves by instituting processes that are as transparent as possible.

DEZELAN. Although the existing statutory and regulatory safe harbors under the federal antikickback law for discounts and rebates apply to all federal healthcare programs, including Medicare Part D, the mechanics of Part D present special challenges. For example, when negotiating with the sponsors of Part D prescription drug plans, it is important that manufacturers keep these discussions separate from any negotiations with the same sponsors with respect to their commercial plans to avoid any allegations that discounts in the Part D program are linked to rebates for products used by enrollees in commercial plans.

71% of seniors find Medicare Part D somewhat or very hard to understand.

Source: Wall Street Journal Online/Harris Interactive Health-Care Poll

OLSON. Under the Medicare Modernization Act's legislation, the U.S. Department of Health and Human Services (HHS) and its enforcement arm, the Office of Inspector General (OIG), cannot interfere directly with the negotiations between drug manufacturers and Medicare Part D drug-plan sponsors or require a particular formulary or price structure. But with Part D, this has radically changed the landscape by creating a new federal prescription drug benefit to which the antikickback fraud and abuse laws now apply. The OIG acknowledges that certain common business practices that are appropriate in other industries, and that are safeguarded by well-defined regulatory safe harbors, can raise legal problems for drug manufacturers that market products to government healthcare programs. Given that the OIG has not yet issued any comprehensive regulatory safe harbors to the antikickback statute for Part D rebates and

THOUGHT LEADERS

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ANNA SPENCER
SIDLEY AUSTIN LLP

There is a lot of uncertainty, but it is clear that fraud and abuse are issues that pharma companies will have to pay careful attention to.

MIKE DEZELAN
SERONO

Although the existing statutory and regulatory safe harbors under the federal antikickback law for discounts and rebates apply to all federal healthcare programs, including Medicare Part D, the mechanics of Part D present special challenges.

STEPHEN ZOCCHI
MODEL N

Manufacturers should begin to evaluate the infrastructure of their systems for handling and processing the potential changes in government pricing calculations and reporting, as this is likely to tax many of the legacy systems that they may be relying upon to manage regulatory compliance today.

discounts, there continue to be significant risks to pharmaceutical manufacturers negotiating prices for their products with large purchasers, such as managed-care organizations.

SPENCER. There are a number of provisions that manufacturers can include in their contracts that will provide valuable protection to them. No. 1, they should include provisions that require compliance with the applicable safe harbors. The reporting obligations of buyers vary based on whether the buyer is paid by the government on a cost, capitation, or other basis. There are elements of payment to Part D plans that are based on cost, and then there are elements that are more akin to capitated payments so the safe harbors are not an exact fit. But you can account for that in drafting.

8% of seniors find Medicare Part D somewhat or very easy to understand.

Source: Wall Street Journal Online/Harris Interactive Health-Care Poll

WINTERTON. When dealing with the PDPs or Medicare Advantage prescription drug plans (MA-PDs), the manufacturer should encourage spon-

For more information, visit gfkmarketmeasures.com.

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LARRY OLSON
GFK MARKET MEASURES

Drug manufacturers have a lot riding on the success of Part D. Its failure will lead to more government regulation of the industry and a greater push for government price controls.

KEVIN BARNETT
CAMPBELL ALLIANCE

Historically, most brand teams have not placed much emphasis on the Medicare population. Thus, this customer segment still represents a blind spot for many.

sors to include the Part D rebates in their disclosures to CMS. This is true during both the bidding stage — June 5, 2006, is the current deadline for 2007 sponsor bids — and the reporting of actual drug costs to CMS as part of the risk corridor evaluations. Manufacturers should also require plan sponsors to disclose discounts as otherwise required and agree to meet and discuss discount disclosures in light of any future government advisories on the topic. During the negotiation process, manufacturers need to ensure fair-trade protections remain in place and maintain a separation of the commercial and government businesses of the plan sponsor. Care also should be taken when negotiating with a plan sponsor that includes Part D beneficiaries in the form of employer group members where the plan sponsor receives the 28% federal subsidy. Inbound drug use must be segregated into best price impacting and nonbest price impacting, as appropriate, given the mix of Part D and eligible and non-eligible populations. Finally, manufacturers need to keep abreast of developing areas, such as pricing treatment of rebates to long-term care entities, to ensure ongoing compliance.

Use of prescription drugs by people who previously did not have insurance is expected to increase by 20% or more.

Source: PricewaterhouseCoopers LLP

OLSON. While Part D is excluded from the "best pricing" contracting model available to Medicaid programs, pharmaceutical marketing teams need to simplify their rebate and discount incentive programs with MCOs and PBMs. More specifically, pricing needs to be as transparent as possible, especially with respect to rebates. Risk-sharing arrangements should be considered as one strategy.

