



Changes in the pharmaceutical industry may present opportunities for health plan sponsors to save money—but only if they are in position to know about and react to them.

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If your plan is seeking ways to control soaring prescription coverage costs, you must position yourself to learn about—and respond to—at least six marketplace challenges that undoubtedly are driving up your plan's costs:

1. Numerous drug prices are increasing exponentially—by 100% or more in periods of less than a year.
2. The Food and Drug Administration (FDA) is approving dozens of new drugs annually, including many high-cost specialty drugs costing more than \$100,000 per treatment per patient.
3. Patients and their doctors are resorting for convenience to “combination drugs” that often combine two low-cost drugs into a single, far more costly product.
4. Compounding and specialty pharmacies are creating—and marketing—high-cost products that haven't even been approved by FDA.
5. Over-the-counter (OTC) drugs are entering the market as low-cost alternatives to much higher cost prescription products, but few pharmacy benefit managers (PBMs) are advising plans to stop covering the prescription drugs.
6. When brand drugs lose their patents, new generics are available at far lower costs, but PBMs frequently are slow to adjust their prices and pass through the lower costs to plans.

Unfortunately, few plans are positioned to learn about these challenges, let alone address them. Large plans may want to consider adding an expert to their staff to track—and respond to—marketplace changes. Given the potential savings, the cost for a new staff member likely would be recov-

ered within a few weeks. Smaller plans need to consider relying on a consulting firm or coalition but first must be sure the retained entity has appropriate experts on staff, which is not always the case.

Finally, virtually all plans will likely need to amend or entirely replace existing contracts with their PBM or with a coalition because such contracts typically preclude plans or coalitions from addressing marketplace changes. Contracts typically state that plans or coalitions:

- Are obligated to use the PBM's standard formula. Otherwise, the contract's price guarantees will be lost.
- Have no right to review, let alone change and improve, the PBM's prior authorization, step therapy and quantity limit programs
- Are stuck with whatever pricing terms and guarantees exist in the contract at its inception, meaning the contract's existing financial terms are soon outdated and the plans and coalitions are without any price protections for all specialty drugs that enter the market during the three-year contract period
- Are subject to the PBM's “exclusive right” to determine and manage all prescription coverage matters.

Below is a description of the cost challenges every plan needs to track—and address—to control plan costs, together with key contract terms every plan should put in place.

Exponential Increases in Drug Prices

During the first six months of 2015, the list prices of five brand drugs as well as several hundred generic drugs increased by 100% or more. The list prices of another nine brand drugs and several hundred more generic drugs increased by 50% to 99%. None of those changes was unusual; drug prices have increased exponentially for years.

A plan or coalition that is aware of both steep price increases and lower cost alternatives is in a position to eliminate coverage for certain drugs. At the very least, the plan can create new prior authorization or step therapy programs to require plan participants to try lower cost alternatives before resorting to more expensive drugs.

The diabetes drug Glumetza® ER exemplifies why this is necessary. During the first eight months of 2015, Glumetza's average wholesale price (AWP) increased by 800%. Factoring in a PBM's approximate discounts,¹ the net costs of a 30-day supply of this drug at each of two dosage levels suddenly shot up to about \$3,300 or \$6,600.

But a plan need not accept such inflated costs. Several far less expensive diabetes drug alternatives are available. Depending on the total dose needed, the net cost of a 30-day prescription of generic metformin ER is approximately \$9 or \$17. By encouraging the substitution of metformin for Glumetza, a plan could save almost \$3,300 or \$6,600 per patient per month.

A plan participant who finds metformin ineffective can add or substitute several other diabetes drugs, all far less expensive than Glumetza. A plan can entirely stop covering Glumetza and be confident every participant can find a lower cost means to control his or her diabetes.

Another example is Pennsaid®, a topical painkiller approved for osteoarthritis knee pain. Its price increased by 493% in less than a year, raising Pennsaid's total net monthly cost² to approximately \$1,400. A plan aware of this price increase could end coverage or at least steer participants to an OTC pain reliever for a few dollars a month or, if need be, to prescription Voltaren® Gel with a net monthly cost under \$100.

Similarly, although numerous generic antidepressants are now available, the prices of two brand antidepressants—Wellbutrin XL® and Pristiq® ER—increased by 65% and 20%, respectively, in less than a year. As a result, Wellbutrin's total net monthly cost per prescription is approximately \$3,900, and Pristiq's is about \$600. The generic of Wellbutrin XL—bupropion XL, with a net monthly cost of about \$145—is an obvious alternative to Wellbutrin XL. For Pristiq, it's the generic of Effexor® (venlafaxine HCL ER), with a net monthly cost of

about \$100 or \$200 depending on dosage level. Eliminating or discouraging Wellbutrin use could save about \$3,755 per patient per month. Taking similar action in connection with Pristiq would result in per patient per month savings of \$400-\$500.

