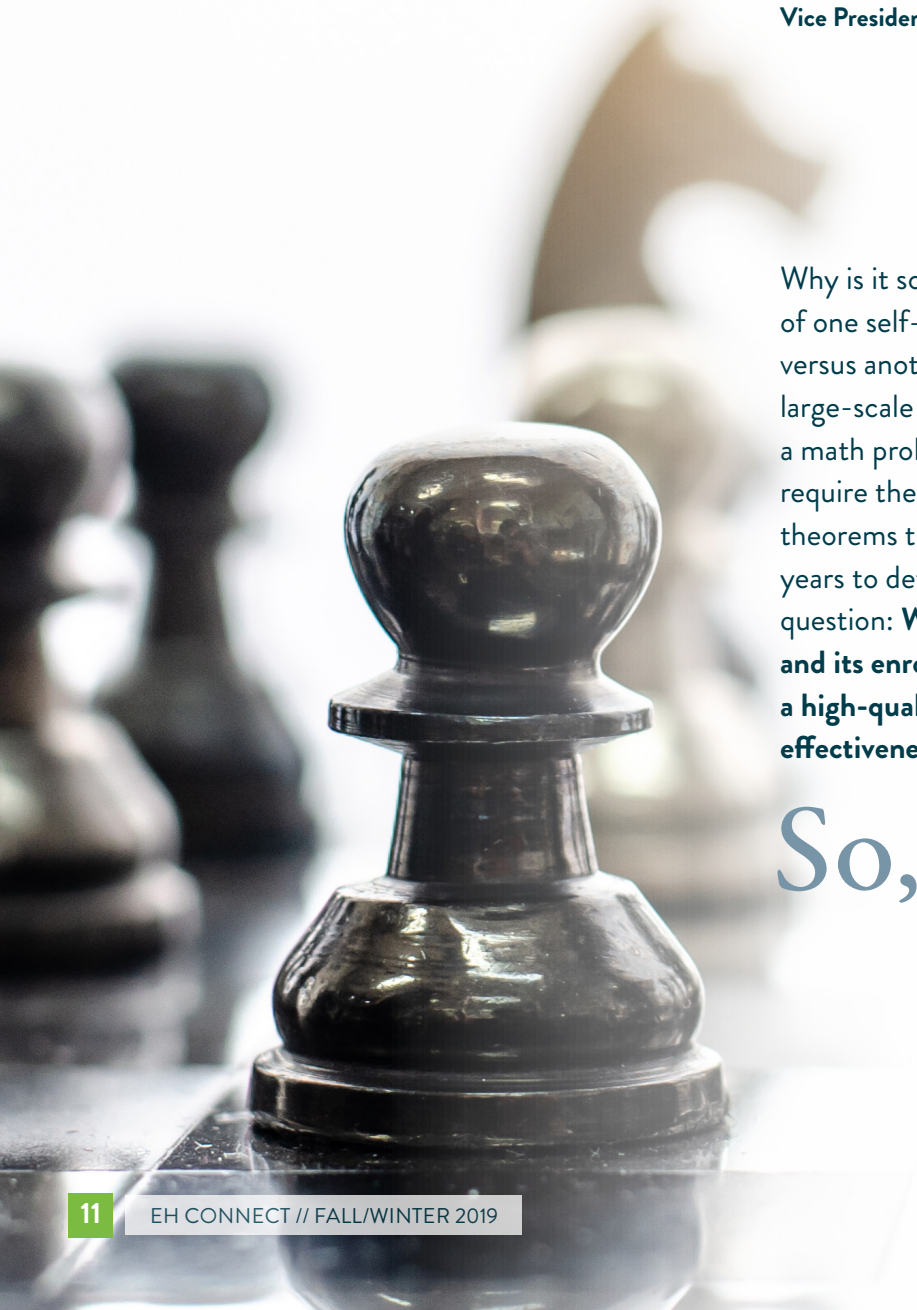
PBM Evaluation Challenges

by David Uldricks, J.D., LL.M. //
Vice President, PBM Contracting and Strategy



Why is it so difficult to determine the value of one self-insured carve out PBM offering versus another? This isn't a life riddle or a large-scale socio-economic question. It's a math problem. As such, it should merely require the application of mathematical theorems that have existed for thousands of years to determine the answer to one basic question: **Which PBM will charge the plan and its enrollees the least while still providing a high-quality benefit in terms of clinical effectiveness and access.**

So, why is this so hard?

To start, the pharmacy benefit is, and always has been, very complex. Every person covered under a benefit plan has his/her own unique set of treatment needs, and there always have been thousands of drugs available for prescribing – each with its own indications, therapeutic alternatives, price, etc. When broken down to the most granular level, a myriad of variables go into the process of ensuring that each patient has access to, is prescribed and utilizes medications that are clinically effective at the lowest possible cost.

