



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

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**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

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\$106 average for a 30-day supply), in an effort to keep pace with the rapidly increasing cost of specialty drugs, according to the Pharmacy Benefit Management Institute (PBMI; Plano, TX).

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 out that most of the money invested by US brand teams goes into offset programs that are aimed at the extremely high-dollar-value specialty, biologic and orphan 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 exchanges under the ACA, would be allowed to use coupons and copay-offset cards 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 medications does not necessarily provide enough of a support mechanism to improve compliance and long-term health outcomes

“It's important for brand teams to recognize the different types of barriers that can lead to low drug compliance,” adds Rago of McKesson. He notes that financial barriers can be addressed by coupons and copay-offset programs, and clinical barriers—related to, say, side effects or lack of efficacy—can be addressed through greater physician and pharmacy support and branded and unbranded educational materials provided by the drug manufacturer and other entities.

Even more vexing, says Rago, are the so-called “cognitive challenges” that must be overcome in order to ensure maximum compliance with the drug regimen. “These include such issues as the patient not truly understanding the severity of the disease (which is especially common for chronic conditions such as high blood pressure or high cholesterol that are asymptomatic), not understanding the role of the medication or the importance of taking the full course of drugs according to their label instructions,” he says.

Industry experts in patient-assistance programs agree: The goal of any brand team should be to offer more than just the copay-offset card itself. A range of other support tools such as refill reminders, educational outreach to the copay-assistance program via patient opt-in mechanism and followup from call centers will help the patient get stay on therapy and experience sustained improvements in outcomes. [4]

With the understanding that patients voluntarily opt in to copay programs, the pharma industry benefits by having a direct link to the patient. With this, manufacturers can provide targeted, actionable information right from the beginning, to make sure patients understand why they are being prescribed the medication, to explain the side effects and provide tips for managing them, to stress the importance of taking the entire course of treatment and so on.

These can be as simple as sending the patient a reminder message (via text or email) once the prescription is submitted electronically, to remind them to pick up the prescription, or to bring their copay-assistance card if necessary.

“With just three to five strategically worded questions at the opt-in stage, the brand team can accurately characterize which patients are highly likely to be adherent and which are not,” says Rago of McKesson, and that can help the team to customize the patient-support outreach that follows once the patient starts the medication.

Advanced programs will use such information to create personalized and customized messages, based on what type of information the patient wants to see, in the preferred format, from the onset of being in the program, to help them get past some of the hurdles and stay on therapy.

There is no one-size-fits-all approach here, says Rago of McKesson. For instance, higher-touch models are appropriate for complex diseases or specialty medications with complicated administration requirements. For these cases, it is often appropriate to establish contact centers with live patient-support representatives “who can have a rich, two-way dialogue with patients who may be likely to fall off therapy and have other barriers to adherence,” he says. Since high-touch programs always have higher costs associated with them, their ROI must be justified brand by brand.

### **Apply analytical rigor**

Pharma companies already devote considerable effort to negotiating rebate terms to attain preferred status or access through contracts with managed care companies. According to Amundsen Group’s Tenaglia, they need to apply the same level of business sense and analytical rigor when it comes to designing and deploying copay-offset programs—to project the actual costs, analyze the ROI of the effort, and understand the impact of the program on patients.

Again, offering a one-size-fits-all approach is not an option. Rather, it’s important to deploy these programs where they are needed most, not necessarily across the board, using both geographic and brand considerations. “You want to design copay programs that make sense—ones that save patients who might abandon their prescription and ones that will not subsidize patients who would have filled their prescription anyway,” says Tenaglia. “Savvy brand teams will analyze how costs associated with copay-offer programs differ in different regions, and analyze those against costs already associated with rebates provided under existing managed-care contracts and use this insight to guide program development.”

For instance, if a given insurance provider is dominant in a given region, and you’ve already paid significant rebates to lower the patient’s drug cost through that formulary program, it does not make sense to heavy up on copay cards in that region at the same time, he says.

Tenaglia suggests that brands can minimize erosion of profit margin by focusing on allocating offset cards to those geographic areas with the greatest price sensitivity (where such assistance really matters)—to support patients who may otherwise simply forgo treatment without such support. For instance, when brand teams conduct studies to analyze anonymous patient longitudinal data (APLD), they can drill down even more precisely into patient price sensitivity, at both the initial prescription pickup and at each subsequent refill. These data can help program designers to identify critical threshold values for OOP costs, after which patients will start to abandon their prescriptions, and tailor their programs accordingly.

"This level of analytical rigor currently only happens in a handful of companies, but it is necessary, because in some cases, copay-offset programs may end up costing more than the rebates given to retain preferred tier status," he says. "When companies don't get this right, they end up paying for the same drug three times—through rebates to managed care, through offsets to the patients, and by incentivizing the reps to tell doctors about the copay-offset offering."