As these examples demonstrate, there *are* often therapeutic alternatives to drugs with astronomical price increases. And plans *can* save large sums of money—per person per prescription—if they learn about and respond to the price increases.

Until then, manufacturers likely will continue to feel free to raise prices exponentially. Most plan participants and their doctors know little about drug prices and have no incentive to care about them, which leads to a final point every plan should consider:

With appropriate information, consumers can understand outrageous situations and will do their part in responding to them. Remember when everyone threw trash from car windows, people dropped cigarette butts onto sidewalks, kids rode bikes without helmets, and seat belts were rarely buckled? Today, such conduct largely has changed because people obtained new information and altered their thinking and actions.

If plans and coalitions provide information about price changes to plan participants and urge them to take price into consideration in their drug choices, it's likely participants will respond, which may be the key to forcing manufacturers to change their conduct.

New Brand Drugs

During the first eight months of this

year, FDA approved 151 novel drug products. As is always the case, very little is known about the efficacy or safety of newly approved drugs. The FDA approval process is based on limited clinical trials—typically lasting only a few weeks or months and usually conducted on only a few hundred or a few thousand people. Moreover, nothing is known about the long-term safety issues that may arise when certain drugs are used as “maintenance” drugs for many years. For these reasons, serious problems may arise for patients who take newly approved drugs.

A 1990 General Accounting Office report counted 130 FDA-approved drugs that were withdrawn from the market over a nine-year period because they were deemed unsafe and often lethal.³ A recent study showed that of 522 novel drugs approved from 1996 to 2012, 11 were withdrawn from the market given safety issues and 75 received postapproval black box warnings. The median time from approval to withdrawal or first boxed warning was 4.2 years,⁴ meaning physicians prescribing—and patients taking—new drugs during the first several years after approval often were missing critical safety information.

Despite these facts, doctors widely prescribe new drugs, undoubtedly because of manufacturers' extensive marketing efforts to both doctors and the public.

It's also important to note that doctors often prescribe drugs for uses beyond those FDA has approved.

In July 2015, FDA approved Entresto™ based on evidence the drug was effective in treating heart failure in individuals (1) who have *reduced ejection fraction*, meaning the heart ventricle

chamber pumps out 50% or less of the blood in the chamber with each heart-beat; and (2) whose condition is classified as NYHA Class II-IV, meaning, at the very least, that ordinary physical activity causes fatigue, palpitation or shortness of breath. In other words, Entresto was approved based on evidence showing it could help heart failure patients who are very ill.

But doctors may prescribe Entresto to millions of other patients whose heart problems do not rise to the described levels. There's no evidence Entresto will be effective for those patients, knowledge is limited at this time about its potential side effects and dangers, and Entresto's likely discounted cost of approximately \$480 per patient per month could greatly increase plans' total costs over time.

FDA last summer approved two new PCSK9 cholesterol-reducing drugs, Praluent® and Repatha®, for certain specified indications. However, doctors may prescribe them to millions of others who simply have high cholesterol, potentially exposing them to unknown dangers. Caution would suggest that a

slower usage uptick would be wise, as it would allow more to be known about these drugs before millions are exposed. That's especially true given these drugs' cost of approximately \$1,250 per month, or \$15,000 per year.

A plan that wishes to protect participants from unnecessary risks, as well as conserve plan assets, needs to track new drugs and ensure its PBM puts in place effective prior authorization and step therapy programs. These programs should steer participants to "tried-and-true" medications before they try new drugs. The programs also should make certain that new drugs are used for their approved "indications." And for those drugs that aren't breakthrough treatments providing remedies that would otherwise be unavailable, a plan might consider delaying coverage until more is known about them.

When implementing all these procedures, every plan should explain its actions to participants by conveying a simple message:

The "latest" is not necessarily the "greatest" when it comes to taking

drugs. While it may make sense for a participant to take risks if he or she can't address a health issue without resorting to a new drug, in all other instances it makes more sense to act conservatively and try drugs that have long been on the market. Otherwise, plan participants may find themselves serving as manufacturers' guinea pigs.

Addressing Problems Related to New Specialty Drugs

Because almost no PBM/client contracts contain any pricing terms for newly approved specialty drugs, these drugs pose two additional problems for plans: (1) When these high-cost drugs enter the market, PBMs can charge any prices they want, and (2) when PBMs negotiate price reductions from manufacturers for these drugs, PBMs have no contractual obligation to pass price reductions through to plans.

The three new hepatitis C drugs—Sovaldi®, Harvoni® and Viekira Pak™—exemplify both problems.