ZOCCHI. In addition to careful preparation of appropriate policies, the manufacturers should begin to evaluate their systems' infrastructure for handling and processing the potential changes in government pricing calculation and reporting. Recent data from a survey conducted by Model N and CSC of more than 60 pharmaceutical manufacturers revealed that only 35% were confident their government pricing systems were flexible enough to adapt to pending regulatory changes. Implementing and fine-tuning policy changes driven by Medicare Part D is likely to tax many of the legacy systems that manufacturers may be relying upon to manage regulatory compliance today.

FARINO. Companies will have to develop policies and controls to ensure they effectively manage compliance risk when contracting with PDPs that also may be commercial customers.

THOMAS. Pharma companies need to stay away from market-share deals, any type of arrangement that might attempt to leverage books of business in the same account or previous arrangements they may have with an account. Companies need to be absolutely transparent in their contract negotiations with the government, and that includes any rebates, chargebacks, or any type of discounts that may be given to a particular customer.

LEVY. It's our concern that the big issue is not short-term recontracting, but what happens when the other shoe drops, when Congress reacts to the costs of Part D. That's when everything is going to change.

Positioning Products for Part D

Brand teams face challenges in terms of having to quickly adapt to the new rules this market segment presents.

WINTERTON. During the initial negotiation period, the industry was under a significant time crunch to get deals signed and benefits in place in time for the Jan. 1, 2006, start up. Dates and events were preset by CMS with little regard for industry readiness at several critical junctures, including state agencies, benefit managers, internal CMS departments, and so on. Because of this time crunch, the sequence of the negotiations was less than optimal. At the same time, PDPs and PBMs were putting forward proposals to CMS regarding their plans without knowing the full extent of the rebates they would be earning from the pharmaceutical manufacturers. Additionally, there were significant gaps and assumptions made around the data used during the negotiation process. Key variables — such as the number of covered lives, the level of government reimbursement, the pricing of pharmaceutical products — were all gray areas. Once the enrollment and utilization details begin to become known, manufacturers will have the opportunity to shape and align their brand strategies with the plan sponsors, based on their ability to influence product selection with the greatest number of members.

BARNETT. Although most brand teams were involved to some extent in their company's core Part D planning during 2005, key repre-

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sentatives on the brand team still may not have a complete understanding of Part D. They also haven't focused on the strategic and tactical adjustments that need to be made for their products. Beyond understanding the core elements of the Part D benefit, a good starting place for brand teams and marketers is to dissect the buying process under Part D, which will require a healthy dose of research and

PATIENT-ASSISTANCE PROGRAMS: PICKING UP THE PIECES

The availability of prescription coverage to the 65 year old and older population under the Medicare Modernization Act (MMA) has significantly impacted the eligibility of lower-income seniors for pharmaceutical patient-assistance programs (PAPs).

On Nov. 7, 2005, the OIG issued a Special Advisory Bulletin providing guidance for pharmaceutical companies sponsoring PAPs for new Medicare enrollees. As of Jan. 1, 2006, Medicare beneficiaries who enroll in Part D will no longer qualify under traditional PAP eligibility criteria.

According to the bulletin, OIG supports efforts of charitable organizations and others to assist financially needy beneficiaries, as long as the assistance is provided in a manner that does not run afoul of the federal antikickback statute or other laws. Cost-sharing subsidies provided by bona fide, independent charities unaffiliated with pharmaceutical manufacturers should not raise antikickback concerns, even if the charities receive manufacturer contributions. The bulletin warns that PAPs could risk violating fraud and abuse laws if they subsidize only their own products that are reimbursed by the Part D prescription program.

The bulletin also warns that PAPs that provide cost-sharing subsidies to beneficiaries enrolled in Part D would raise concerns that these subsidies would be used to help Part D enrollees meet the $3,630 true out-of-pocket expense limits, while increasing the number of patients using their own products.

"Before the passage of MMA, OIG had very little interest in PAPs that provided heavily discounted or free drugs directly to uninsured patients because there were no federal dollars involved," says Larry Olson, director of MMA studies at GfK Market Measures. "To minimize fraud risk, pharmaceutical manufacturers need to establish procedures to verify whether existing recipients of PAPs have enrolled in a Part D plan and to transition Part D enrollees to nonpharmaceutical-sponsored PAPs."

The OIG bulletin did conclude that lawful avenues exist for pharmaceutical manufacturers and others to help ensure that all Part D beneficiaries can afford medically necessary drugs. This creates an opening for disease-specific nonprofit organizations, according to Robert N. Falk, counsel and healthcare special matters and investigations at Powell Goldstein.

"In this bulletin, OIG takes unusual pains to describe how manufacturers can continue to provide support to patients still in need," he says. "In light of this issuance, we believe that manufacturers should be quite receptive to outreach from disease-specific nonprofits interested in developing programs to serve patients who may be covered by Medicare Part D but still need financial assistance. Further, without a replacement vehicle, patients currently benefiting from PAPs may find themselves without the financial assistance they need to afford their drugs. In this environment we anticipate that new partnerships between nonprofits and manufacturers are likely to form."

