PCMA 2016 *PBM Policy Forum*

Market-Based Solutions for Lowering the Cost of Prescription Drugs

During the Pharmaceutical Care Management Association's (PCMA) annual *PBM Policy Forum*, industry leaders convened to discuss policy solutions to burgeoning drug prices. Speakers focused on market-based solutions such as the use of biosimilars, specialty pharmacies, and value-based contracting, as well as managing costs in the medical benefit. Presentation summaries are below.

How Policymakers Can Leverage Competition to Reduce Rx Costs

Mark Merritt - *President & Chief Executive Officer*, PCMA

Recognizing that high drug prices is one of the thorniest and more prevalent issues in healthcare today, Mr. Merritt kicked off the discussion by acknowledging that business practices and policy solutions need to preserve patient access at affordable costs.

"The drug pricing debate involves more than the unit price of drugs. In building on PBMs' success in managing drug trend in the commercial market, we must create more competition in the market, align incentives for prescribers, patients, and payers alike, and reduce the costs of pharmacy services," Mr. Merritt noted.

To create the appropriate market-based solutions to lower the cost of prescription drugs, Mr. Merritt highlighted the importance of the FDA's role in approving generics and competing brands as quickly as possible, the necessity of building out value-based purchasing contracts, and modernizing Medicare Part B away from its current unmanaged fee-for-service payment model.

Additional solutions for high drug prices that policymakers could consider include:

- Accelerating FDA approvals of drugs that face no competition;
- Making copay coupons an illegal kickback for all insurance that receives any federal subsidy;
- Modernizing Medicaid pharmacy to make it more like the commercial market and Medicare Part D;
- Creating new incentives for physicians to prescribe biosimilars; and
- Avoiding "any willing pharmacy" mandates that limit specialty pharmacy options and undermine patient safety.

Managing High Impact Pipeline Drugs: Evolving Payer Considerations

Farrah Wong - *Director, Pipeline and Drug Surveillance*, OptumRx

Over 70% of the total pharmacy drug spend is represented by five disease states: inflammatory conditions, hepatitis, multiple sclerosis, HIV, and cancer. Each of these rely heavily on the use of specialty medications. Incentives developed through the Orphan Drug and Accountable Care Acts continue to drive novel drug development.

With over 1,900 biologic drugs in the pharmaceutical pipeline, costs to the healthcare system are anticipated to continue rising.

Whereas traditional medications require 2 to 3 years of development time and $2 to 5 million in developmental costs, biologic drugs require over 5 years and $100+ million to be developed. With these high costs, very few manufacturers have the resources to develop biosimilars, thus resulting in reduced competition across the biologics market.

PBMs closely analyze pipeline data for the early identification and management of key drugs that are anticipated to have a significant cost impact on health plans and other payers. By overlaying this data with anticipated clinical outcomes, clinical expert consultations, and treatment guidelines, PBMs are able to forecast the estimated utilization and costs of these drugs in advance and develop programs that address potential patient adherence barriers.

Nevertheless, the incentives provided through Medicare's protected classes are continuing to drive the development of high cost cancer drugs. Dr. Wong described how protected classes create incentives for manufacturers to develop treatments for niche indications that yield high returns on investment long-term. Many of these drugs are approved based on surrogate endpoints that may suggest long-term survival benefits, but the real outcomes are never known until several years later.

PBMs require more outcomes data from manufacturers to ensure these treatments are safe, effective, clinically appropriate for patients, and can increase patient survival. Improved outcomes data and competition in the market will allow PBMs to continue identifying the most effective treatments for patients while ultimately lowering costs.

What Makes Specialty Pharmacies Special and Why They Are Crucial to the Future of Drug Cost Management
Everett Neville - *Senior Vice President, Supply Chain*, Express Scripts

Describing the role and value of specialty pharmacies, Mr. Neville highlighted the creation of specialty pharmacies in the late 1980's to provide a new, intricate level of service to patients with rare and complex diseases.

If used inappropriately, specialty drugs may cause significant side effects and other health problems for patients. Mr. Neville estimated about $300 billion a year is wasted by patients not taking their medications correctly or taking the wrong medications, resulting in additional medical costs, increased hospital admissions, adverse side effects, and Emergency Room visits.

Compared to traditional pharmacies, specialty pharmacies contain costs and manage more complex criteria for patients using specialty drugs. When specialty pharmacists guide patients through each step of their treatments, and apply PBM

tools to the process, these pharmacies achieve markedly different impacts on clinical outcomes and cost reductions from unmanaged patient care, up to a 50% difference in trend.

Specialty pharmacies implement payer plan design while monitoring the safety and effectiveness of medications in everyday environments. For example, even though two equally effective hepatitis C medications were on the market, Mr. Neville described how specialty pharmacies helped patients adhere to a more complicated daily regimen that resulted in fewer side effects, instead of forcing patients to take a less complicated, but more side effect prone regimen. These PBM-led actions resulted in cutting the price of therapy in half, saving the health care system $5 billion dollars.