When these drugs entered the market between December 2013 and December 2014, PBMs could invoice plans at whatever prices PBMs chose. And they did. Based on an analysis of several PBM clients' claims data, it appears most plans were being charged more than the list prices reported in the media.⁵

Moreover, when PBMs reportedly extracted large price reductions from the hep C drug manufacturers in December 2014 and January 2015, PBMs weren't obligated to pass through those reductions to their clients. Based on an analysis of client data, few plans appear to have reaped the benefits of those re-

takeaways

- Health plan sponsors may want to hire a staff member or use a consultant to keep track of pharmaceutical marketplace changes.
- Contracts with a PBM or coalition may need to be amended or replaced to allow a plan to address these changes.
- A plan that is aware of very steep price increases in a particular drug is positioned to take advantage of lower priced alternatives.
- Because often long-term dangers aren't known about newly approved drugs, a plan may want to be sure its PBM has effective prior authorization and step therapy programs in place or delay coverage until more is known.
- Plans need to be in a position to benefit from price discounts on specialty drugs.
- As new, easily accessible and less expensive OTC drugs become available, a plan needs to take advantage of them as quickly as possible.

ductions. And to this day many plans are still being invoiced without price reductions.⁶

A plan that checks its own claims data likely will find that when each of these drugs entered the market—and thereafter—the plan was invoiced at or relatively close to the prices reported by newspapers, or more than \$80,000 per person per 12-week treatment. And the invoiced price probably didn't change, even after the PBM purportedly negotiated steep discounts for these drugs.

Making matters worse, after the PBM negotiated discounts with manufacturers, it's very possible that the plan's claims data reflected an increased number of hep C drugs dispensed. That's because several PBMs appear to have agreed to weaken—or eliminate—their prior authorization programs in exchange for obtaining price reductions from the manufacturers (which PBMs typically didn't pass through to plans). As a result, several PBMs are no longer restricting hep C drug access to those patients who really need the drugs, meaning many plans are paying for far more drugs.

To prevent all these consequences from taking place with new, high-cost specialty drugs, most plans need to change their PBM or coalition contracts to ensure they contain the following terms:

- A stated automatic “default discount guarantee” that the PBM must satisfy every time any new-to-market specialty drug is dispensed from a specialty pharmacy
- The plan's “right to renegotiate” and improve any specialty drug discount, if and when the plan learns that better discounts are available
- The plan's “right to carve out” any drug and have another vendor dispense it, should the plan believe its PBM has failed to provide competitive discounts (which will provide the plan with leverage to negotiate better discounts)
- The right to review any PBM prior authorization, step therapy and quantity limit program to verify that all programs are in the plan's interest and to customize any program if need be.

Together, these contract terms will position a plan to respond effectively to the costs of new specialty drugs.

Combination Drugs

Manufacturers are creating an increasing number of “combination” drugs. Often, these combo drugs add no in-

cremental value other than the convenience of enabling an individual to take one drug instead of two. Unfortunately, their price tags typically don't reflect that fact.

Vimovo® is an example. Approved in 2010, the drug combines naproxen (Aleve®) and the proton pump inhibitor (PPI) esomeprazole magnesium (Nexium®) in a single tab-

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let. Vimovo's claim is that patients who are trying to relieve arthritis or other pain with Aleve can avoid potential stomach problems from the Aleve by having Nexium in the same tablet. But Aleve and Nexium can be purchased separately over the counter at a relatively modest cost—under \$40 per month.

In contrast, the AWP list price of Vimovo is almost \$30 per pill. Since doctors typically prescribe two pills daily, a 30-day prescription of 60 pills carries a total net cost of approximately \$1,400. Vimovo's price tag makes clear why plans should ask participants to take the two pills separately.

Another drug, Duexis®, combines ibuprofen (Motrin®) and famotidine (Pepcid®), both of which are also available over the counter. Duexis' AWP list price has increased by more than 40% during the past nine months, resulting in a current per pill AWP of almost \$20 and a total 30-day net cost (factoring in a PBM's approximate discounts) of more than \$900. Wouldn't it be fair for a plan to ask participants to buy the two products separately over the counter, for a cost of under \$15 per month?

bio



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Notably, several of the FDA's new drugs in 2015 have been combo drugs of dubious value, especially given lower cost alternatives. For example, Prestalia® combines an ACE inhibitor and a calcium channel blocker to address blood pressure issues. In their generic forms, a 30-day supply of the two drugs would cost about \$30. In contrast, a 30-day supply of Prestalia costs about \$165.

Given that approximately three million people are using these drugs in combination, plans' added cost from allowing participants to use this convenience "combo" product makes little sense, especially given the need for all plans to preserve their resources to provide real value to plan participants.

Drugs the FDA Hasn't Even Approved

At the turn of the 20th century, before the federal government controlled the manufacturing or marketing of drugs, doctors were prescribing numerous drugs that purported to cure anything and everything imaginable. More than 15,000 potions were being sold, with names like Lydia E. Pinkham's Vegetable Compound, Mrs. Winslow's Soothing Syrup and Swaim's, which claimed to cure "cancer, scrofula, rheumatism, gout, hepatitis and syphilis."

