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PAP Programs Struggle to Plug Healthcare Insurance Gaps

Prescription assistance programs get medicine to some patients, while delivering some image-building benefits to the industry—*By Mike Faden*

LAST MONTH MARKS the third anniversary of the Partnership for Prescription Assistance (PPA), the patient assistance program run by PhRMA to connect needy patients with sources of free or low-cost medicines. Some 4.8 million patients have been assisted by PPA, which pools the individual member-company prescription assistance programs (PAPs) into a coordinated, national effort; according to Ken Johnson, SVP at PhRMA, more than $10 billion worth of pharmaceuticals have been dispensed.

PAPs have been around for years, if not decades, and states and other entities run equivalent assistance programs, although PPA is believed to be the largest private-industry effort. Manufacturers say providing effective PAPs is a matter of corporate responsibility, though there's also the question of how much of the effort is a defensive measure to improve the industry's public image, and to forestall the drive toward expanded universal healthcare coverage, which has become on of the political hot buttons during this election season (*Pharmaceutical Commerce*, March, p. 24).

One thing is for sure: PhRMA sees a direct link between PPA, and its attendant publicity, and a thawing of public opinion about the industry, which reached a low point after the Vioxx debacle and financial improprieties during 2004-05. "The good news is that more and more Americans are beginning to see us in a better light," said Billy Tauzin, PhRMA executive director, during the association's annual meeting in March.

What next?

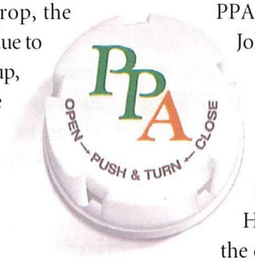
Meanwhile, PhRMA, member companies and the public health community are pondering how PAPs could evolve to meet coming healthcare needs. The U.S. population's problems are shifting, and PAPs are only partly addressing those shifts. Most PAPs are not aimed at the swelling ranks of the "uninsured" – people who have insurance but cannot afford drugs due to high co-pays, deductibles and other medical costs.

Another major change was the introduction of Medicare Part D. Previously, many seniors relied on PAPs for their medications. After Part D, much of the over-65 population migrated into commercial plans, and overall PAP volumes dropped as a result.

After that Part D-related drop, the numbers are rising again, partly due to a surge among the 55-64 age group, says PhRMA's Johnson: "We are starting to see an uptick in use of the programs. We have also seen a lot of people who are nearing retirement age suddenly find themselves out of work. I think it has to do with economic times more than anything."

Last year, PhRMA companies delivered more than 20 million prescriptions through PAPs, Johnson says. That represents about 0.5% of the 3.8 billion total US prescriptions in 2007, as calculated by IMS Health, or about 1.5% of the total number of branded-drug prescriptions.

Most PAPs still target the uninsured. Though PAPs vary widely depending on the manufacturer, drug and disease state, they have common elements. Most manufacturers publish eligibility criteria, which typically specify evidence of a lack of drug coverage, U.S. citizenship or residency and income below a certain level – often 200% of the Federal Poverty Level, but higher in some cases. Overall, about 75% of people who seek help through the PPA website PPARx.com, get help, Johnson says.



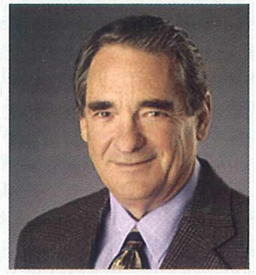
RxCrossroads (Louisville, KY) is a logistics and services provider that runs PAPs for various manufacturers including Merck & Co. David Hileman, RxCrossroads VP, says the design of a program and its eligibility guidelines are primarily based on a manufacturer's budgetary considerations and philosophy towards community involvement and commitment to the programs. Predictive tools can model the number of patients likely to enter the program: factors include demographics (if the population is older, fewer are likely to use the PAP because of Part D) and the number of people suffering from the disease. Overlay financial statistics, and manufacturers can begin to get an idea of how many people will come through the program based on how they set eligibility criteria.

