Don't Pay Too Much For Generic Fills

Pass-through pricing is a good way for a payer to realize the benefit of increased prescribing of generic drugs

By Linda J. Cahn

Many facts are widely circulated about generic drugs, including these:

- Today, 7 out of 10 prescriptions are filled with generic drugs.
- The average price of a generic drug prescription is just under one fourth the average price of a brand drug prescription: $35.22 vs. $137.90.
- Almost 80 percent of FDA-approved drugs have generic counterparts — 10,072 of the 12,751 drugs listed in the FDA's Orange Book.
- Approximately 2.6 billion prescriptions are filled with generic drug products each year.
- Generic medications account for 69 percent of all prescriptions dispensed in the United States but only 16 percent of all dollars spent on prescriptions.
- Generic drugs saved the health system $824 billion from 2000 to 2009 and $140 billion in 2009 alone (that's $383 million a day), according to IMS Health, a company that tracks drug sales.
- In 2011 and 2012, six of the 10 largest-selling brand drugs in the U.S. will lose their patents, potentially enabling even greater use of generic drugs.

However, here's one fact that rarely surfaces amid all the discussion of generic drugs: The entities paying for most of the cost of drugs — insurance companies, large and small corporations and unions, and the federal and state governments — are paying far more for generic drugs than sellers' actual generic drug costs.

Let's look at the reasons why payers are overpaying — and sellers are making such large profits — and how payers can change their predicament and maximize generic drug savings.

Misclassification of generic drugs

Most payers' drug costs are controlled directly by the terms of their contracts with pharmacy benefit management companies (PBMs) or indirectly by their insurers' contracts with PBMs.

Most PBM contracts begin with a definition section that typically defines the phrases "brand drug" and "generic drug," although in a surprising number of instances, no such definitions are present. In either case, PBMs' ambiguous definitions — or lack of definitions — allow them to manipulate drug classification.

In the September issue of Managed Care, I wrote at great length about the problems arising from this misclassification. On one hand, when invoicing clients, PBMs can misclassify many generic drugs as brands and thus overcharge clients as well as falsely claim that PBMs have satisfied generic and brand contract guarantees.

On the other hand, when passing through rebates to satisfy contract guarantees or when reporting on generic utilization rates, PBMs can do the opposite and misclassify many brands as generics, and thus pass through less than the payer may be entitled to.

Thus, my last article indicated the importance of writing airtight definitions of "brand drug" and "generic drug" in PBM/client contracts to prevent PBMs from misclassifying drugs. And my article provided details about how to do so.

Additional steps

Thus, writing definitions that generate accurate, predictable, and enforceable generic drug classification is the first step that payers must take to maximize generic drug savings and ensure lower aggregate drug costs. However, payers must take several additional steps. The most important is to replace "traditional pricing" contract terms with "pass-through pricing" terms.

Nearly all contracts between PBMs, and clients

today — whether the clients are insurance companies, large or small corporations or unions, or government entities — are based on traditional pricing, which allows the PBMs to make an unknown profit spread between the amount PBMs pay for drugs and the amount PBMs invoice clients for the same drugs. Since PBMs refuse to disclose their acquisition costs for drugs, their profit spreads cannot be detected by their clients.

Pass-through pricing

Pass-through pricing is structured entirely differently. It requires a PBM to bill a client using the same figure that the PBM paid for each drug dispensed.

For retail drugs, the PBM must bill the client using what it paid the retail pharmacy. For mail order drugs, if the PBM uses a third-party vendor, the invoiced cost must match the PBM's payment to the vendor.

But if the PBM has its own subsidiary mail order pharmacy, the PBM's invoiced cost to its client must match the PBM's acquisition cost, and the contract must specify how acquisition cost will be determined (FIFO, LIFO, WAAC, and so on).

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Many PBMs claim to be providing pass-through pricing but are not doing so. Instead, they are providing pass-through pricing for retail drugs but not for mail or specialty drugs.

On its face, this hybrid form of pricing might appear to offer some benefit to clients. In actuality, it's unlikely to do so, since PBMs typically just increase their spreads on mail and/or specialty drugs and thus take back the savings that clients might otherwise have obtained from retail pass-through pricing.

Thus, if clients actually want to obtain the full benefits of pass-through pricing, they must insist on an all-or-nothing approach: Either the PBM provides a pass-through for every drug — retail, mail, and specialty — and the PBM collects its profits in a single administrative fee, or the client will move on and find a PBM that will do so.

Assuming that a PBM client decides to implement genuine pass-through pricing, it must also eliminate all contract language that allows the PBM to bill the client based on the PBM's maximum allowable cost (MAC).