According to Verispan, of the 42 million Americans age 65 and older, about 14.4 million, or one-third, have incomes lower than 150% of the federal poverty level. These patients, many of whom are enrolled in PAPs, will no longer be eligible for free drugs.

The transition of lower-income seniors to Medicare prescription drug coverage programs is a public-health challenge for MMA plan administrators and pharmaceutical companies. According to Verispan, understanding how millions of patients in PAPs are receiving their medications after Jan. 1, 2006, is key. For pharmaceutical companies, the over-65 population is of particular interest since this group spends nearly four times as much on personal healthcare compared with the rest of the population and as of Jan. 1, they all have prescription coverage. Verispan has recommended that pharmaceutical companies measure the over-65 patient population by income and brand use for patients in and out of PAPs.

According to Warren Levy, chief strategy officer and senior VP at Vox Medica, the biggest question with respect to PAPs now is an opportunity question.

"A huge portion of the population that was served by PAPs no longer will be served, and companies now need to look at the role of PAPs going forward as an opportunity," he says. "PAPs were always an unusual innovation. There aren't that many businesses, if any, that were as helpful to people who couldn't afford products. It was a farsighted approach to begin with, and companies now are looking at what the next generation of PAPs will be."

Sources:
Robert N. Falk, Counsel, Healthcare Special Matters and Investigations, at Powell Goldstein, Washington, D.C. For more information, visit pogolaw.com.
Warren C. Levy, Chief Strategy Officer, Senior VP, Vox Medica, Philadelphia. For more information, visit voxmedica.com.
Office of The Inspector General, Special Advisory Bulletin: Patient Assistance Programs for Medicare Part D, Nov. 7, 2005. For more information, visit oig.hhs.gov.
Larry Olson, Director of MMA Studies, GfK Market Measures, Blue Bell, Pa. For more information, visit gfkmarketmeasures.com.
Verispan, Yardley, Pa. For more information, visit verispan.com.

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analysis. Key questions that need to be addressed include: Who are the key stakeholders — MCOs, PBMs, physicians, beneficiaries, pharmacists; what does the flow of money, products, and services look like; what are the perspectives, roles, and motivations of the different stakeholders; and what tactics and messages are most appropriate for positively influencing the various stakeholders?

DEZELAN. We don't position products separately in Medicare Part D. We are focused on education awareness and understanding Medicare Part D and assisting our existing patients who are eligible with the transition.

37% of U.S. adults 65 years old and older plan to enroll in Medicare Part D.

Source: Manhattan Research

THOMAS. Medicare Part D called attention to a different mix of customers. Everyone knows that the 65 and older age group has higher product use than any other age bracket, but up until this point efforts addressing this patient population weren't there for a majority of products impacting this demographic. It is now imperative that all mar-

Sound Bites from the Field

NEARLY HALF OF THE CMS-APPROVED MEDICARE PART D PLAN SPONSORS PARTICIPATING IN A GFK STUDY INDICATED THEY MAY WELCOME SOME PHARMA MANUFACTURER SUPPORT IN HELPING SENIORS NAVIGATE PART D IN THE FORM OF GENERAL, STRICTLY OBJECTIVE EDUCATIONAL EFFORTS. PHARMAVOICE ASKED INDUSTRY EXPERTS WHAT CAN PHARMA COMPANIES DO TO REACH OUT TO ELDERLY CONSUMERS WITH INFORMATION ABOUT MEDICARE PART D?

JILL BALDERSON is VP of Strategic Marketing for HealthEd, Clark, N.J., which develops patient-education programs for pharmaceutical and healthcare marketers. For more information, visit healthed.com.

"From the consumer's perspective, receiving information is only a small part of the Part D challenge. Part D information now appears in supermarkets, senior centers, pharmacies, physicians' offices, senior-targeted publications, and on the Internet. It's much more difficult for consumers to take the next step — assemble details about their own prescriptions, what they are, how much they really cost, and then do the math to understand the impact Part D participation will have on monthly cash flow. Once they've chosen and enrolled in a plan, many seniors will need additional help on an ongoing basis to manage their benefits and costs, which may vary month to month. Pharma could help in a number of ways, including developing educational materials and training for community-based Part D counselors and supporting dedicated counseling providers in much the same way they support other patient-advocacy and support organizations."

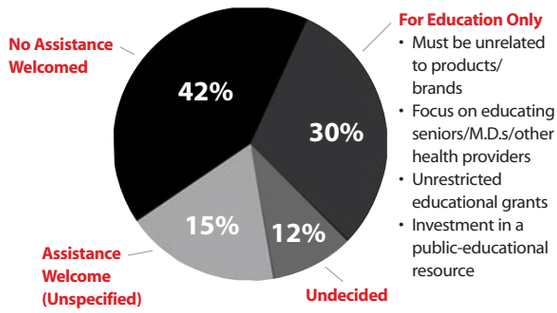
NEIL B. KRUGMAN is a Partner at Waller Lansden Dortch & Davis Nashville, Tenn., a law firm whose clients include public and private corporations, government agencies, and business enterprises in the United States. For more information, visit wallerlaw.com.