Today, more drugs are available for prescribing and for more indications than ever. Intuitively, it makes sense that the complexity of the pharmacy benefit would grow along with the number of medications available for prescribing. But the complexity of the pharmacy benefit has grown at a much higher rate than the growth in the number of drugs available for prescribing thanks, in part, to the Drug Price Competition and Patent Term Restoration Act (popularly known as the Hatch-Waxman Act of 1984), and thanks, in part, to advances in technology.

The Hatch-Waxman Act changed U.S. patent laws in ways that significantly facilitated the entry of generic drugs into the pharmaceutical market. And it was very successful. Prior to the Hatch-Waxman Act only one-third of brand drugs had any kind of generic competition. Today, almost all drugs have direct or indirect generic competition, and almost all pharmacy benefit plans have generic dispensing rates above 80%. The rise of generic competition to brand drugs has provided massive savings to U.S. consumers and pharmacy benefit plans over the years. But there have been consequences.

Over the years following the passage of the Hatch-Waxman Act, advances in technology enabled brand drug manufacturers to focus their innovation efforts on the development of biologics and specialty drugs, and the fierce generic competition fostered by the Hatch-Waxman Act drove them to do so. Biologics are very expensive to manufacture, and even today the approval process for "generic" biologics (a.k.a. biosimilars or follow-on biologics) is much more cumbersome than the approval process for a traditional generic drug. These factors combine to create a significant obstacle for the development of robust generic competition to brand name biologics. That lack of generic competition in the biologics space has driven brand drug manufacturers to invest most of their resources into the development and marketing of biologics and specialty drugs.

As a result, over the past two years the number of approvals for new biologics and specialty drugs has been roughly twice the number of approvals for new traditional brand drugs.

And that rate is understated because many of the "new" traditional brand drugs coming to market are just modifications of existing brand drugs.

The dominance of biologics and specialty medications in pharmacy benefit plans will continue to increase for the foreseeable future, and the development of a robust generic market for biologics is in its infancy.

Because biologics are so expensive, one utilizer of a biologic can significantly alter the financial health of a pharmacy benefit plan. For this reason, comprehensive formulary and clinical management strategies are more important than ever, and this has increased the complexity of pharmacy benefit management at an exponential rate.

Given the importance of effectively managing the utilization of a pharmacy benefit, one would think that part of the evaluation of differing PBM programs would consider the cost effectiveness of the differing formularies and clinical programs. That does happen, but typically the analysis is centered around member disruption, and not so much on driving cost-effective utilization. This isn't because the evaluator is lazy or incompetent, it's because the evaluator rarely has all the needed information – namely, drug level rebates. And without drug level rebates it is impossible to determine whether one formulary does a better job than another in terms of driving the lowest net cost in a therapeutic class.

Drug level rebates are the most closely guarded secret for many PBMs, and the reluctancy to disclose them is frustrating, but it is not without merit. The rebates that a drug manufacturer pays to a PBM for any given drug can vary greatly among different PBMs. Part of the variance is due to the differing formulary and clinical management strategies each PBM adopts, but the other part of the variance is the negotiating power of the PBM itself. PBMs with high levels of negotiating power would lose much of that leverage if drug level rebates were public knowledge.

While PBMs rarely share drug level rebates, typically they offer rebate guarantees that are aggregated at some level along with discount guarantees that are also aggregated. The challenge for the evaluator is the construction of these guarantees often differs from PBM offering to PBM offering. For instance, claims adjudicated through a Veteran's Affairs benefit are typically excluded from rebate guarantees because the method for determining the pricing for these claims is regulated by federal law and is different from the commercial segment. Exclusions like these are straightforward and easy to identify and quantify. But today, many PBMs are adding stipulations to their discount and rebate guarantees that alter the way the guarantee is calculated and are based on information that is vague to all but the PBM. For example, many PBMs exclude limited distribution drugs from discount and rebate guarantees. What is considered a limited distribution drug may vary significantly from one PBM to another. And for any one PBM, what is considered a limited distribution drug today may not be considered a limited distribution drug tomorrow, and vice versa.

The difference in what is considered a limited distribution drug between PBM offerings typically depends on contract language and the robustness of the PBM pharmacy network.

PBMs that include single source brand and generic drugs in their definition of limited distribution drugs will have a much larger limited distribution drug list than PBMs that do not follow this practice. Similarly, PBMs with a thin pharmacy network will have a larger limited distribution drug list than PBMs with a robust pharmacy network.

Excluding limited distribution drugs from discount and rebate guarantees allows PBMs to make their guarantees artificially appear higher than they would without the exclusion because the exclusion reduces the number of claims the rebates are measured against. Today's PBM contracts are riddled with more guarantee stipulations that artificially inflate guarantees than ever. As a result, it is increasingly difficult to evaluate the true value of any particular PBM offering.

The construct of a PBM offering has little, if any, inherent financial value regardless of whether the offering is transparent or traditional, riddled with guarantee stipulations or not. The challenge for the evaluator is identifying the differences in PBM offerings and assigning a value to them. This is no small task and it is more difficult than ever, but it can be done through a lot of hard work, analysis and discussion with the PBM being evaluated. The key is to truly understand the pricing terms and to understand how the PBM's utilization management strategies will affect utilization in the future.