Virtually every PBM/client contract in today's marketplace contains a contract definition and pricing terms related to MAC. The definition allows the PBM to generate its own prices for any drug it places on its MAC list, and it can generate its own prices for as many or as few drugs as it wants. The MAC definition also allows the PBM to change the prices that it generates whenever it wants.

The contract's MAC pricing terms can be structured in any number of ways — applying MACs to retail drugs only, or to retail and mail drugs, or to generic drugs only, or to both generic and brand drugs.

If you skim your contract with your PBM, you'll likely find references to MAC throughout the contract, and you'll undoubtedly see what I mean if you carefully read those references.

Since your goal is to obtain "pass-through pricing" for every drug dispensed, when you negotiate a new contract, you must eliminate all MAC terms from the contract, since the MAC concept is antithetical to the pass-through pricing concept.

Actual costs

The MAC allows your PBM to invoice you whatever it wants. The pass-through concept requires your PBM to bill you based on its actual costs.

The sole MAC reference you may want to include in the contract is a simple provision making clear that the PBM's continuing generation of MACs (for example, for the purpose of paying retail pharmacies) will have no effect on the PBM's obligation to provide pass-through pricing to you, since the PBM must invoice you, its client, based on its actual costs, whatever they might be, and however the PBM might generate them. Pass-through pricing has at least four striking benefits for all clients that implement it.

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The benefits

First, it eliminates the misalignment of PBMs' and clients' incentives, since PBMs no longer have an incentive to favor higher-cost drugs that may offer them larger profit margins.

Second, pass-through pricing enables clients to know the actual cost of every drug dispensed, which in turn enables clients to encourage their covered members to favor lower-cost drugs by way of lower copayments and programs, such as step-therapy, prior authorization, and mandatory generic programs.

Third, pass-through pricing introduces competition into the PBM industry, since PBMs' profits are reflected in a single administrative fee, meaning clients can compare the proposed fees and can require PBMs to lower those fees if they are not competitive.

Fourth, pass-through pricing results not only in lower administrative fees but lower drug costs, since PBMs must pass through their actual drug costs, rather than generate an unknown profit spread and invoice their clients at prices far higher than the PBMs' actual costs.

Pass-through pricing is particularly important in connection with generic drugs, since PBMs' profit margins on generic drugs are high. Read any Securities & Exchange Commission (SEC) filing of a publicly traded PBM, or listen to any investor conference call, and you are likely to see or hear a PBM stating that it makes a significant part of its profits from generic drugs. For example, here are a few excerpts from the public filings of the largest PBMs:

> "[O]ur gross profit continued to benefit from the increased utilization of generic drugs (which normally yield a higher gross profit rate than equivalent brand name drugs) in both the pharmacy services and retail pharmacy segments." (Caremark 2009 10K filing with the Securities and Exchange Commission, page 76.)
>
> "Our diluted earnings per share increased 22.5 percent … and net income increased 16.1 percent .... These increases primarily reflect higher generic dispensing rates … [among other matters]." (Medco 2009 10K, page 47.)

My consulting firm witnesses the high profit margins PBMs make on generic drugs, whenever we conduct an RFP for a new client, and compares the average costs per prescription that our new clients were paying under their existing PBM contracts, with the amounts that these clients will probably pay if they require their next PBMs to provide pass-through pricing for all drugs. Our analyses focus in particular on commonly used generic drugs, such as the proton pump inhibitor (PPI) omeprazole, the cholesterol reducer simvastatin, the sleep inducer zolpidem tartrate, and the antidepressants fluoxetine HCl and sertraline HCl.

We consistently discover that our clients' existing PBMs are grossly overcharging for these drugs and that our clients will be able to save large sums by obtaining pass-through pricing from their next PBMs for all such drugs.

For example, Table 1 (page 24) contains the results of our omeprazole analyses for three recent new clients, comparing the current costs per pill and per prescription under each of the clients' existing "traditional pricing" contracts with the likely costs per pill and per prescription if each client were to obtain pass-through pricing. Although the number of covered lives and retail/mail mix varied for the three clients — and their incumbent PBMs also differed — our analyses showed that all three clients were losing a large portion of their potential generic savings because of the inflated costs their PBMs were charging for omeprazole.

While the extent to which each PBM client was being gouged differed, the incumbent PBMs were gouging all three clients, since no client should pay an average amount of even $50.41 (the lowest of the three average amounts charged) for an omeprazole prescription that could easily be dispensed for approximately half that amount.

