BY DENISE MYSHKO

MEDICARE PART D

A Positive Return

INDUSTRY EXPERTS EVALUATE THE IMPACT OF MEDICARE PART D ON BENEFICIARIES and the pharmaceutical industry and project what further market shaping events are to come.

For consumers, the implementation of Medicare Part D has mostly been positive — reduced out-of-pocket costs and improved access to medicines.

According to a study by The Amundsen Group Inc. based on prescription data provided by Verispan, seniors who lacked prescription drug insurance in 2005 reduced their daily, per dose, out-of-pocket costs by more than two-thirds (69%).

At the same time, access to medicines improved. The number of prescriptions filled each month — both brand and generic — increased from 1.7 in 2005 to 3.3 in 2006. The Amundsen analysis also found that the total monthly out-of-pocket cost of medicine for these seniors declined by an average of 45% in 2006.

The study found that the savings and improvements in access were even more significant for low-income seniors receiving an enhanced Part D benefit. These seniors reduced their average monthly out-of-pocket costs by 75% — from $41 per month in 2005 to $10 per month in 2006.

According to research from GfK Market Measures, patients find that obtaining their prescriptions is now fairly easy and that participating in a Part D plan is helping them afford their medications.

Additional results reveal that the reputation of the health plan, including whether a physician or pharmacist recommended it, the number of medications covered by the plan that a patient takes, the monthly premium and copay amounts are the top priorities in patient selection and satisfaction with a Part D plan.

"The overall impact of Part D has been positive in many ways," says Bob Jansen, VP of managed markets, Wolters Kluwer Health. "More patients now have access to prescription drug coverage than in the past and typically at greater benefits. For example, more Medicaid dual eligible patients are rolling over to Part D. Additionally, there's greater access to a greater variety of medications because of CMS's review of drug formularies and minimum standards for formulary coverage and, lastly, there is a movement of use going from Medicaid to Medicare, which offers greater profit potential for pharma."

CHARLES STEVENS
Parexel

AS PART D MATURES, THE INDUSTRY WILL HAVE TO RECOGNIZE THAT IT NEEDS TO ADOPT NEW STRATEGIES and transform business models to ensure that products will continue to be made available to beneficiaries under Part D.

UPS AND DOWNS

Mitigating some of the positive results in 2007 are findings from a recent study by Avalere Health, which predicts that if consumers remain in their current Medicare prescription drug plans the average beneficiary will experience a 21% increase in his or her monthly premiums for 2008.

"The shift in premiums from year to year reflects a close calibration by the plan sponsors to maintain customer loyalty, remain competitively priced, and achieve profitability," says Bob Atlas, senior VP of Avalere Health.

On the whole, experts say Medicare Part D is having a positive impact on the pharmaceutical industry, and overall there will be continued benefits as more and more seniors move to a Part D plan and continued access is provided.

One downside, Mr. Jansen says, is that employers are expected to continue to move from the Retiree Drug Subsidy (RDS) to a straight Part D benefit, which may negatively impact pharmaceutical companies through a reduction in benefit coverage from the self-insured retiree sector.

"Another potential downside would be the evolution of the contracting piece from MCOs to the federal government," he says. "The federal government would become the largest payer of prescription medications overnight and be able to wield enormous influence over rebates and pricing. There is an area of opportunity for both pharma companies and healthcare providers regarding patient compliance through the donut hole phase for standard eligible patients."

Contracting will become progressively more difficult with increasing pressure to lower costs, agrees Richard DeSimone, cofounder, director, and chief financial officer of EKR Therapeutics Inc.

"Medicare Part D is the predecessor of a much larger and comprehensive government-centric payer system in the United States," Mr. DeSimone says. "With political momentum in the United States accelerating toward more government intervention in the healthcare system and demographics trending toward more Medicare roles, Medicare Part D provides a view to the future of the payer model."

Mr. Jansen says the contracting environment will continue to migrate to tighter controls as more data become available on the Part D plans, product status within Part D plans, and the ability of Part D plans to demonstrate movement for various pharmaceutical brand products.

"In addition to greater data review, the Part D plans will also expect higher discounts as their costs continue to increase and as consolidation in the market starts," he says. "The product choices, while monitored by CMS, will probably narrow and the utilization management controls will continue to increase through the pharmacy claim adjudication process. Controls such as step therapy, for example the required use of simvastatin before Lipitor is authorized, may become more common as generic prod-

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ucts reach the market. As a result, pharma companies will need to assess different contracting strategies to address the increase in POS processes to ensure accessibility to their products."

AS MEDICARE MATURES

The pharmaceutical industry has benefited from the implementation of Part D, since it has greatly expanded Medicare beneficiary access to needed medications, says Charles A. Stevens, VP and general manager, health policy and strategic reimbursement services, at Parexel International Corp.