Similarly, the treatment of high cholesterol requires a right patient, right drug, right time approach. With specialty medication options costing $14,000 per patient per year, specialty pharmacies used PBMs' limited networks and step edits to properly identify patients who would benefit most from these PCSK9 Inhibitor medications and ensure their use was closely monitored. With their access to patient lab results and records, specialty pharmacies generated a 90% difference in spend for managed patients, compared to unmanaged care in a traditional pharmacy setting.

Many pharmacies call themselves specialty pharmacies, but they do not dispense or oversee the appropriate use of actual specialty medications. There are hundreds of "captive" pharmacies that specialize in dispensing a limited number of medications for select manufacturers. These pharmacies instead specialize in evading benefit design, and cost the healthcare system a great deal. Those in the industry take great offense at having these pharmacies referred to as "specialty pharmacies."

Mr. Neville concluded by saying that as an industry, we need to focus more on what a specialty pharmacy is. Specialty pharmacies employ highly trained pharmacists who work with high need patients and provide around-the-clock life-saving treatment and support.

Managing the Escalating Cost and Utilization of Medical Benefit Drugs
Alan Lotvin - *Executive Vice President, CVS/specialty*, CVS Health

Medical pharmacy management involves drugs paid under the medical benefit, and are more commonly recognized in Medicare as "Part B" drugs. Dr. Lotvin estimated that approximately 50% of drug spend is comprised of specialty drugs. Half of this spend is administered and paid for under the medical benefit, and two-thirds of these medical benefit drugs are used to treat cancer. With the cost of these drugs increasing dramatically in recent years, it is necessary to identify solution-oriented approaches that manage costs to best preserve patient care and access. PBMs have led the way in developing solutions to drug management in the medical benefit.

PBMs encourage the use of prior authorization tools in the medical benefit. Dr. Lotvin explained, "by using relatively non-aggressive prior authorization, it's possible to take out 3% of the drug spend under the medical benefit." This involves simply limiting medication approval to all medical guidelines and allowing physicians to bring forth peer-reviewed evidence to receive medication use approval. Dr. Lotvin went on to point out that "when applied to the Medicare population, this could save $1.3 billion. Without impairing or restricting care, it is possible to make a huge impact on the budget with a relatively small amount of work."

Technology provides visibility and control of price variation under the medical benefit. PBMs use these systems to assess how much health plans are paying for medical benefit medications and have identified vast variations caused by mistakes in claim submissions and even fraud. Through claims systems, PBMs can limit inappropriate, excessive payments and save payers 2 to 4% on overall costs. By applying these post-service, pre-payment edits to the Medicare population, patient care would not be affected, yet significant savings would result.

Dr. Lotvin highlighted the value of better aligning physician incentives to choose the right products for their patients. With the tremendous degree of consolidation in cancer care, physicians have gained more market power, thus creating issues with patient access and managing expenses. In an environment where medications are reimbursed in a cost plus system, physicians are incentivized to choose the most expensive products. Manufacturers are similarly incentivized to price drugs higher to create a greater degree of margin and attractiveness for these physicians.

"The idea of aligning the physicians' incentives with the payers' incentives is good, and I understand the restrictions and the challenge that [CMS] faces in moving structures. We need to think about how this plays into the marketplace with respect to access to oncologists, follow-on impacts on drug selection, and follow-on impacts on potential pricing strategies from other economically rational actors," Dr. Lotvin concluded.

The Challenges of High Cost Drugs for Medicare
Sean Cavanaugh - *Deputy Administrator & Director, Center for Medicare*, Centers for Medicare & Medicaid Services

Mr. Cavanaugh addressed how CMS is now thinking about prescription drug utilization, management and costs. "The Medicare Part D program is in great shape, with over 40 million beneficiaries receiving benefits, and premiums having been essentially stable since the passage of the Affordable Care Act. We have been touting the successes of the program and rightfully so, with many in this room having helped contribute to the success of this program, and we thank you."

Medicare Part B is an important source of drugs for beneficiaries and has been growing rapidly, with the size of the Part B spend doubling in recent years. In

January 2015, Secretary Burwell announced goals for the transformation of Medicare payment, calling to move all Medicare fee-for-service (FFS) payment systems to value-based models. CMS has already achieved transitioning 30% of all FFS systems, with all other systems moving this direction.

In determining how to achieve the greatest value from prescription drugs, CMS is focusing on how to define value and restructure programs to derive the greatest value from the system. Five guiding principles include:

- Increasing prescription drug payment transparency, with the recognition of respecting proprietary company information.
- Implementing value-based payment models across the healthcare system and policies that support these models for prescription drugs.
- Aligning incentives toward value from beneficiaries all the way up the chain to manufacturers.
- Balancing access with affordability in Medicaid programs when state infrastructure projects challenge patients' access to drugs.
- Strengthening CMS' role in the drug approval and innovation processes.