"Pharma manufacturers' support of educational efforts targeted toward seniors who still haven't enrolled in the program would be meaningful, of course. But I'm not sure that more 'objective educational efforts' are the only keys to increasing the drug program's success. Certainly there's a group that still needs basic education about the program, but I suspect there are a lot of folks who are familiar with the program basics but hesitant about enrolling because of confusion over which plan has the best coverage of the drugs important to them. If I'm, or my doctor is, loyal to a specific drug, I want to know which PDPs and MA-PDs in my locale have that drug in their formulary and how much I'm going to have to pay for that drug in Plan A versus Plan B versus Plan C. The pharmacy chains and drug-benefit plan sponsors already have some of this information on their Websites, but it is organized a little differently. And some pharmaceutical manufacturers may already be doing a good job of providing such information to the public.

In general I've been surprised how difficult it is to glean this information from the pharma manufacturers' Websites. In other words, people need help in sifting through the welter of objective educational information already out there to find the plan that is subjectively right for them. I'd like to see the pharma manufacturers do a better job of providing this sort of specific, practical information about their drugs, even if it could be considered to be in their self interest. In the long run, I think this information is apt to have a more positive impact on the program's chances for success than helping to underwrite 'objective educational' public seminar No. 65,001."

JOHN MCCREEDY is Executive VP of DestinationRx, San Francisco, a software and services firm focused on the pharmacy

CIRCUMSTANCES UNDER WHICH MCOS WOULD WELCOME ASSISTANCE FROM MANUFACTURERS FOR PART D



Source: GfK Market Measures, Blue Bell, Pa.
For more information, visit gfkmarketmeasures.com.

keters understand the 65 years old and older age group, are able to segment this group based on the product portfolio, and understand the use of prescription products within this area. The utilization is as much as 50% of total drug usage in the United States among this patient population; the pricing associated with that much volume can dramatically impact a company's financial results.

sector that specializes in designing, developing, and implementing CDH solutions for government and commercial clients. For more information, visit destinationrx.com.

"The first step is to support all organizations that work with seniors to make sure they understand the value of consumerism as it relates to price and selection of drugs, including organizations such as NCOA and the Coalition to Advance Prescription Drug Education. Physicians should not be put in the position of having to explain the Part D benefit. For example, CARxE, The California Medical Association, and The California Hospital Association have launched a statewide program where volunteers can help patients get a clear idea of their needs and then make the information available to the provider staff for confirmation or consultation before the beneficiary enrolls in a plan."

STAN NOWAK is President and CEO of Silverlink, Burlington, Mass., a provider of personalized voice solutions for client communication focused on the healthcare market. For more information, visit silverlink.com.

"It's clear that the solution to senior confusion about Part D is not more information, but the right information delivered at the right time, in digestible increments. I think there are several opportunities for pharma companies to contribute to that effort. On a small scale, pharma companies could be sponsoring events, led by leaders of local senior communities, to educate seniors and help guide them through program decisions. To reach more seniors, a simple solution would be to provide funds to PDPs and MA-PDs that are engaged in productive outreach and communication. Another idea would be to help develop and support effective MTM and adherence programs for different drug and disease categories. The goal should not be to dump more Part D information out there, but rather give seniors the information they need to make smart decisions."

OLSON. Pharmaceutical brand managers need to develop a detailed understanding of how specific products will be impacted by Medicare Part D. Brand managers who are carefully segmenting and profiling the Medicare population will be able to effectively align and position their products with the unique requirements of each segment. With the prevalent use of USP guidelines by Part D sponsors in designing their formulary structures, participating managed-care organizations need only offer two drugs, including generics, per therapeutic class, creating fierce competition for preferred formulary status. Therefore, other than just price, brands need to be positioned in alignment with strong evidenced-based outcomes, demonstrating their long-term cost effectiveness to support their products' Part D value proposition. Brands need Part D-specific value propositions, positioning, and messaging.

SPENCER. We have witnessed a range of issues challenging manufacturers seeking Part D coverage of their products depending on the category of the product and the cost of the product. The CMS "all or substantially all" guidance is a very controversial guidance that identifies six categories of drugs, including anticancer drugs, in which all of the products in that group, unless they are included in the exclusion list found in the guidance, must be included on the formularies for all plans. As a manufacturer wanting to ensure access under Medicare Part D to its products, if the drug at issue fits in one of those six categories it is obviously very good because the plan has no choice in whether to include the drug in its formulary. Importantly, that guidance is only good for a year; but if a company can fit its products within that guidance, that is a good way to go. Brand teams that handle drugs in one of those six categories are in good shape. For other brand teams, getting on formulary is still a key issue, especially if there are pharmaceutical drug equivalents to the products they are handling.