Grossly overcharging

Our analyses consistently reflect that PBMs are grossly overcharging for other generic drugs as well. For example, Table 2 (page 24) contains the results of our simvastatin analyses for the same three clients comparing their existing costs per pill and per prescription under each of their existing traditional pricing contracts with their likely costs per pill and per prescription if each client were to obtain pass-through pricing for every retail and mail simvastatin prescription dispensed.

In the initial stage of our RFPs, we also show clients the total savings they might obtain were they not only to require their PBMs to pass through the actual costs for commonly used generic drugs but were the clients also to increase their mem-

TABLE 1
PBMs' inflated omeprazole charges and clients' potential savings from requiring pass-through pricing

	Traditional pricing		Pass-through pricing		Conservatively stated average savings	
	Current average cost per pill	Current average cost per Rx	Conservatively stated average cost per pill	Conservatively stated average cost per Rx	Per pill	Per Rx
Client #1	$ .91	$60.71	$ .40	$27.17	$ .51	$33.54
Client #2	$1.30	$50.41	$ .40	$16.26	$ .90	$34.15
Client #3	$1.61	$109.53	$ .40	$27.97	$1.21	$81.96

bers' utilization of such drugs (and decrease the utilization of more expensive drugs in the same therapeutic category). We do so by estimating the market share shifts in drug utilization that we have seen when other clients implement step therapy or prior authorization programs and/or restructure their copayments to encourage members to use less expensive generic drugs.

For example, Table 3 (page 25) shows the PPI analysis we presented to Client #3 above, in which we estimated the savings that would result were Client #3 not only to change the average cost of omeprazole by obtaining pass-through pricing, but also to increase omeprazole's percentage of PPI market share from 18.5 percent to 56.5 percent by implementing new programs (and decrease the use of more expensive drugs, such as Nexium).

As Table 3 reflects, this client (providing coverage to approximately 185,000 covered lives) could obtain savings of approximately $5.4 million solely from obtaining pass-through pricing for every retail and mail order omeprazole prescription dispensed and implementing programs to increase omeprazole's market share of the PPI drug category.

In short, significant savings can be generated simply from requiring every PBM to provide pass-through pricing for every drug dispensed, particularly every retail and mail generic drug dispensed, and thereafter increasing that drug's use.

Quarterly guarantees

Because PBMs cannot predict what their actual pass-through costs will be during the life of a contract — and their clients must be able to evaluate each PBM's pass-through costs and determine which PBM is most likely to offer the lowest pass-through costs — pass-through pricing contracts must also contain guarantees as to how good the PBM's pass-through costs will be.

We recommend that every PBM client require that its PBM satisfy six average quarterly guarantees, for each of the three dispensing channels (retail, retail 90-day, and mail). Here's the contract language:

> PBM warrants that its pass-through pricing each contract quarter will result in costs that, on average, will be at least as inexpensive for the client as the costs that result from applying the following average quarterly guarantees:
>
> 1. **average quarterly brand drug dispensing fee**
> 2. **average quarterly generic drug dispensing fee**
> 3. **average quarterly brand drug ingredient cost** (excluding dispensing fees)
> 4. **average quarterly generic drug ingredient cost guarantee** (excluding dispensing fees) for all generic drugs within a 180-day exclusivity period
> 5. **average quarterly generic drug ingredient**

TABLE 2
PBMs' inflated simvastatin charges and clients' potential savings from requiring pass-through pricing

	Traditional pricing		Pass-through pricing		Likely average savings	
Simvastatin	Current average cost per pill	Current average cost per Rx	Likely average cost per pill	Likely average cost per Rx	Per pill	Per Rx
Client #1	$ .51	$31.52	$ .25	$16.06	$ .26	$15.46
Client #2	$ .47	$15.49	$ .25	$8.86	$ .22	$6.63
Client #3	$1.86	$139.06	$ .25	$19.10	$1.61	$119.96

TABLE 3
Likely savings from pass-through pricing and increasing the market share of low-cost drugs

Drug names In PPI therapeutic category	Current market share of each drug	Current total ingredient costs (x1,000) based on PBM's inflated price for omeprazole and low omeprazole use)	Potential future market share of each drug, if programs are implemented to increase omeprazole use	Likely future ingredient costs (based on pass-through pricing and increased omeprazole use)
Zegerid	1.5%	$97	1.5%	$78
Aciphex	6.8%	$488	5.0%	$286
Nexium	41.9%	$4,114	15.0%	$1,142
Omeprazole	18.5%	$1,297	56.5%	$384
Pantoprazole sodium	7.2%	$388	6.0%	$191
Prevacid	21.8%	$2,195	15.0%	$1,168
Prilosec	0.8%	$69	0.0%	——
Protonix	1.4%	$95	1.0%	$53
Total PPI costs	100.0%	$8,743	100.0%	$3,301

cost guarantee (excluding dispensing fees) for all generic drugs other than those within a 180-day exclusivity period

6. **average quarterly generic drug ingredient cost guarantee** (excluding dispensing fees) for all generic drugs that are both within and outside a 180-day exclusivity period ("all-in" generic guarantee)

Note that of the six guarantees for each channel, four concern generic drugs, with one related to generic drug-dispensing fees and the other three related to generic drug ingredient costs. The fourth and fifth guarantees in the list allow a PBM to provide a weaker guarantee for generic drugs that are still within the exclusivity period but thus enable the PBM to provide a very aggressive guarantee for all generic drugs that are not within the exclusivity period.

