Copay programs' increased value to manufacturers is matched by rising criticism

January 15, 2014

Despite proven medical value, coupon and copay offset programs continue to draw fire from insurers; meanwhile, will the programs extend to ACA insureds?

Suzanne Shelley, Contributing Editor

Coupon or copay-offset provisions are aimed at the "out of pocket" (OOP) expenses of commercially insured or cash-paying patients. When such a discount program is used, the drugmaker pays the differential between what the patient's insurance plan will pay for that drug, and the wholesale price plus dispensing fee paid back to the pharmacy. The goal is to ensure that the patient's final OOP cost is capped by the dollar figure offered by the coupon or copay-offset program. "When a patient can use a coupon or copay-offset card to pay a lower rate than a top-tier copay, they are much more apt to fill that prescription," says Devin Paullin, EVP at Physicians Interactive (Marlborough, MA).

Coupons and copay-offset programs are currently available for nearly 400 branded products, with the majority being for chronic conditions for which drug treatment could be expected for several months or more and can easily cost hundreds if not thousands of dollars per month.

In one study of more than 10 million prescriptions for over 5 million patients, researchers found that when patients had copays of $50, their prescriptions were three times more likely to be abandoned at the pharmacy than when there were no OOP costs, and over twice as likely to abandon the prescription when they had a copay of $25. [1]

Today, a confluence of factors is driving the deployment of copay-offset programs. One big driver that has made many medications less affordable for financially strapped patients is tier creep—"whereby Tier 2 drugs no longer carry a $25 copay, but a copay closer to $35–$75—resulting in lower medication adherence," says Chris Dowd, SVP for PSKW (Bedminster, NJ).

Copays and the copay differential between tiers continue to grow. In 2012, copays for retail pharmacy generic and traditional brand prescriptions grew between 10% and 13% while specialty copays grew by 26% (from $84 to $106 average for a 30-day

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Tighter economic conditions and competitive pressures from other in-class products are also driving demand: Manufacturers are realizing that "remaining competitive in their respective markets if other products in the class already offer copay programs is an important factor," notes Tracy Foster, president of Lash Group, an AmerisourceBergen Consulting Services company (Charlotte, NC).

Pharma marketers have a variety of resources for managing copay-offset programs. Dedicated vendors include PSKW, Physicians Interactive, Opus Health (a unit of Cegedim, Bedminster, NJ), Trialcard (Cary, NC), Lash Group (Charlotte, NC, a unit of AmerisourceBergen Consulting Services), Triplefin (Scottsdale, AZ; now a unit of H.D. Smith Medical Solutions), McKesson Patient Relationship Solutions (Scottsdale, AZ), Medimedia Health (Yardley, PA) and QPharma (Morristown, NJ). Various copay-assistance programs are available from the many operators of patient assistance programs; and vendors of consumer-oriented, retail patient services such as Catalina Health (now a unit of Adheris) and Inmar, Inc. (Winston-Salem, NC).

Formulary fight

Where the insurance industry cries foul is with the longstanding argument that the very existence of these copay programs undermines the formulary-tier-designation efforts that are so strenuously negotiated with drugmakers. This has the potential to undermine the insurer's bottom line in two ways: (1) By allowing physicians to prescribe outside the tiered formulary system, thus forcing insurers to reimburse for more costly branded drugs when cheaper, on-tier drugs (both branded and generic) are available, and (2) by denying insurers rebates (contracted with drugmakers as part of the tier-designation negotiations) that might have been available had an on-tier therapy been prescribed. The formulary model is a key cost-containment initiative used by payers.

"With these offsets, some brand teams who might never be able to win a preferred formulary bidding process can get directly to the patient and pay no rebate to the insurer, which changes the balance of power in the negotiating process," says Mason Tenaglia, managing director at Amundsen Group (Burlington, MA).