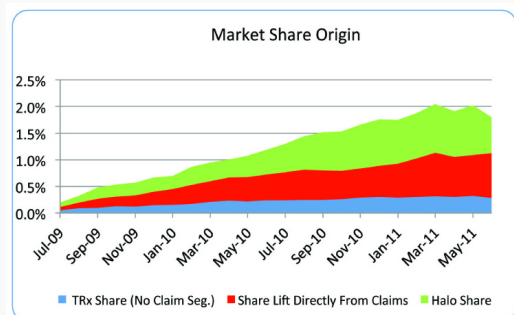


Fig. 2. PSKW's analysis of claims data shows a "halo effect" on prescribers who will increase scripts for a drug with a coupon, regardless of actual use of that coupon. Credit: PSKW

The funds devoted to copay and offset programs can be a vital part of overall pharma marketing budgets. "Because brand teams can measure and manage these programs, they can be as effective as any major promotional avenue at a fraction of the cost," points out Dowd of PSKW. At Physicians Interactive, Paullin notes that, "Another important advantage of e-coupons is that they provide a mechanism for small and mid-tier pharmaceutical companies to deliver cost-savings programs to physicians all over the US without the burden of a costly sales force."

Copay-offset programs are equally valuable at launch, and later in the product lifecycle, to help speed market penetration and make new drugs more affordable during the initial period when a new

medication would likely have a Tier 3 copay before the manufacturer can establish the contract with the drugmaker.

PSKW's Dowd notes that there is a "halo effect" with physicians simply because of the existence of patient support. Non-coupon patients (i.e., patients whose plans do not have high copays) are more likely to be prescribed a drug that the physician is aware of through the existence of the program. (Fig. 2).

### The e-prescribing environment

Traditionally, coupons were paper documents, often handed over by the rep during a physician visit, along with samples. Sometimes the physician remembered that a coupon exists for a prescription; sometimes not; sometimes, the paper coupons are locatable in the sample closet; sometimes not. These logistical difficulties are being addressed both by e-prescribing and electronic health record (EHR) systems now in wider use by physicians, and by online sample closets where physicians order samples directly from manufacturers.

With the growth of EHR systems, the capability of creating an electronic coupon, accessible (or present) at the point of prescribing, is on the rise. Savvy consumers are also aware of online sites that aggregate coupons from many manufacturers.

The home run in this environment is when an electronic coupon is coupled with the electronic prescription, and both the patient and physician are aware of it at the point of prescribing. But getting there is not a simple task. PSKW's Dowd notes that the EHR market is highly fragmented (there are estimates of more than 500 EHR vendors) with varying degrees of system interoperability. He notes that all stakeholder groups must working to address these challenges in order to optimize the capabilities of e-coupon programs.

At Physicians Interactive, Devin Paullin notes that "Clinicians are very open to receiving select services from pharma manufacturers within their mobile devices and EHR—if it adds value and is relevant to their workflow

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and to the delivery of quality care, they will use it.” A recent Physicians Interactive study of 2,300 physicians, nurse practitioners and physician assistants revealed that medication vouchers and coupons were “the most requested pharma resources to have access to directly within the EHR software.”

Some EHR vendors have open access to marketing information from manufacturers, and inclusion of a coupon program is fairly straightforward. Another evolving channel is online drug information databases offered by vendors like PDR Network, Epocrates and others; prescribing information for drugs can be accompanied by a discreet reminder that a coupon is available. The watchword in all this is not to interfere with the physician’s “digital workflow” of navigating an EHR system. Properly designed, the electronic coupon is a welcome component; poorly designed, it becomes an irritation.

“We’re still in the first generation of integrated products that will improve adherence and outcomes, and we are still learning, but—as an industry—we’re all approaching this very responsibly (in terms of clinical, legal and regulatory requirements) and there are rules in place in all of these EHR systems to minimize commercialism,” says Paullin.



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### Formulary exclusion—the ultimate revenge?

**Last January**, when pharmacy benefits manager Express Scripts (St. Louis) announced that it would exclude 48 medications from its 2014 national preferred formulary (which maintains a three-tier benefit strategy, to segregate generics, preferred branded drugs and non-preferred branded drugs), the PBM did not hide its antipathy toward copay-offset programs. According to the company, a range of factors (including clinical information, cost and market share movement) was considered in the decisionmaking, but not coincidentally, 93% of these recently de-listed therapies have a discount coupon or copay-offset card associated with them.

“By excluding these products [from our national formulary], this strategy renders those cards useless,” said Steven Miller, CMO for Express Scripts, in an October 2013 interview at [Pharmalot.com](http://Pharmalot.com).

Express Scripts serves 100 million people, of whom 30 million have their benefit on the national preferred formulary. “We put the pharma industry on notice that we would be more aggressive this year. Our preference would be to not exclude everyone and get everyone down to lowest possible cost and preserve largest choice. But it’s clear if you’re willing to lower pharmacy choices, you can drive greater economics and still preserve health,” said Miller.

When CVS Caremark made a similar move in revising its 2012 formulary to exclude 34 drugs, the company wrote that its intention was “to help plans achieve lower total costs...” and “to counter aggressive direct-to-consumer advertising and increased marketing efforts by big pharmaceutical companies that promote the use of higher cost brand drugs.”

The impact of such decisions is that “patients will now be required to either change therapy or pay 100% OOP, and

they are the victims of the PBM battle for brand control,” says Rick Randall, chief innovation officer of TripleFin. “The physicians and patients are stuck in the middle trying to manage their disease in a consistent manner while the PBMs focus is on increased rebates.” Moreover, he says, formulary decisions vary by payer, PBM and other factors; in that environment, how does a patient maintain therapy for a given drug?

PBMs tend to speak more loudly about conserving the payer dollars of the benefit programs they run, but not quite so loud about the rebates that they negotiate with manufacturers. As sources interviewed for this article note, changes in negotiating power when manufacturers sit down with the PBM representatives are going to be a factor in how the discussions conclude. [EC](#)



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