Fast-forward 100 years and drugs must now be approved before they can be marketed, but vendors can still combine and apply drugs in ways that have never been tested. For example, vendors are taking oral medications and using them to create "pain patches" even though there's no scientific evidence that these patches actually work.

Accordingly, a plan that is covering unapproved pain patches like Sinelee®, QRoxin and Reciphexamine may be wasting a considerable sum of money, since these pain patches typically

cost more than \$4,000 per script. Notably, lidocaine patches with proven efficacy are available at a cost of about \$700 for a monthly supply of 90 patches, and far lower cost OTC oral pain relievers may also relieve the relevant pain.

Note that it's not enough to eliminate these three products. New versions are continuously entering the market. Therefore, to avoid squandering money on an ongoing basis, a plan must position itself to play whack-a-mole and end coverage of all such products as they enter the market.

New OTC Drugs

Most plans may not be aware that they can now rationally end coverage of all prescription drugs—brand and generic—in three therapeutic categories: PPIs, non-sedating antihistamines and intranasal steroids. That's because nearly all pharmacies carry several OTC PPIs (including Prilosec OTC®, Prevacid®, Zegerid®, Protonix®, omeprazole and, most recently, Nexium). Moreover, most pharmacy shelves are also well-stocked with OTC non-sedating antihistamines (like Claritin®, Allegra® and Zyrtec®) and intranasal steroids (like Flonase®, Nasacort® and fluticasone).

Note that if a plan provides coverage to individuals with very low incomes, it could end prescription coverage for the drugs in these categories but still cover the OTC drugs. However, given the higher cost of the prescription products, there's absolutely no reason for a plan to cover them.

When new, easily accessible and less expensive OTC drugs become available, to protect plan assets, a plan needs to be aware and take advantage of these drugs as quickly as possible.

Brand Drug Patent Losses and Newly Available Low-Cost Generics

Plans can also ensure savings by monitoring brand drugs' loss of patents and the marketplace entrance of therapeutically similar generic drugs. When a brand drug loses its patent, prices typically remain high during the 180-day period when a first-to-file manufacturer is the only entity allowed to market a generic drug. However, when other generic manufacturers enter the market thereafter, generic prices typically plummet.

Unfortunately, many PBMs fail to track falling prices and continue to invoice clients at higher prices for many months. A study conducted on three drugs—the generics for Lipitor®, Zyprexa® and Seroquel®—showed that several PBMs were still

dramatically overcharging their clients for these drugs several months after available generic prices had taken a nosedive.⁷

To ensure a plan maximizes savings from new low-cost generics, a PBM contract with a plan or its coalition must allow the plan or coalition to:

- Obtain a complete set of claims data at least monthly
- Review the data to determine the prices the plan is being invoiced for newly available generic drugs
- Require that the PBM, if the plan or coalition discovers its PBM is ignoring falling prices and failing to reduce invoiced costs, provide the plan or coalition with a “right to negotiate discounts” for these drugs.

Conclusion

Changes are occurring relentlessly in the prescription drug marketplace. Unless a plan puts itself in the position to learn about—and respond to—all such changes, it is likely to find itself in serious trouble and without the ability to prevent skyrocketing costs. 📍

Endnotes

1. Since every PBM/client contract contains its own AWP discounts for drugs, the drug prices stated in this article represent estimates of the amount a plan may actually be paying. Unless otherwise indicated, estimates are as of late August 2015. Note, too, that some PBM/client contracts contain no discounts whatsoever for some drugs, meaning the prices indicated in this article may significantly underestimate the amount a plan may be paying.

2. In the remainder of this article, rather than repeating in each instance that “net costs” factor in a PBM’s estimated AWP discounts, the term *net costs* is used to reflect that fact. Because PBMs refuse to disclose which drugs result in rebates—let alone the amount of rebates passed through to a client—“net cost” figures factor in approximate discounts but do not include rebates.

3. U.S. General Accounting Office. Report to the Chairman, Subcommittee on Human Resources and Intergovernmental Relations, Committee on Government Operations, House of Representatives. *FDA Drug Review: Postapproval Risks 1976-85*. April 26, 1990. Available at <http://archive.gao.gov/d24t8/141456.pdf>.

4. M. Rosenthal, “A Life Preserver for the Flood of Boxed Warnings,” *Pharmacy Practice News*, October 2014, available at www.pharmacypracticenews.com/ViewArticle.aspx?d=Policy&d_id=51&i=October+2014&i_id=1112&a_id=28492.

5. L. Cahn, “Focus on the Patent Cliff to Maximize Generic Savings,” *Managed Care*, November 2012, available at www.managedcaremag.com/archives/1211/1211.generic_pricing.html.

6. Ibid.

7. Ibid.