While all major drug companies offer PAPs for the uninsured, Hileman and others involved with PAPs say the situation with Medicare Part D enrollees is more complex—and continually changing.

Many pharmaceutical companies initially backed off from offering assistance to people enrolled in Part D plans, following CMS and OIG guidance in 2005 that discussed whether PAPs might be used to subsidize drugs that were paid for by Medicare Part D, presenting a "heightened risk of fraud and abuse."

"For most manufacturers, the interpretation was something like 'it appears that people on Medicare Part D plans cannot get assistance,'" says Karissa Laur, AstraZeneca's director of patient assistance programs.

In 2006, the situation changed again following OIG clarification that pharmaceutical companies could in fact help Part D beneficiaries as long as they did so outside Part D. For example, the cost of the provided medications cannot contribute towards a patient's out-of-pocket costs, so it cannot help patients get through the "donut hole" that requires them to pay all out-of-pocket costs between $2,510 and $5,726. "That's when we started developing our own plan specifically for people in Medicare," Laur says.



"Our PPA efforts... began to cut through all the clutter of criticism and complaints, and Americans began to see, yes, we did have good, strong, and warm beating hearts, and we really cared about our patients."

– Billy Tauzin, PhRMA

The plan, the AZ&Me Prescription Savings program for people with Medicare Part D, launched in November 2006. In 2007, the program attracted nearly 11,500 participants, but takeup has increased sharply is on track to exceed that number in 2008, Laur says.

Reasons may include the company's efforts to educate patients and advocates, she says, as well as the gradual clearing of the confusion about PAPs for Part D recipients.

Minding the rules

Running programs for Part D has caused extra administrative work for manufacturers, who have different rules to track and make sure they comply, says Bridget Metcalf, director of the coverage and reimbursement services division at Quorum Consulting (San Francisco). For example, PAPs may supply uninsured people with a drug for six months or a year starting from when they are accepted; however, manufacturers are required to provide continued eligibility for Part D beneficiaries through the calendar year. In addition, consultants say an increasing number of manufacturers are looking at sharing data with CMS as an additional form of verification and to guard against drug diversion.

Though the number of manufacturers offering assistance to Part D beneficiaries has increased, there's still great variation within the industry, says Hileman, of RxCrossroads. "It varies from manufacturer to manufacturer as to what they will do with patients who reach the donut hole and cannot afford to pay – some allow them in on an exception basis, some have a whole separate program for them. Some are really hard-nosed and say 'even if you're eligible but haven't enrolled [in a Part D plan], you can't come into the program.'"

One factor that does makes it easier for Part D participants is that seniors generally

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information, the PPARx website also lists state assistance programs and other resources.

Several more modestly funded independent websites also act as competing focal points for people seeking help, and provide a broad range of information about assistance programs including PAPs. Some get funding from pharmaceutical companies. They include RxAssist, founded in 1999. Janet Walton, deputy program director, says the site gets roughly 100,000 visitors a month, about 25% of them unique visitors, and answers 100 to 150 emails and phone calls per week. NeedyMeds was started even earlier, in 1997. It aims to be simple to use, with information easily accessible, says NeedyMeds president Rich Sagall. The site gets about 9500 unique visitors a day, he says.

Doing well by doing good

At the Ninth Annual CBI Assistance Program Conference (Baltimore, March 4), Market Strategies International (Livonia, MI) released results of a syndicated study of the impact of PAPs on company perceptions. Among primary care physicians, PAPs contributed to manufacturers' overall corporate image. Physicians with a good image of a company's PAP were more likely to engage in positive behaviors towards that company, such as prescribing, says the study's author Jack Fyock. The companies with the most positive images were Pfizer, Merck, Novartis, AstraZeneca and GlaxoSmithKline, although Fyock says there is no clear leader.