Number 6 — the "all-in generic guarantee" — enables a PBM client to routinely and quickly monitor and audit PBMs' satisfaction of the generic guarantee without retaining an auditor.

To prevent disputes about whether PBMs have satisfied all of the guarantees, contracts must contain a definition for drugs that are within the 180-day exclusivity period by incorporating the Hatch-Waxman Act definition; contain formulas for how each guarantee will be calculated; and identify which drugs will be included or excluded from each of the formulas in calculating whether the PBM satisfied its guarantees.

The third point above is critical, because otherwise PBMs can eviscerate the guarantees' utility. For example, many PBMs exclude all insulin drugs, and products from any guarantee coverage, and they charge whatever they want for such products. On the other hand, most PBMs include drugs dispensed to veterans or section 340b drugs, notwithstanding that the steep discounts on those drugs are a result of government programs (not PBMs' efforts). Thus, PBM/client contracts should state that *all* drugs will be included in the relevant guarantees — including all insulin drugs and products — but excluding drugs dispensed to veterans or through 340b programs.

Ideally, guarantees should be stated as quarterly — not annually — guarantees. Requiring quarterly guarantees can discourage PBMs that are trying to win or retain business from offering contract guarantees that the PBM is unlikely to satisfy.

Quarterly guarantees

After all, with quarterly guarantees, a PBM's failure to fulfill its guarantee obligations is likely to become known to the client within six months, whereas with annual guarantees, the client is unlikely to complete an annual audit until 15 to 18 months after the contract's inception, at the earliest, which might encourage a PBM to offer guarantees that it cannot satisfy.

PBMs use three methodologies to pay retail pharmacies: a discount off AWP, the PBM's MAC, or usual and customary (U&C). With the first two approaches, the drug's cost is broken down between an ingredient cost and a dispensing fee, and

it is therefore clear how to allocate the cost of the drug in calculating satisfaction of the contract's ingredient cost and dispensing fee guarantees.

But if the PBM pays the retail pharmacy based on the pharmacy's U&C, the relevant claims contain only the U&C cost. Accordingly, unless a PBM/client contract specifies how U&C costs will be allocated between the ingredient cost and dispensing fee, PBMs are free to allocate the total cost of the drug in whatever way they choose when determining whether the PBM satisfied its ingredient cost and dispensing fee guarantees.

Unfortunately, almost no PBM/client contracts state how U&C adjudicated drug costs will be allocated.

As a result, if a PBM thinks it might not otherwise satisfy its ingredient cost guarantees, it can allocate a part of U&C adjudicated drugs' costs to dispensing fees, meaning the ingredient costs of all such drugs will be lower, making it appear that the PBM provided a higher AWP discount, and thus enabling it to satisfy its ingredient cost AWP discount guarantee.

On the other hand, if a PBM thinks it might not satisfy its dispensing fee guarantees, it can allocate the entire cost of U&C adjudicated drugs as ingredient costs and record "$0.00" as the dispensing fee, making it appear that the PBM provided lower average dispensing fees than it actually provided.

To guard against such manipulation and to better be able to compare apples to apples in an RFP, payers must specify in their contracts exactly how U&C adjudicated drug costs will be allocated.

Obtain maximum-price guarantees

If a payer obtains pass-through pricing for all drugs — and the contract requires the PBM to guarantee that its pass-through prices will satisfy the average quarterly guarantees — the payer will have a reasonable degree of comfort that it will obtain good generic drug prices.

However, a payer may still want to obtain greater assurance of low costs for the most commonly used generic drugs. After all, generic drug guarantees are for each channel, and are average guarantees across many generic drugs, not guarantees for any specific generic drug.

Accordingly, we urge you to take additional steps to ensure that you obtain all savings available on certain commonly used generic drugs.

Focus on those drugs that you are including — or may want to include — in savings programs (such as a step therapy, prior authorization, or mandatory generic program).

