

Academy of Managed Care Pharmacy

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The Academy of Managed Care Pharmacy (AMCP) Managed Care & Specialty Pharmacy Annual Meeting, held March 27 to 30 in Denver, drew 4,000 managed-care pharmacy professionals and stakeholders. Selected highlights follow.

Pharmaceutical Marketplace Trends: Dollars Down, Hurdles Up

- Douglas M. Long, MBA, Vice President, Industry Relations, QuintilesIMS, Ponte Vedra Beach, Florida

In 2016, dollar growth in drug spending decelerated, prescription growth accelerated, and 90-day prescriptions rose to 14% of all prescriptions written (a trend that will continue except in the specialty space).

After double-digit growth in 2014 and 2015, 2016 saw 6% market dollar growth. Much of the decline stems from a \$3 billion drop in sales of hepatitis C treatment as this market matures and managed care organizations tighten controls. Additional declines stemmed from patent expirations for notable drugs, such as esomeprazole (Nexium, AstraZeneca), rosuvastatin (Crestor, AstraZeneca), and aripiprazole (Abilify, Otsuka). Generic sales dropped from \$69 billion in 2015 to \$67 billion.

The most seismic shifts in 2016 stemmed from pricing and politics. For instance, Mylan's branded EpiPen drew attacks for its \$600 list price. But very few people pay list price, and the negotiated price was less than \$300.

According to a recent Pharmaceutical Research and Manufacturers of America analysis, total retail and nonretail (physician-administered) drug sales have held steady at 14% of U.S. drug spending since 2008 and are expected to remain at this level through 2024.¹

Presentations at the meeting showed that the trend toward "managed costs" over managed care is changing slowly. For pharmaceutical companies, formulary access is getting harder, taking longer, and yielding less satisfactory results. Today's reality is half the access at twice the cost. Formulary restrictions and blocks have become more widespread. In a climate where differentiation no longer guarantees access, rebates have skyrocketed. With the growing debate over drug costs, manufacturers and pharmacy benefit managers are feeling pressure because rebate negotiations have obfuscated the real cost of drugs.

Net sales pressure comes from high utilization management, restrictive formularies, changing benefit designs (with higher copays and deductibles and increased use of prior authorization) and use of patient savings programs. As a result, manufacturers' list prices and net prices have never been further apart.² Discounts deepen every year—the closer to patent expiration, the larger the rebates.

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QuintilesIMS estimates that patient savings programs now constitute \$8.3 billion in manufacturer expenditures, up from \$1.9 billion in 2013. The average budget percentage for all brands is 19%, up from 13% in 2013. How does this change manufacturers' mindsets? A decade ago, drug companies sold their products to doctors. With drug coverage continuing to fall, manufacturers have shifted their attention to payers.

Based on a QuintilesIMS conference in March, access trends can generally be characterized as: stricter payer management; higher patient out-of-pocket payments; continuing criticism of drug prices; and increasing use of value-based reimbursement models. In the next five to 10 years, pharmaceutical companies that can't demonstrate improved outcomes will likely lose sales.

However, we are approaching a tipping point of payer price sensitivity and willingness to reimburse. Managing that balance will be crucial. The coming decade will witness a shift away from deep rebate programs and a move toward greater price transparency and increased management of medical benefits. For 2017, branded drug list prices will grow by no more than single digits, with net prices rising in the range of 2% to 5%.

Addressing Affordability Crisis Demands Better Data, Realistic Expectations

- Steven G. Avey, MS, RPh, FAMCP, Vice President, Medimpact Direct Specialty Clinical Programs, San Diego, California

The promise of the human genome—that knowing its sequence would enable pharmaceutical developers to target much more specific patient populations, perhaps avoiding side effects and identifying specific patients for whom a drug might work best—is coming true. The past five to 10 years have witnessed the development of cancer drugs and other medications with companion diagnostics—genetic tests to determine which patient populations will benefit most from particular drugs. But this advance has narrowed the marketability of specific therapies to smaller groups at much higher prices than anyone anticipated, particularly in the specialty sector.

In response, managed care organizations first raised copays on specialty medications to levels well above those of non-specialty medications. "Copays have always been somewhat of a conundrum for us because we know that it is important that members have a stake in the game," Avey said. Yet exorbitant copays can reduce adherence.

Copays of \$10 or \$25 for nonspecialty drugs typically represent 25% to 30% of actual drug costs. But in the specialty arena, even higher copayments typically cover no more than 2% of the medication's cost. The real difficulty comes with the growth of high-deductible plans. Members must pay 100% of drug costs until they meet their deductible, and they will delay getting medications or won't take them appropriately. For patients struggling with copays, manufacturers offer coupon programs.