However, doctors were relatively indifferent about some of the areas into which pharma companies pour resources, such as presenting helpful information on their PAP website—perhaps because many doctors delegate the day-to-day details of enrolling patients to ancillary office staff. Fyock suggests that when pharma companies talk to physicians about PAPs, they emphasize the aspects that matter most to busy doctors – such as their efforts to minimize the work a physician has to do when enrolling a patient.

The pharmaceutical industry has an even bigger reason to ensure that PAPs are effective and help the industry's image. As PhRMA's Johnson observes, "we're fighting hard to preserve a free-market healthcare system ....and there's a lot of concern that we won't continue to have that free market system if millions of people continue to fall through the cracks."

Whether PAPs can do much to help remains an open question. Pharma manufacturers should have publicized their efforts five to ten years ago, says Peter Pitts, president of the Center for Medicine in the Public Interest in New York. "Now that they have to, it almost looks like a self-serving proposition. It is too little, too late to have an impact on public opinion and the legislative outlook." **PC**

PAPs for the Underinsured: Managing PAPs can clash with OIG rules

Most PAPs are not designed to help the underinsured – the growing number of people who have insurance and whose income may be too high to meet PAP eligibility guidelines, yet struggle to pay for drugs due to high co-pays, deductibles and other medical costs.

A Consumer Reports healthcare survey late last year categorized 24% of all respondents as underinsured. Of those, 28% said they had delayed filling prescriptions.

Observers say one reason for the surge in numbers is that insurers increasingly place high-priced drugs, such as oncology treatments, in price tiers that require patients to pay a percentage of the drug's cost rather than a flat co-pay.

"We recognize it's a growing problem," says Ken Johnson, senior VP at PhRMA. "It's something we are wrestling with as an industry, to figure out how we can help people." He points to insurance companies as the source of the problem. "This is a coverage problem more than it is a cost of prescription medicine problem. This is one that the government may have to address," he says.

For now, though there's no broad solution, a handful of foundations are addressing the problem by providing patients with cash assistance towards out-of-pocket costs such as co-pays.

An example is the HealthWell Foundation, founded in 2004, which awarded some $44m to nearly 20,000 patients last year, including many enrolled in Part D plans. The foundation operates funds for various cancers, arthritis, asthma and other conditions such as age-related macular degeneration.

David Knowlton, a member of the HealthWell board, says the problem is a broken reimbursement system in which cost is being shifted to patients by both private and public-sector payors. "When co-payments were originally created they were intended to act as a disincentive for overutilization – but it has just become cost shifting," he says. "Huge amounts of cost are being shifted to people who have chronic or serious diseases, and don't have any choice but to access the healthcare they require."

The foundations have attracted some press scrutiny because of the relationships between the pharmaceutical industry and the disease treatments supported by the foundations. Funding still comes largely from pharmaceutical companies; the foundations often narrowly target diseases for which there may be only a handful of approved treatments, including those provided by companies that provide funding. The federal anti-kickback law does not allow the industry to directly pay out-of-pocket costs for Part D patients; however independent foundations can do so under certain circumstances. HealthWell says the OIG issued a favorable opinion about its operations. "I agree with the need for OIG to be rigorous in seeing that these foundations don't get abused," Knowlton says. However, he points out, by helping the underinsured the foundations are addressing a problem that others, to date, are not.

Other foundations include Patient Access Network, which last year provided an average $3,500 in assistance to about 15,000 patients, according to executive director Julie Reynes. PAN's funding is about $50 million a year, she says.

Reynes says PAN made several changes following an OIG opinion last year. The foundation is largely operated by the Lash Group, a subsidiary of AmerisourceBergen; following the opinion PAN hired Reynes, moved its headquarters to a new location, and ensured that Lash Group staff working for PAN are separated from other Lash group operations, Reynes says. She says part of her mission is to get more funding from outside the pharmaceutical industry. "We'd like to see the donor base is diversified," she says. "I would really like to see insurance companies step up."

– Mike Faden