Draw up an exhibit list for your contract of all such drugs and contractually require your PBM to provide a per-unit maximum price guarantee, at retail and mail, for each commonly used drug you have listed on your exhibit list.

Make clear in your contract that for each of the specified commonly used generic drugs, the PBM not only must satisfy its pass-through pricing, and average quarterly guarantee obligations, but also must satisfy the maximum price guarantee on the exhibit list.

By requiring maximum guaranteed prices for those commonly used drugs that you are likely to feature in your generic drug savings programs, you are likely to increase your generic drug savings. However, there are three additional steps you should take that will further increase your generic savings.

Newly available generics

According to an FDA analysis, the first generic competitor for a brand drug product prices its product only slightly lower than the brand-name manufacturer.

However, with the entrance of a second generic manufacturer, the average generic price falls to nearly half the brand drug price. As additional generic manufacturers enter the market, prices continue to fall, though more slowly. If many manufacturers produce the product, the average price falls to 20 percent of the brand drug price — or lower.

Although payers may assume that PBMs closely monitor and quickly adjust their own payments to retail pharmacies as prices plummet for newly available generic drugs, evidence indicates such an assumption may be in error.

For example, in October 2007, Walgreens partially attributed a quarterly loss after several large quarterly gains to the elimination of the extensive profits that it had been making from sales of the generic version of Zocor (simvastatin) during the first nine months after Zocor lost its patent in June 2006.

Clearly, if PBMs paying Walgreens for simvastatin had continuously adjusted their payments to

Walgreens to track simvastatin's declining cost, Walgreens's profits would not have been so high for so many months. Nor would Walgreens's profit have suddenly plummeted when PBMs, presumably, finally adjusted their payments.

Demand meetings

Accordingly, we recommend that clients contractually require their PBMs to provide a quarterly Newly Available Generic Drug Report that will identify all generic drugs that became available during the previous quarter.

We further recommend that clients contractually require their PBMs to meet with them quarterly to review, evaluate, and agree on maximum guaranteed prices for all generic drugs listed in previous quarterly reports. Clients' pass-through costs for all such drugs can then be as good as are available in the marketplace.

Given that six of the ten largest selling drugs — including the top two selling drugs, Lipitor and Plavix — are scheduled to lose their patents in 2011 and 2012, it is reasonably likely that this approach will prove worthwhile.

As many MCOs and HMOs realize, although pharmacies like Walmart provide steep discounts for many drugs to walk-in, uninsured customers, PBMs frequently charge far more when those same drugs are dispensed from the PBMs' mail order pharmacies.

Accordingly, large payers should contractually require that PBMs' mail pharmacies match discount pharmacy prices.

To do so, payers should identify the discounters that are in the payer's geographical area that are most likely to matter. Contracts should then establish a procedure for determining which drug costs will be matched, and for how long the matching requirement will remain in effect.

Your goal should be to ensure that your PBM matches at mail the retail discounts that are most frequently provided, for as long as the retail pharmacies may have the discounts in effect, as long as the discounts do not constitute loss leaders for the retail pharmacies.

Right to renegotiate

Given that most payers execute PBM contracts with at least a three-year duration, every contract should give payers a right to renegotiate pricing terms and guarantees — on a quarterly or annual basis, depending on the term or guarantee — coupled with a right to end the contract with 90 days notice, with or without cause.

No matter how strong a contract may be at its inception, the prescription coverage marketplace is changing too fast for any client to allow itself to be stuck with a contract's terms for three or more years.

Every contract should state that each quarter, a client has the right to negotiate prices on newly available drugs and to renegotiate maximum guaranteed prices for certain commonly used generic drugs and all specialty drugs. The contract should also state that yearly, the client will have the right to renegotiate its administrative fee and the contract rates that are stated for each average quarterly guarantee.

The contract should also state that all newly negotiated terms must be at least as good as those previously provided, unless marketplace conditions preclude that result, in which case the PBM will have the burden of proof to demonstrate that fact.

As for the right to cancel the contract with 90 days' notice, including that provision will ensure that every PBM will negotiate in good faith.

Guaranteed savings

Generic drugs can provide enormous savings to payers. However, almost no payers are maximizing their potential generic drug savings. Instead, payers are allowing PBMs to retain enormous profit spreads on generic drugs.

By writing entirely different contracts — and using your purchasing power, especially during requests for proposals to require PBMs to provide entirely different contracts — you can change the situation and retain *all* savings available from generic drugs.

Accordingly, as soon as you are within 15 months of your current contract's expiration date, take the steps that are necessary to dramatically reduce your drug costs, and draft and demand an entirely different form of PBM contract.

You'll be amazed at the savings you can generate. And you will help to change the entire PBM marketplace.

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