"As Medicare Part D matures, the industry will have to recognize that it needs to adopt new strategies and transform business models to ensure that products will continue to be made available to beneficiaries under Part D," he says.

But Keith Mandia, senior director, managed care product management, at Verispan, says the generic erosion of branded market share in Part D is happening much more quickly than in the commercial third-party stream.

"When looking at de-identified longitudinal patient data, regardless of whether the patient is continuing on the same therapy, switching to another therapy, or naive to the therapeutic category, Part D patients are more likely to fill a generic than commercial third-party or Medicaid patients," he says.

Mr. Jansen says as with managed care in the early 1990s, some utilization controls are being implemented, which could limit a brand's opportunities unless the benefits can be clearly differentiable.

"Branded products must deliver a clear value proposition to the physicians, patients, and payers," he says. "As payers evaluate options, the keys to brand differentiation will be in clinical outcomes, patient access, physician value, and the cost-value equation. Pharmaceutical companies are spending significant resources to understand what happens to patients who enter the donut hole coverage gap. What is refreshing is that these companies are taking a proactive approach to understanding this subset of patients to assess ways to help seniors maintain continuity of care and quality of life, even as they struggle to overcome the financial burden of the donut hole. That said, I think overall the impact of Medicare Part D will continue to be positive as the most needy populations will receive valuable medications."

Mr. DeSimone says the desire of the industry to focus on healthcare outcomes will compete with the government-led payer objective to lower costs.

"State Medicaid programs and other government-run payer systems, facing increased costs, will continue to push toward generic drugs, and pharmaceutical companies will have more difficulty achieving formulary wins, and patients will face a more complicated challenge obtaining coverage for their products," he says.

Mr. Mandia says in some high-volume markets the generic utilization rate is greater than 10 percentage points between Part D prescriptions compared with commercial third-party payers, and that essentially, Part D has quickened generic impact on branded performance.

"Although more likely to take a generic medication, Part D patients appear to be more persistent — length of time on therapy — than commercial third-party patients," he says. "We have seen data that show naive voluntary and subsidy-eligible patients are staying on medications longer than naive commercial third-party patients."

Mr. Mandia says a Verispan primary research study conducted in 2007 suggests that some pharmacy directors and managed care executives are going to be noticeably tougher in their Part D contracting with manufacturers than with their commercial books of business, but that plans will also be firmer with pull-through and utilization management.

"In reality, some utilization management techniques will be much more effective in voluntary patients than in the subsidy-eligible population, because subsidized Part D patients have less price sensitivity because of their low co-pays," Mr. Mandia says. "An interesting side note in our primary research was that 60% of managed care executives were unsure whether the coverage gap impacted compliance of their company's Part D members."

A study by Wolters Kluwer Health looked at the impact of the donut hole gap in coverage in the first year of Medicare Part D.

Wolters Kluwer Health estimates that a total of 32%, or 4.2 million, Medicare Part D standard eligible patients entered the donut hole by the end of 2006. The study found that generic use was much higher in the Medicare Part D population versus the commercial population.

Patients appeared to pick and choose brands, perhaps based on their loyalty to the brand or those therapies that they perceive are most important to them. Of the top 10 most prescribed therapeutic classes, therapies where patients were least likely to drop or switch to a generic were beta blockers, thyroid hormones, and diabetes.

Categories where enrollees were most apt to discontinue or switch include anti-ulcerants