64% of consumers who make healthcare decisions for an adult plan to enroll that adult in a Medicare Part D plan.

Source: Manhattan Research

FARINO. A big issue for marketing organizations right now is understanding how CMS is going to manage the program going forward. It is pretty clear that CMS understands that cost-effectiveness of care is something that it will need to consider long term for this program to be viable to the government. This has

JEFFREY THOMAS
VENTIV ACCESS SERVICES

Companies need to be absolutely transparent in their contract negotiations with the government, and that includes any rebates, chargebacks, or any type of discounts that may be given to a particular customer.

implications to companies in terms of how they position their products and what types of marketing strategies they develop for their products. It also will have an impact on drug development in terms of understanding how the product is going to be developed and labeled, because long term, if the program works for CMS, it will spill over to the private markets also. This is not going to happen in the next 24 months, but over time pharmaceutical companies are going to be pressed hard to demonstrate cost-effectiveness and understand how customers use their products. Pharmaceutical manufacturers will have to work more effectively in terms of finding products that contribute to their customers' end goals, whether their customers are providers, physicians, or payers.

Changing Strategies

Pharmaceutical companies are reshaping their marketing strategies because of Medicare Part D and will need to continue to refine these plans as

PharmaVOICE Reader Survey: Medicare Part D

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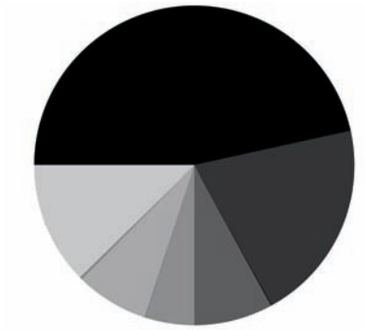
COMPLEXITY OF MEDICARE PART D CONTRACTS THAT ARE BEING PLANNED AND IMPLEMENTED:

- **24.3%** Less complex than current managed-care contracts
- **24.3%** As complex as current managed-care contracts
- **16.2%** More complex than current managed-care contracts
- **35.1%** Don't know at this point

WHAT IS THE LIKELIHOOD THAT MMA PART D WILL AFFECT VARIOUS OTHER AREAS OF YOUR PRODUCTS' BUSINESS?

	Not Likely	Somewhat Likely	Likely	Very Likely	Extremely Likely
MANAGED CARE	23%	10%	26%	29%	13%
FSS AND OTHER GOVERNMENT PRICING PROGRAMS (I.E. PHS)	32%	26%	19%	19%	3%
MEDICAID AND STATE SUPPLEMENTS	19%	13%	29%	35%	10%

WITH THE POSSIBILITY OF DUAL OR EVEN TRIPLE ELIGIBLE PATIENTS UNDER STATE ASSISTANCE, MEDICARE, AND/OR MEDICAID, HOW CONFIDENT ARE YOU ABOUT AVOIDING DOUBLE OR TRIPLE DIPPING ON REBATES?

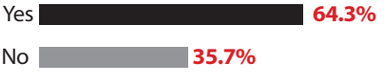


- **47.1%** Somewhat confident
- **23.5%** Not confident at all
- **5.9%** Confident
- **2.9%** Very confident
- **5.9%** Extremely confident
- **14.7%** Don't know

IN 2007, WHAT CHANGES DO YOU ANTICIPATE REGARDING PRESCRIPTION DRUG PROGRAMS?

- **36.7%** Consolidate/fewer plans
- **20%** Visible impact to commercial managed care
- **16.7%** Remain stable/similar to 2006
- **16.7%** Increase in complexity of deal structure
- **10%** Other

ARE THE CHANGES IN MEDICARE FORCING YOU TO RE-EVALUATE YOUR COMMERCIAL AND GOVERNMENT CONTRACTING SYSTEMS?



more information about the market becomes available.

FARINO. Information about the customer, the products, how the products are used in the customer setting, and what is driving use is going to become even more critical. CMS is going be gathering a lot of information on products and care under Part D. Payers, PBMs, and PDPs are going to be required to provide CMS with a lot of information, and marketing organizations are going to have to be up to speed on what the information shows and be able to adapt to it.

OLSON. As Medicare beneficiaries enroll in Part D, pharmaceutical company marketers need to continue developing and refining their targeted messaging strategies to this unique population. Part D is providing drug manufacturers with a solid opportunity to partner with physicians and pharmacists to help seniors understand the benefits of enrolling in the program. Comprehensive outreach programs to seniors via their family members and caregivers, as well as through patient-advocacy groups, need to be developed. Knowing that seniors, and even their physicians, continue to remain confused and need information, drug makers can provide both general and plan-specific information to these critical stakeholders. In the months ahead, there are solid opportunities to build increased awareness among those Medicare beneficiaries who have not yet enrolled in Part D and educate eligible patients about how to qualify for access to their prescription medications. It should be kept in mind that seniors are, on average, far more cost conscious than other age groups.