A 2011 white paper by the Pharmaceutical Care Management Assn. (PCMA; Washington, DC) set off alarm bells for many industry observers by stating that drug coupons and copay-offset programs "could raise prescription drugs by $32 billion over the next decade," and offering a stinging indictment of the pharma industry for pursuing such subsidy programs.

"Many payers—including Express Scripts as a PBM—while supportive of programs to facilitate patient access for high-cost specialty drugs, are not supportive of these programs as a mechanism to undermine formulary placement," says Kevin Cast, VP, global pharmaceutical business development, at United BioSource, an Express Scripts company (Blue Bell, PA). "This incurs additional expenditures with no additional health benefits for the patient."

In response, Cast says, "Some payers are allowing members to fill their prescriptions only at pharmacies that don't accept copay cards; another payer tactic to counter their use in competitive drug classes is to remove those medications from the formulary altogether."

However, coupon advocates say that the payers' portrayal of copay-offset programs is not always fair or accurate. "The problem with the PCMA paper, which generated a lot of media attention, is that it is not backed up by a single analysis of actual data in any therapeutic class," says Tenaglia. "There are studies that show that the combined medical and pharmacy costs for such debilitating conditions as cancer, rheumatology-related disorders and multiple sclerosis can actually be reduced when patients remain on therapy. And it is clear in all those classes that copay support increases adherence."

After conducting several years of empirical analysis through a variety of longitudinal studies, the Amundsen Group asserts that copay-offset program usage is not correlated with lower generic utilization in any of the major drug classes, and points

drugs—such as TNF inhibitors, therapies for multiple sclerosis, HIV, Hepatitis B and C, oral oncology products and so on—for which there are no alternatives available (generic or otherwise), and for which the OOP cost for patients can easily run into hundreds or thousands of dollars per month.

"Insurers can argue that these offset programs drive patients to use more costly branded drugs (in lieu of cheaper branded options or generics), but studies have shown that more than 40% of the time, in the absence of a copay-offset program, if the patient cannot pay the OOP expenses, they won't switch to a cheaper drug—they will simply forgo the medication," says Mick Kolassa, managing partner of Medical Marketing Economics (MME) LLC (Oxford, MS). "The insurance industry will end up losing considerably more money over the long run, in terms of covering related medical expenses that arise when the patients don't control their conditions through the use of medication."

Even the Pharmacy Benefit Management Institute conceded this point. In its "2012 –2013 Prescription Drug Benefit Cost + Plan Design Report," the organization writes: "Plan sponsors must develop effective strategies beyond higher cost-sharing for managing specialty drug spend given the detrimental effect that further copay increases for specialty drugs are likely to have on medication adherence."

"We've done the analysis across many therapeutic classes, and there is no clear data that shows that there is higher branded drug utilization in classes that have generics, but this is what the insurance continues to assert," adds Tenaglia of the Amundsen Group.

According to a 2013 study published in the New England J. of Medicine, less than 8% of copay assistance cards or coupons are for products for which there is a generic available. [2]

Today, pharmacy spending currently accounts for roughly 10% of healthcare costs. Supporting the idea that prudent use of drug therapies pays its own dividends, a recent Congressional Budget Office study [3] notes that every dollar spent on pharmaceuticals saves two dollars in overall healthcare costs. "The converse of this is that every dollar not spent on pharmaceutical interventions costs the industry $2 in healthcare costs, and the numbers used in that CBO study were very conservative," says Kolassa. He asserts that copay assistance is actually "helping to subsidize the health insurance industry" itself.

Meanwhile, the claim that copays exist primarily to influence prescribers, is dubious at best. "A coupon would not likely be the reason any doctor would write a prescription," says Paullin of Physicians Interactive. "But once the physician has selected the therapy, the coupon can help increase both affordability and adherence for the patient."

"Even payers, who are largely critical of such programs, understand that affordability impacts adherence," says Foster of The Lash Group.