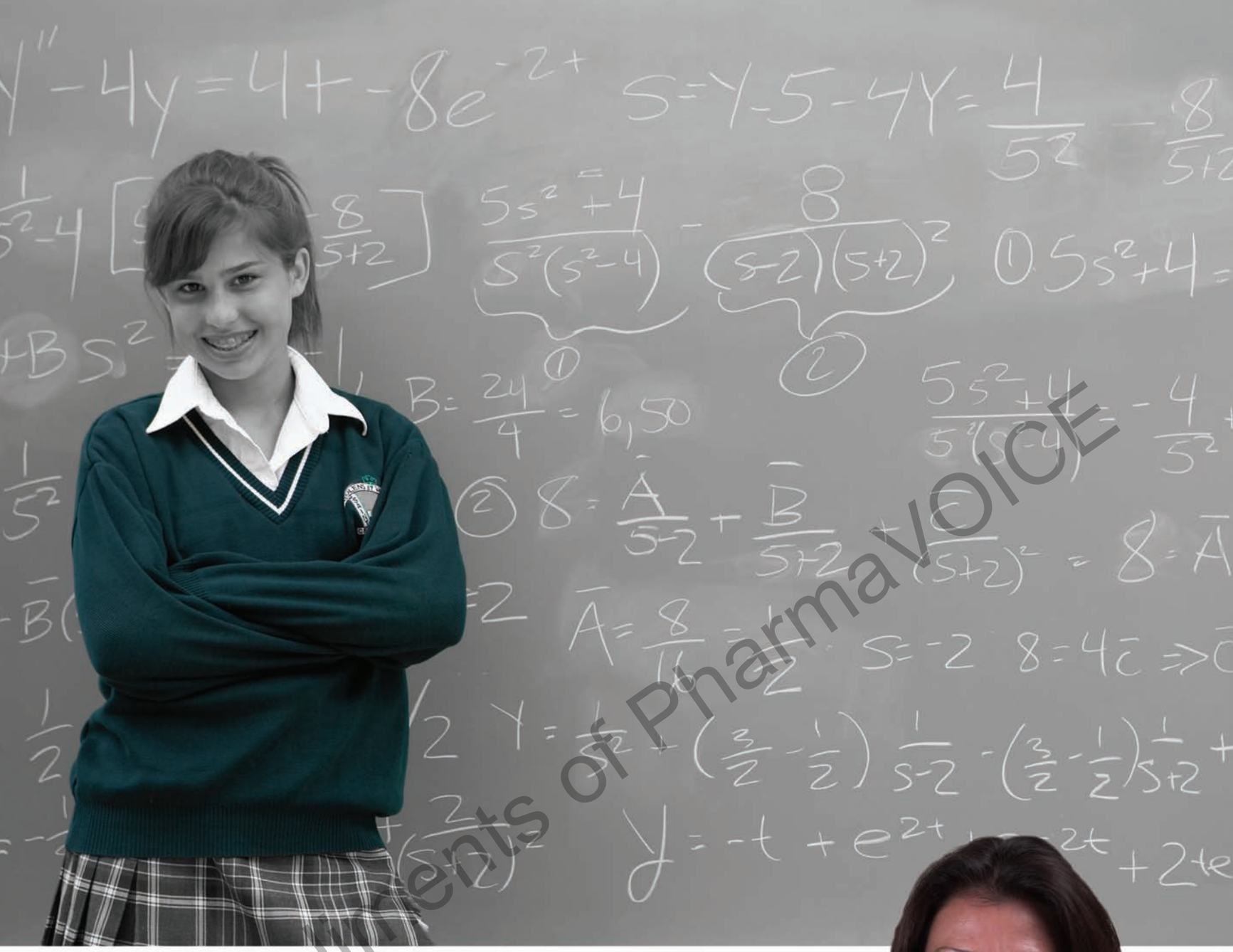
KEITH MANDIA
Verispan

IN SOME HIGH-VOLUME MARKETS THE GENERIC UTILIZATION RATE IS GREATER THAN 10 PERCENTAGE POINTS between Part D prescriptions compared with commercial third-party payers.

Prescription Drug Plans

- The top 10 prescription drug plan (PDP) sponsors in Medicare have more than 80% of the people enrolled in stand-alone PDPs.
- Among those top 10 plan sponsors, all have raised their premiums, with the exception of two: CVS Caremark's SilverScript plan and First Health's Part D Premier plan.
- Based on Avalere's enrollment-weighted premium methodology, the Humana PDP Standard (currently with the second-highest enrollment) raised its premium an average of 69%.
- The largest increase — 89% — is in United's Medicare Rx AARP Plan-Saver PDP, which as of July 2007 had more than 900,000 enrollees.

Source: Avalere Health LLC, Washington, D.C.
For more information, visit avalerehealth.net.



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and diuretics, both of which have over-the-counter treatments available.

Wolters Kluwer experts found that patients did not restart brand medication once their benefits reset in January 2007. If patients had already switched to a generic, they were less likely to switch back to a brand.

A FOCUS ON PHARMACOECONOMICS

The long-term impact of an increasing focus on healthcare outcomes and pharmacoeconomics will mean that the industry must demonstrate product value in new ways, says Parexel's Mr. Stevens.

"This trend will become increasingly important to payers in the U.S. market, just as it has been for many years in European markets," he says. "The industry will need to address these issues very early in a product's development process and clinical-trial design to effectively demonstrate product value to managed market payers."

Mr. Stevens says the key trends to watch in the area of pharmacy benefit management will be managing pharmacy budgets by understanding a product's clinical value, negotiating price concessions, and increasing patient financial obligations for access to certain products.

"Outsourced partners will play an increasingly important role in helping the pharmaceutical industry to realize future success in the area of reimbursement," Mr. Stevens says. "The need for the industry to quickly understand market changes, develop appropriate strategies, and implement workable tactical plans will require a greater reliance on in-depth, global strategic reimbursement expertise to help it compete in an increasingly complex payer landscape."

Richard Leff, M.D., managing partner at Small Dog in the Corner Consulting LLC, says in oncology specifically, the relationship between specialty pharmacies and manufacturers has diminished the importance of pharmacy benefit management in the past few years.