In addressing CMS' recently proposed payment model for Part B drugs through the Innovation Center, Mr. Cavanaugh described the potential models that will be used to pay for Part B drugs in light of the penalties that currently exist for physicians who would like to prescribe lower cost drugs. These proposed programs are not intended to "create an incentive for physicians to use higher cost drugs, nor tilt unfairly toward lower cost drugs, but to try and hit a sweet spot of neutralizing the incentives so that physicians' decisions really aren't made with profit or financial incentives, but clinical incentives."

Equally important, since the Part B benefit is an unmanaged benefit, CMS is proposing a series of processes and tools that could be used to better manage costs, including indication-based pricing, reference pricing, reduced patient cost sharing to drive adherence, and clinical decision support tools. In looking to improve the use of medications, CMS is requesting feedback that looks critically at the scale, scope, and distribution of these current proposals.

Value-Based Contracting and How it is Being Applied in the Commercial Marketplace for Savings
Chris Bradbury - *Senior Vice President, Integrated Clinical Solutions and Specialty Pharmacy*, Cigna Pharmacy Management

As the industry continues to experience explosive innovation, patients and all stakeholders must be committed to the affordability and sustainability of the healthcare system. Mr. Bradbury highlighted the importance of aligning reimbursement around value instead of volume. "We've taken these (value-based) principles and brought them to certain aspects of the PBM industry because they

hold great short-, medium-, and long-term promise to improving the healthcare of the individuals we care for, but also addressing affordability."

The use of real-world clinical and financial outcomes is driving the acceleration of value alignment. Data beyond what is provided in pharmacy claims can provide insights that enhance decisions and increase competition. Outcome incentive agreements with manufacturers are growing and depend on medical data to assess specialty and chronic condition programs. Many of the current programs focus on downside risk, with manufacturers owing back additional rebates if the drug doesn't perform as expected. To transition these programs to upside risk models, more flexibility from the government will be required to allow drug prices to start lower and then progress upwards based upon performance as more value is recognized.

Value-based contracts usually involve drug categories that have quantifiable, widely accepted outcomes metrics that allow for the assessment of clinical and financial value. Each of the top five specialty drug classes qualify for these innovative contracting options. One of the most important contributions data obtained through these contracts is the direct application of real-world results in informing and shaping ongoing patient care.

Mr. Bradbury emphasized that, "All stakeholders across the industry must come to an agreement on how to approach regulators on how to make this work in a way that manufacturers will be supportive of. Then we can collectively advance the understanding about outcomes and drive to better value alignment over time."

This research-driven path requires trust, collaboration, and a willingness to seek out insights. In the midst of increasing expenditures, PBMs are asking manufacturers to stand by their products in the real world and rely on the support of specialty pharmacies to provide the right support to patients and providers.
"There is a joint desire to research, to have insights, to advance medication treatment to create headroom for the next set of innovations coming down the path that will have a profound impact on hundreds of thousands of lives, and we've got to keep it affordable," concluded Mr. Bradbury.

The FDA's Role in Competition: Streamlining Approval Processes and Facilitating Biosimilars
Rich Moscicki - *Deputy Center Director for Science Operations, Center for Drug Evaluation and Research*, Food & Drug Administration

Mr. Moscicki addressed the FDA's recent advances in expedited review programs, biosimilars, and generic approval programs.

Building on the success of the Prescription Drug User Fee Act (PDUFA) drug approval programs, the FDA is focused on creating an equally robust approval process for biosimilar drugs. As of April 2016, 60 biosimilar programs are in progress with the Biosimilar Development Program (BPD), with two biosimilar

products already having been approved. The division is working to provide guidance to the industry key issues, with eight draft guidances and four finalized guidances already finalized. Two additional guidances will be published this year, including one on the interchangeability of biosimilars.

Despite the success of generic drugs in the market, the Generic Drug User Fee Amendments of 2012 (GDUFA) program was established to modernize the generics approval process. The FDA is now committed to reviewing generic drug applications in 10 months or less, an ongoing challenge given that generic drug applications take on average five rounds of review to be approved. In order to address this significant backlog, the FDA launched a new IT system and hired nearly 1,000 employees, resulting in the elimination of 90% of their initial backlog.

Mr. Moscicki shared that FDA leaders prioritized the approval of backlogged applications based on public health priorities, including those classes with sole source drugs on the market. Although the FDA could not consider the cost of drugs as a prioritization factor, by prioritizing the application of sole source drug classes, the FDA succeeded in addressing competition in the market.

While Mr. Moscicki was not worried about the development of a biosimilar backlog, he raised the concern that the user fees generated by biosimilar drug applications is still small compared to the exponential growth expected in the program. Their priority is determining how to adequately resource the division in light of their anticipated growth. “So far user fees have not put us in complete position to be able to address what we think will ultimately be a very large load. It’s our place to do with what we have.”