Coupons under the ACA

While Pharma may not like the situation, it has long accepted that patients in Medicare, Medicaid, Veterans Administration (VA) programs or other federal healthcare programs are not eligible to use pharma coupons, copay-assistance cards or similar subsidy-type programs, because they are viewed as illegal inducements that have the potential to violate the federal anti-kickback statute (AKS).

But a far more grey area has been the lingering question of whether or not coupons and copay-offset programs would also be barred from being used in the health exchanges established by the Patient Protection and Affordable Care Act (ACA, or Obamacare), which—according to one side of the argument—could be construed as federal programs, given that there is some level of federal subsidy involved in the exchanges.

Specifically, all stakeholders have been holding their breath, waiting to see whether or not previously uninsured patients, now finally insured through healthcare

that are aimed at making certain medications more affordable. As of press time, the answer remains far from clear.

In late October, Kathleen Sebelius, HHS Secretary, attempted to resolve this question in a letter to Congressman Jim McDermott (D-WA), but critics of the copay assistance programs say that her characterization of the situation was both misguided and misinformed and will have no legal standing over the long run.

Specifically, the Sebelius letter says that HHS does not consider qualified health plans purchased through the ACA insurance exchanges to be "federal healthcare programs" for the purpose of the federal anti-kickback rules.

"Given the recent conflicting guidance from HHS and CMS around Qualified Health Plans, manufacturers should be very cautious with their approach to providing cost-sharing assistance to patients enrolled in these plans," says Scott Dulitz, VP, product support, at UBC. Mark Merritt, president and CEO of the PCMA, went farther in a statement: "Now regulators need to take the next step and formally determine what everyone already knows: That federal anti-kickback laws apply to the ACA."

Some in Congress agree. Senator Chuck Grassley (R-IA) wrote to Sebelius and the Dept. of Justice, saying it was "extremely disturbing" that the HHS Secretary is "intentionally attempting to strip away these vital protections by administrative fiat."

"It is unclear exactly who has the authority to declare whether exchange plans purchased with federal subsidies are federal healthcare programs," says Kevin McAnaney, a Washington, DC-based attorney and former HHS executive who specializes in anti-kickback and Stark laws. He notes that the only agency with jurisdiction over the AKS "would appear to be the Dept. of Justice (DOJ)," saying: "While HHS has regulatory authority to create safe harbors for conducts that otherwise might violate the AKS statute, nothing the Sebelius letter said is binding and HHS can reverse their position at any time, and DOJ can reverse it through rulemaking."

Proponents of drug coupons and copay-offset programs say that it is a cruel twist of fate that previously uninsured patients—once enrolled in one of the ACA health exchanges—would still be denied access to the coupons and copay offsets that are already available to patients with private insurance.

"How do you tell patients in the ACA that they are not entitled to the same discount coupons that aim to make certain drugs more affordable as patients who already enjoy private-sector insurance plans are entitled to?" says Derek Rago, VP and GM of McKesson Patient Relationship Solutions. "Under ACA, it should be all about trying to finally provide uninsured Americans with some form of health insurance, with the ultimate goal of improving patient outcomes."

And Sebelius' position has possible political significance, as well. The Obama administration "cannot come out and say that the exchanges operated under the ACA are 'a federal program'—people would scream 'socialized medicine' or 'a government takeover of healthcare,'" says Kolassa of MME. "It was especially important for Sebelius to reiterate that the ACA establishes a broad private/commercial insurance market—not a government program—and thus, by definition, the potential to violate the AKS statute would not apply."

"If that distinction were to ultimately be reversed, the issue will become so much bigger than just copay cards alone," he adds.

Best practices in program development

While they may be under fire, it's clear that coupon and copay-offset programs are here to stay. Experience in the early years has brought to light several ways in which drugmakers can make these programs as effective and valuable as possible, for both the pharma brand team and the patient.

At the end of the day, the price at the pharmacy counter is not the sole motivator for patients to be healthy and stay on therapy, and simply lowering the cost of

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