DEZELAN. While we are not reshaping our marketing strategies in the near term, we recognize the growing importance of public payers such as CMS and state Medicaid programs.

THOMAS. It has become necessary for companies to pay particularly close attention to the 65 year old and older patient population, as well as the long-term care segment. It's important for marketers to address a number of areas, such as: different types of patient-education programs that make it easier for these groups to understand what they are taking; outcomes specific to particular products linked to this patient population; and compliance and persistency issues within this group of patients. Older patients require different considerations, which now, more than ever, are being brought to light. Most of these issues have been managed in some general terms but

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TONY FARINO
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Part D is going to have a far-reaching impact on how products are used in the marketplace, how the cost and effectiveness of care are viewed, how drugs are developed, and how drugs are marketed.

haven't been specifically identified relative to the geriatric segment.

SPENCER. While marketing guidances have been issued by CMS, it appears that those guidelines do not apply directly to pharma companies. Instead, they only apply directly to Part D plans and their contractors, including contract physicians. But the concepts articulated in the marketing guidelines are definitely instructive for manufacturers because they provide insight into what the government considers fraudulent practices. Plus, they are indirectly applicable whenever a manufacturer develops materials on Part D for physicians. The guidelines make it clear that whatever information is provided under Part D about the benefits offered or which plans are covering what, it is critical that that information be accurate, not misleading, and not contain any material misrepresentations. The information that manufacturers are putting together concerning Part D for physicians or enrollees needs to be carefully structured and compliant at least with core concepts or requirements under the CMS marketing guidelines.

Medicare could boost industry revenue by $20 billion in the next 10 years.

Source: Friedman Billings Ramsey

WINTERTON. At a fundamental level, manufacturers have realized, or are in the process of realizing, that the Part D market is not one cohesive set of 42 million Americans making product selection, compliance, and persistency decisions. This market is comprised of multiple submarkets that include those who were previously Medicaid Dual Eligibles, cash patients, employer groups, Medigap (H,I,J) participants, Medicare - Choice, low income with no coverage previously, and state pharmaceutical assistance program beneficiaries. These populations will likely respond very differently to marketing strategies and programs implemented by pharmaceutical manufacturers aimed at achieving a global response within the Part D market. Manufacturers need to reshape their strategies to optimize the impact within these submarkets while achieving their overall objectives for their Part D business.

BARNETT. To date, many brand teams have focused primarily on contracting with Part D sponsors. While securing formulary access under Part D is critical, there are myriad items that brand teams still need to address from a strategic and tactical perspective. Questions brand teams should be addressing for their products include: What is their unique value proposition and corresponding messaging for physicians and beneficiaries; how can they strengthen their product's value proposition for Part D; what changes to their promotional mix are necessary to optimize performance vis-à-vis Part D; what does the Medicare population look like for their product category, and how can they effectively promote to this customer base; and what tactics, programs, and materials will be required to be successful under Part D?

Best Practices

As companies develop their marketing strategies, experts interviewed for this Forum offer their best practices for positioning products for this evolving segment.

OLSON. First, companies must consider the difference between a MA-PD and a stand-alone prescription-drug plan. Each has different perspectives and priorities. MA-PDs are responsible for both the medical and pharmacy benefits, and they are more involved with overall patient outcomes and the value that pharmaceuticals can provide. Stand-alone PDPs manage only the pharmacy side and are utilization-management driven. As part of the Part D drug benefit, MCOs will have increased influence over drug use and pricing, with more lives under coverage and controlling incrementally more volume per beneficiary. This dynamic will continue to add more elasticity of demand to the pharmaceutical market as consumers will make more rational decisions in their consumption of drugs. An important marketing strategy to consider is supporting MCO Part D sponsors as they are required by CMS to develop and implement their medication therapy management programs (MTMPs). These MTMPs are intended to improve patient outcomes, especially for chronic and complex diseases such as diabetes that typically carry a host of concomitant medical conditions.

Medicare could boost industry earnings by $4 billion in the next 10 years.

Source: Friedman Billings Ramsey

DEZELAN. Generally, the biggest hurdle we face is educating patients on how to enroll and get answers to common questions they may have. With any new program of this scale and size, there are bound to be initial hurdles that we can help to mitigate. We are trying to educate patients on how they can get access to Medicare Part D information. It is important to understand the patient population. Most of the advertising and education in the marketplace is focused on seniors. The majority of patients in our therapeutic areas are disabled, so we've developed segmented marketing and educational programs focused specifically on multiple sclerosis and AIDS patients and providers. Our goal is to help patients transition smoothly to Medicare Part D.