One way to manage specialty spending is to avoid waste. This means ensuring that a drug is appropriate for a particular member, is being taken at the proper dosage, and, in certain

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areas (such as oncology), is being taken with the right combination of other medicines. It also means ensuring that patients don't discontinue therapy early. This is particularly important in hepatitis C, which typically requires a full three months of dosing.

Medication adherence is complex. Many consultants tell clients with 80% adherence that they should be at 90% or higher. Very high adherence matters in some therapeutic classes, such as hepatitis C and human immunodeficiency virus (HIV). But with many other therapies, Avey said, "There is no evidence that pushing beyond that 80% mark adds any clinical benefit. In those cases, we don't want to focus more on reaching 80% or 90%. We want to look for the people who are under 50% or 60% adherence. We know that those patients are not getting the full benefit of the drug, and perhaps no benefit whatsoever."

Increasing adherence increases drug spending, which leaves payers wondering what they get in dollars and cents by raising adherence. With specialty medications, no robust studies have shown that high adherence lowers medical costs. With HIV, studies have shown that high adherence rates improve health status to a level where patients may need fewer medical services. But generally, it's important to set proper expectations with a payer, so they understand that increasing adherence improves health status but will not necessarily reduce medical spending.

To regain some control, payers are beginning to use risk-sharing arrangements with pharmaceutical companies that tie contracts to outcomes. If a pharmaceutical company prices its drug at a certain level, saying that it expects a certain number of patients to see improvement, post-marketing evidence might show the benefits to be somewhat smaller. To link contracts with outcomes, pharmacy benefit managers and health plans need to provide much better reporting. But there are many opportunities to show that a given medication reduces side effects or exacerbations, for example. "We have contracts with our specialty pharmacies through which we hold their feet to the fire on adherence, with class-specific performance measures they must meet," Avey said. "Enacting such programs could help payers better manage their specialty spend without sacrificing or disrupting patient care."

Value-Based Contracting Faces Hurdles

- Michael Ciarametaro, MBA, Vice President of Research, National Pharmaceutical Council, Washington, DC

The meaning of drug-spending increases and the value of a particular drug rest largely in the eye of the beholder. Although people often use the terms affordability, value, and budget impact interchangeably, these concepts differ vastly. Affordability is the ability of a person or organization to purchase a good or service, as determined by their available budget. Value measures cost relative to benefit, and budget impact measures resources used with no reference to benefit.

Affordability depends on the stakeholder's viewpoint. Patients focus on their out-of-pocket expenses, Ciarametaro explained, or their ability to purchase a medicine or health care service. Purchasers focus on their ability to pay premiums for both risk protection and health care access. And society focuses on the ability to pay for improved population health, versus competing priorities such as highways and police.

Underlying the idea that increased drug spending is inherently negative is the assumption that it's possible to determine whether society is paying the right amount or too much for drugs. Because no one has definitively determined how much we should spend, he said, there's no objective yardstick to support such judgments. What is clear, he said, is that most of the improvement in health outcomes in the past 20 years has come from improved drugs. If one considers diseases that historically caused the greatest disability and death, such as ischemic heart disease and human immunodeficiency virus, we have seen significant drops in mortality and disability-adjusted life years—driven most often by effective medications.

Drug innovation also drives increased drug spending. Although protected brands and generics contribute around 40% of drug-growth dollars,² a larger proportion stems from new products reaching the marketplace. The number of drugs coming off patent peaked around 2012, Ciarametaro said, and the savings associated with generics decreased between 2012 and 2015. "Then we saw some greater uptake of branded products, and a very significant increase in the amount of the brands coming to the market. Within the last five years, the lion's share of actual increases has to do with new products coming to market."

He suggests that payers base coverage decisions and benefit design on value. "And there is no single value for a drug," he said. If one breast cancer drug provides overall survival (OS) equivalent to standard of care, but with much less toxicity, patients may experience significantly more symptom-free days. Another drug may provide significant OS improvements, but at the cost of increased toxicity. How patients value these therapies will depend on how they prioritize quality of life versus OS, Ciarametaro said. "As you're designing your formulary, when those differences exist, you must take them into account."

To simplify the value discussion, he suggested that the pharmaceutical industry structure development efforts from the start around items that matter to payers and patients. For example, he said, drug labels often use intermediate measures for parameters such as hemoglobin A1c. While these measures correlate with payers' budgets, contracting based on hospitalization or emergency department visits would provide a much clearer link. "That's one of the benefits of value-based contracting outside the label."

However, he said, the U.S. health care system lags in adopting value-based contracting because of legal concerns related to contracting outside of Food and Drug Administration–approved labels, among other issues. Other regulatory concerns involve Medicaid's best price, average sales price, and antikickback statutes. "Each of those creates disincentives for setting up value-based contracting, which is one of the primary reasons why we haven't seen greater adoption of those types of vehicles in the United States," he said.

REFERENCES

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