CHECKING ALL THE RX BOXES

SIIA's Drug Pricing Task Force Finalizes Cost-Containment Roadmap

Written By Bruce Shutan

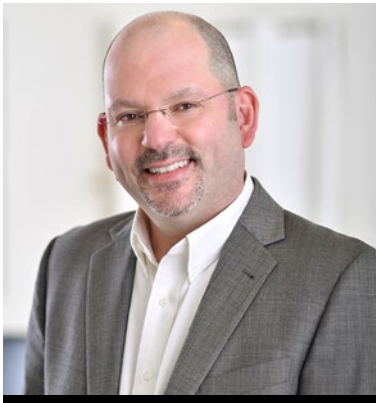
Over the past two years, SIIA's Drug Pricing Task Force has been working to develop a targeted list of recommendations on how self-insurance industry stakeholders can better control the rising cost of pharmacy spend, including high-cost specialty drugs.

Much has happened during that time. An 18-member group of industry experts including clinicians, brokers, stop-loss carriers and TPAs to claims and pharmaceutical management firms were divided into subgroups to address three key areas: plan documents, roles and responsibilities, and finances. Their mission to produce a handy resource will be formally unveiled at a Spring Forum session in Orlando, Fla.

The task force was created to help tackle a stark reality. "Pharmaceuticals now represent pretty much the largest spend when it comes to claims from a health perspective," observes Doug Bloomquist, a task force member and SVP with StarLine Group whose focus is on plan documents. "When we look at claims, you can easily forecast what the overall spend is going to be for a member or a patient just based on the drugs that they utilize."

Dealing with a complicated, fractured and nontransparent drug procurement and distribution process proved to be an uphill battle, according to Steve Kelly, another task force member as well as chairman and co-founder of ELAP Services whose focus is on the finance area. He says another challenge was the lack of standardization in how plan documents are worded for prior authorization and different methods used for cost containment. His hope is that the task force's work will rectify these issues moving forward.

INTERDEPENDENCY AND THE NEED FOR COLLABORATION



Shaun Peterson

Interdependency among the three subgroups cannot be overstated, says SIIA Drug Task Force Chair Shaun Peterson, VP of stop loss for Voya Financial who's also on SIIA's board of directors. "It's the old adage: a chain is only as strong as its weakest link," he says, noting that each pillar needs to be set up in a way such that they're holding their own.

For example, the plan document needs to define clear actions that need to be performed around managing high-cost drugs, but also stipulate the roles and responsibilities of key stakeholders, which he believes is the hardest part about the process. "If people aren't doing what they need to do in the process, you're not going to get there," Peterson notes.

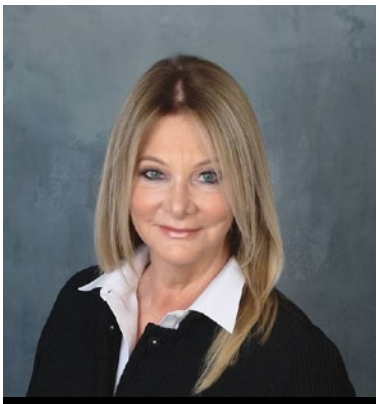
Additionally, the pursuit of high-quality care and outcomes must be built into the financing component. When all three areas are addressed, he says employers will be able to effectively execute their objectives.

With specialty drugs representing an increasingly complex segment of the health care industry, the task force let simplicity serve as its guide. "What we wanted to build was a very simple roadmap that could be utilized by anyone who's a SIIA member, be it a self-funded group, broker, TPA, stop-loss carrier, etc.," explains task force member Marien Diaz, VP of excess loss claims at Symetra Life Insurance Company whose focus is on roles and responsibilities.

Each of the work groups merged their recommendations into a single document that she calls a "condensed checklist" with all the essential components required for managing a self-insured employer's pharmaceutical challenge. In its most practical form, she says the document can be printed and taken to a meeting or used as a tool by service providers for a conference call with customers or prospects.

For the part she worked on, Diaz and her subgroup colleagues focused on issues such as how to schedule and approach communication between all the necessary parties to make sure they're on the same page.

That included suggesting the frequency and content of those meetings, mindful that it's not easy to adequately address everyone's concerns when there are so many moving parts. She says every meaningful dialogue must start with crystal-clear expectations, noting that the task force's final document will help align stakeholder objectives moving forward.

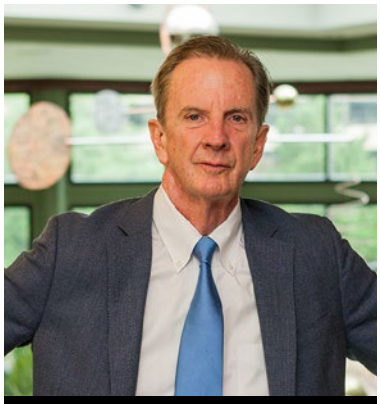


Marien Diaz

"By enhancing communication," Diaz says, "we are hoping to actually translate all that good dialogue into contractual provisions in the agreement that facilitate the management of these solutions."

For Bloomquist, the biggest takeaway from his work on the task force was a recognition about the necessity of having strict guidance on how high-cost drugs are handled. "You need to be able to provide clear definitions around terms, and they need to be concise in order to be able to make the plan document itself an effective central mechanism of controlling costs," he explains.