SPENCER. When marketing directly to the PDPs, one thing manufacturers have to be careful of is making sure the information they are providing on their product is accurate and complete. If it is not, there could be potential liability where coverage is secured when it was clinically inappropriate.

THOMAS. This area is evolving right now as people try to understand how to position their products within the PDPs and what they need to do relative to meeting the needs of the PDPs, which are going to be more patient-outcome-based and require more patient edu-

cation at a level that seniors can understand. A thorough understanding of the differences between a PDP and MA are critical to the short- and long-term success of a strategy. The responsibilities and cost variances between managing just the pharmaceutical product, on the one hand, versus the Rx/medical benefit combined, on the other hand, are substantial.

BARNETT. Much of the interaction that pharma companies have had with PDPs and MA-PDs around Part D has been focused on contracting for 2006 Part D formularies. When developing a marketing strategy for Part D sponsors, it is critical to understand the different perspectives and motivations of PDPs versus MA-PDs. While MA-PDs are responsible for the medical and pharmacy benefit for their enrolled Medicare beneficiaries, PDPs are only responsible for the pharmacy benefit. This difference has important implications for the value proposition and the corresponding positioning and messaging for these customers. Given their sole focus on the pharmacy benefit, PDPs are likely to be much less interested in any offset in medical costs that pharmaceuticals can provide. In contrast, MA-PDs are likely to be much more receptive to the broader value proposition that branded pharmaceuticals can provide, such as using pharmaceuticals to improve outcomes in patients subsequently results in a decrease in medical benefit costs. The relationships between MCOs, PBMs, and pharma companies are shifting under Part D as the parties begin to interact across two different books of business — Medicare Part D and commercial managed care. Thus, companies need to determine the implications of these changing dynamics and make appropriate adjustments in their approaches to marketing and selling to MCOs and PBMs.

ZOCCHI. Marketing partnerships are already emerging between plan sponsors and perceived trusted advisors for seniors, such as plan affiliations with seniors' organizations and retail pharmacy chains. Seniors are faced with a daunting amount of information and an equally large set of choices, so marketing strategies built upon reference-based or trusted referrals emerge as potentially strong components of a marketing mix for plan sponsors.

WINTERTON. There has been a real mix of direct and indirect marketing strategies aimed at, first educating then securing the Part D-eligible senior. But certain facts still remain: the Medicare program is a large, complex system that is undergoing substantial changes; there is a significant amount of confusion on the part of seniors regarding the Part D benefit and which plan is right for them; there are

MARKETING STRATEGIES UNDER PART D

THERE CONTINUE TO BE SIGNIFICANT CHALLENGES TO GAINING A CLEAR UNDERSTANDING OF EFFECTIVE PART D MARKETING STRATEGIES.

CHIEF AMONG THESE ARE THE FOLLOWING THREE AREAS:

- **TIMING OF INCOMING CLAIMS.** Part D rebate claims are likely to just be arriving in the May to June time frame. These claims are likely to be incomplete in many cases and may be adjusted later by plans once updated information is made available. Experience has shown that during program start up, the information trickles in at first and then, over time, ramps up to the appropriate levels.
- **START-UP LOGISTICS.** There have been implementation snags along the way with Medicaid dual eligibles, SPAP programs, employer groups, and general confusion on the part of the Medicare recipients. Gov. Ed Rendell (PA) felt the need to pay for certain Medicaid Dual Eligible prescriptions in his state because of the problems implementing the new Part D benefit.
- **INFORMATION DELAYS.** There are built-in delays to the structure of the program because of components, such as Medicaid, that bill claims based on reimbursement dates, not dispensing dates. The first-quarter 2006 Medicaid claims will start arriving by June, and they will contain numerous claims for products dispensed during 2005, before the new benefit kicked in. The claims may also be higher or lower than expected due to some of the implementation problems noted above.

IN THE MIDST OF THIS CHAOS, MANUFACTURERS MUST ACCURATELY ASSESS THE PART D OPPORTUNITY AND MEASURE HOW EFFECTIVELY THEIR STRATEGIES ARE REALIZING THE OPPORTUNITY.

THE FOLLOWING THREE SHORT-TERM FACTORS SHOULD BE CONSIDERED DURING THIS OPPORTUNITY ASSESSMENT:

- **THE BREADTH AND DEPTH OF COVERED LIVES CONTROLLED BY THE VARIOUS DRUG PLANS.** Presumably, tighter controls could be garnered by fewer PDPs with deeper numbers of lives in their plans. Whether the industry can sustain more than 500 PDPs nationwide will influence the potential for additional bargaining power they will have with pharmaceutical manufacturers.
- **OBSERVED CHANGES IN BEHAVIORS BY THE VARIOUS SEGMENTS MIGRATING INTO PART D.** It is important to note how seniors' selection and tendency to use prescription drugs will change as a result of the Part D benefit. These changes will likely be influenced by the segment they were in before the Part D benefit.
- **THE LEVEL OF MIGRATION TO PART D FOR EACH OF THE VARIOUS SEGMENTS.** This will determine both the potential for Part D strategies and the product profit and loss trade offs that are being made in the Part D market.