"In oncology, adoption of new oral agents has been slowed," he says. "Because of the pricing of cancer therapeutics, most beneficiaries address the entire $3,600 copay with their first month's prescription. Copay assistance foundations supported by manufacturers have been moderately helpful but have not eliminated physician resistance. Prelaunch comprehensive solutions will be key to maximizing early adoption of new agents."

Dr. Leff predicts that this trend is likely to continue as more high-priced niche oral cancer agents enter the market.

"Benefit management programs designed to guide utilization of high-use agents are less equipped to influence this complex market," Dr. Leff says. "Because each type of cancer presents unique market challenges, it is difficult for outsourced partners to develop sufficient expertise to achieve results attainable with in-house teams."

Lynn Shepherd, senior VP and managed markets practice leader at Vox Medica, says there will be increased pressure on pharmaceutical companies to effectively tell their value story to pharmacy and therapeutics (P&T) committees and influencers.

"The maturing of evidence-based medicine and the momentum toward more shared doctor-patient decision making are important drivers of this changing paradigm," she says. "These trends also point to significant opportunities for pharmaceutical companies to collaborate with clinical and managed care partners on new care delivery models and practical tools that can help facilitate appropriate pharmaceutical care.

LYNN SHEPHERD
Vox Medica

THERE WILL BE INCREASED PRESSURE ON PHARMACEUTICAL COMPANIES TO EFFECTIVELY TELL THEIR VALUE STORY TO P&T COMMITTEES AND INFLUENCERS. The maturing of evidence-based medicine and the momentum toward more shared doctor-patient decision making are important drivers of this changing paradigm.

Medicare Part D: The First Year

- After one year, more than three-quarters of expected enrollees joined a Part D plan, or 23.9 million of the 29.3 million anticipated by The Centers for Medicare & Medicaid Services (CMS).
- More than half, 58%, of Part D beneficiaries previously held some private drug coverage, while 14% previously paid for therapies totally out-of-pocket. Almost a quarter, 24%, had previously received coverage under Medicaid.
- Generic drugs comprise 58% of prescriptions in Part D, compared with 57% of all retail prescriptions.
- The previously uninsured benefited the most from Part D, saving 60% of their previous cost and increasing their use of pharmaceuticals by 26%.
- Among Medicare beneficiaries older than 65 who did not have drug coverage in 2005, a quarter joined a Part D plan in 2006. More than half, 55%, continued with a Part D plan in 2006.
- Under Part D, patient compliance with therapies for chronic conditions increased in 4 out of 5 therapeutic categories.
- Previously uninsured seniors in Part D increased their use of all medications, including both generics and brands, by 26% while their out-of-pocket costs per prescription decreased by 60%.
- Seniors switching from third-party coverage to Part D increased their prescription use by 10%, while their out-of-pocket drug costs decreased by 17%.
- Only 6% of enrollees entered the donut hole, and a sizable portion of those enrollees did so in the final days of the year.

Source: IMS Health, Plymouth Meeting, Pa. For more information, visit imshealth.com.

DR. RICHARD LEFF
Small Dog in the Corner Consulting

IN ONCOLOGY, THE RELATIONSHIP BETWEEN SPECIALTY PHARMACIES AND MANUFACTURERS has diminished the importance of pharmacy benefit management in the past few years.

Whether the initiatives are around reducing medication errors, identifying patients who could benefit from earlier intervention, or mitigating polypharmacy risks in seniors, there is much opportunity to improve quality of life, quality of care, and reduce costs — and to demonstrate the true value of medicines."

Robert G. Paglia, R.Ph., executive VP, director of Sudler & Hennessey Managed Market, says a recent S&H agency survey of pharmacy and medical directors uncovered a few formulary-management trends that will have a significant impact on the pharmaceutical industry in the future.

"We conducted interviews with six key decision makers from large national health plans about orally administered cancer therapies," he says. "We were not surprised to hear their concern about the 'out-of-control' prices being charged for these products. When asked what they were going to do, if anything, to address their concerns, two participants stated that their companies were initiating basic formulary management restrictions. In addition to the prior authorizations already in place, they would only authorize the use of these drugs for labeled indications. This differs significantly from long-established policies that would also authorize use if a medication's indication was listed in one of the major drug compendia."

He says Sudler & Hennessey's primary research, as well as secondary research, has uncovered a growing movement to use the electronic pharmacy-claims systems to further restrict the use of drugs to their labeled indications.

"The electronic system is already set up to accept patient diagnosis codes and programming it to match diagnosis with the labeled indications for each drug would be quick and simple," Mr. Paglia says. "The physician would just have to include the diagnosis code on the patient's paper or electronic prescription for these restrictions to work. This is exactly what is happening in several state Medicaid systems." ✦

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