It's also paramount given the complexity of these costly drugs that self-insured health plan sponsors assemble a team that he says includes an employer point person, legal representative, broker, TPA, PBM and others who meet on an annual or semi-annual basis to discuss Rx treatment trends.



Steve Kelly

STICKER SHOCK

Kelly has found that the price discrepancies and randomness by which specialty drugs are reimbursed to be rather startling and a wake-up call for substantive change. At its worst, he says the arrangement smacks of predatory pricing. "It's very difficult for us to have any say in how these prices are generated if we only get involved at the very end of the process," he cautions.

The emotionalism surrounding treatment of serious conditions that often involve a life-or-death matter makes it difficult to negotiate prices, Kelly notes. In trying to do the right thing for families, he laments that it means "paying a price that's completely unreasonable and unsustainable for the future."

Indeed, concern is mounting over new high-impact specialty pharmaceuticals moving out of the R&D pipeline and into the marketplace. With at least five such scripts receiving FDA approval last year, some featuring price tags of more than $1 million for a single dose or treatment of rare conditions, pharmacy benefits management will become increasingly difficult.

"These drugs have a set price tag from the moment that the FDA approves them," Diaz notes. "Obviously, there's the patent law that protects the manufacturer to keep that price for a number of years. So, somehow we have to figure out a way how to make this sustainable for employers, but also the stop-loss carriers that are taking on the lion's share of that risk."

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As these costly drugs get approved, Diaz says one huge challenge will be ensuring that their high price tags are actually generating the intended results. That effort will involve communicating and partnering with drug manufacturers to help mitigate risks and including language in an employer's plan document regarding expectations on drug efficacy.

One area of pharmacy innovation that's exploding is the oncology category. Diaz questions whether or not physicians and specialists are using those drugs as intended with regard to step therapy. "Sometimes," she says, "if you just go to the most expensive and newest drug, it may not be the ideal solution for that particular patient from a clinical perspective… With the continued advances in oncology specialty pharmacy, there needs to be clinical validation, along with the cost-containment approach."

Bloomquist is highly concerned about rising Rx costs, citing reports that nearly 40 new high-cost genomics could flood the market within the next four to five years. Some of the other areas that are catching his attention include CAR (chimeric antigen receptor) T-cell therapy, as well as oncology scripts and so-called orphan drugs that treat extremely rare conditions. With regard to the latter category, he describes it as problematic for reining in, say, a drug costing $5 million that may be prescribed for only 20 people.

What concerns Peterson is a lack of competition associated with the way drug manufacturers are able to lock out the production of similar scripts during a window of exclusivity. Alternative therapies cannot reach the free market until a particular drug comes off patent. "Your hands are kind of tied a bit," he explains, though hopeful that costs will fall over time as more competition moves into the space.

An area that has raised eyebrows involves cell and gene therapies which, while not technically drugs, are billed as pharmaceuticals. He predicts a continuation of significant inflation and no shortage of new specialty pharmaceuticals being brought to market.

While manufacturer assistance programs help patients afford new treatments and close coverage gaps, Peterson cautions that they may or may not help the actual plan sponsor who's paying the bill. Instead, he says their best hope is protections associated with stop-loss policies and emergence of vendors that are providing solutions to manage costly cell and gene therapies.

MINDFUL OF MIRACLES

When weighing the high cost of certain pharmaceuticals relative to the overall medical spend, Peterson says it's easy to often lose sight of the fact that these new therapies offer miracle-like treatments or cures and with "every one of these claims, there's a person behind it."

Five years ago, he observes, children with spinal muscular atrophy would die within the first two years of their life, whereas today they have a few options. "One of them is certainly durable, if not curative," he adds, excited about what sort of medical care his children and grandchildren will receive based on the emergence of promising therapies.

The caveat, however, is limited evidence of efficacy. Most studies of these drugs, for example, were only about three or four years. "We need plenty of history behind us to say they're actually curative, and we just don't have it yet," according to Petersen.

Describing the best-practices document as a critical first step to establish a foundation upon which the task force can build out meaningful discussions, Kelly would like to see the group continue to explore collaborative and holistic solution. ■

Bruce Shutan is a Portland, Oregon-based freelance writer who has closely covered the employee benefits industry for more than 30 years.

CHECKLIST AT A GLANCE

1. **Plan Document Best Practices**

- Utilization Review
- Prior Authorization:
- Steerage
- Step Therapy
- Limitations
- Incorporate clinical and financial components

2. **Roles & Responsibilities Best Practices**

Employers

- Vetting Process
- Plan Document Review

Brokers

- Vetting Process
- Consider Customized Solutions
- Plan Document Review
- Understand the Plan Document

Medical Management Professionals

- Select Partner
- Patient Management Checklist
- Off-label Drug Use Checklist

TPA-PBM

- Combining Medical and Pharmaceutical Data Elements Checklist
- Follow Plan Document Best Practices Check List

Stop Loss Carrier

- TPA-Stop-Loss Partner Relationship Checklist
- PBM Data and Interface Checklist
- Large Claim Notices and Stop Loss Claims Checklist

3. **Financial Best Practices**

- Specialty Drug Utilization & Cost Management Options
- Medical Rx Stand Alone Programs
- Rx Benefit Stand Alone Programs

4. **Cell & Gene Therapy**

Helpful Links

- FDA Biologic Information
- FDA Approved Drugs
- FDA Novel Drug Approvals
- FDA Approved Drug Information & Resources
- SIIA Member Resources