OVER THE LONGER TERM ADDITIONAL ITEMS SHOULD BE CONSIDERED IN SHAPING A PART D STRATEGY:

- **THE TOTAL COST OF THE PART D BENEFIT.** If the costs spiral out of control, it is likely that more controls will need to be placed on the program. Predicting the long-term costs of a start-up program this complex is a daunting task. When the Medicaid program first started, the early predictions of rebates to be paid were dramatically underpredicted based on the start-up phase.
- **HOW EMPLOYER GROUPS WILL CHOOSE TO PARTICIPATE BEYOND 2006.** Currently, employer groups have shown a clear preference for retaining their membership in the short term where more traditional managed-care controls have helped keep their cost structures down. The rate at which lives move from employer groups to PDPs will have a strong influence on the negotiating power of both managed-care and Part D providers.
- **OTHER FACTORS TO BE CONSIDERED.** Over time, things will become known that are unknown now. These factors include the future level of subsidies, the amount of control the Part D providers have, the response of the marketplace to the program, etc. All of these data points will form the mosaic of future marketing strategies.

Source: Joel Winterton, SET Enterprises, Phoenix.
For more information, e-mail joelwset@aol.com.

WARREN LEVY
VOX MEDICA

Medicare Part D is acting as a catalyst for change, and beyond 2006 the risk/opportunity equation is mostly about the enterprise, not the individual brand.

Pharma companies are re-engineering their marketing practices, which have traditionally been focused at intermediaries.

JOEL WINTERTON
SET ENTERPRISES

Manufacturers need to prepare and protect themselves on multiple fronts when working within the confines of Medicare Part D.

counter-marketing efforts from employer groups to retain beneficiaries in their plans, threatening loss of all medical benefits if seniors sign up for a separate PDP sponsor; seniors typically don't possess the information or desire to discern the myriad plan options, more than 500 nationally and more than 60 options in many states; and seniors will respond differently to marketing practices based on their current coverage. These and other factors must be considered by plan sponsors when developing their marketing practices and products. Essentially, Part D sponsors will need to customize their educational and promotional programs for Part D recipients based on the recipient's receptivity, knowledge base, and level of engagement in the process.

Rebates, or discounts, are expected to increase as a result of Medicare Part D by 5% to 10%.

Source: PricewaterhouseCoopers LLP

FARINO. In addition to being very attentive to the compliance risks, companies should have an administrative infrastructure behind these contracts as well as assess whether they are paying the right amount in rebates.

Working Together

Plan sponsors will look to educate and promote to seniors through a mix of advertising channels, as well as through personalized communications.

OLSON. The push to build critical mass for Part D membership by MA-PD and PDP sponsors has been aggressive since the enrollment period began Nov. 15, 2005. Large managed-care organizations, in particular, have developed and implemented highly targeted direct-to-Medicare patient communications campaigns. Lately there has been a more refined shift to target Medicare patients' family members and caregivers to motivate these significant influencers to become involved in the enrollment decision-making process. Plan sponsors, such as United Healthcare and Humana, also have entered into comarketing arrangements with large retail pharmacy chains, such as CVS and Walgreens, and effected cobranding deals with such national organizations as AARP, making registration in their Part D plans easier for seniors. Recent research has shown that MCOs would welcome unrestricted educational grants or support of public information campaigns as favorable forms of assistance from manufacturers, in addition to their direct development of objective educational initiatives.

THOMAS. Some carriers have put together education programs for the physicians, office staffs, and pharmacists — the primary intermediaries for patients and the people who seniors and caregivers would go to for information. It is in a sponsor's best interest to make sure patients understand what is available to them, how to access information, and how to best use their money relative to the benefit they are receiving. Medicare has always been individual versus a group scenario. In certain instances, this will require some companies to recraft their messages and strategies because of this shift in the payer mix.

LEVY. Pharma companies and sponsors in many ways have to be partners in developing these communications. I don't think that we have thought through the best ways to approach patient communications, which right now are enormously fragmented. If there are going to be real breakthroughs in communications, particularly around Medicare Part D, they are going to come from collaborations. We need to figure out how to get integrated, helpful information to patients that gives them the best capability to make decisions. The most impactful communications occur between patient and physician, and neither the plan sponsors nor the pharmaceutical companies are maximizing this patient-physician interaction. It will be more efficient and effective if plan sponsors, pharmaceutical companies, device manufacturers, various advocacy groups, and so forth work collaboratively to assist patients and physicians. ✦

Medicare Part D is expected to cost the government $724 billion over the next 10 years.

Source: PricewaterhouseCoopers LLP

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