July 2019

The American Journal of
PHARMACY BENEFITS®
Translating Evidence-Based Research into Value-Based Decisions®

Prescription Benefits Consultant Sees Opportunities for Employers in Debate Over Rebates

Prescription benefits consultant Chris Robbins, chief executive officer of Arxcel, describes the finger-pointing in Congress over lowering drug costs this way: "If it weren't so true, it might be almost humorous."

Mary Caffrey

Rule Eliminating Rebates Leaves Plenty of Uncertainty

A policy from the Trump administration to benefit patients and alleviate the high cost of prescription drugs would eliminate rebates from pharmaceutical companies to pharmacy benefit managers (PBMs).

Laura Joszt

Cigna, Express Scripts Capping Insulin Co-Pays at $25 for Participating Commercial Members

A day after stakeholders told a House of Representatives subcommittee about problems accessing and paying for insulin, Cigna and its pharmacy benefit manager Express Scripts said they are launching a program for patients with diabetes in their commercial plans so that they pay no more than $25 for a 30-day supply of insulin.

Allison Inserro

Current and Future Status of Drug Pricing Reform as the Blueprint Approaches the 1-Year Mark

Several efforts are underway nearly a year after the Trump administration released its blueprint to lower drug prices in May 2018, but tracking their outcomes depends on what metric is used to define drug prices, according to a session at the Academy of Managed Care Pharmacy Managed Care & Specialty Pharmacy Annual Meeting, held March 25-28 in San Diego, California.

Christina Mattina

Is There an Alternative to PBM Rebates? ICER Paper Examines 3 Options

With discussion and debate happening for months in Washington, DC, over drug pricing and the role of pharmacy benefit managers (PBMs), the Institute for Clinical and Economic Review (ICER) published a white paper this week that analyzes 3 possible alternatives to the pharmaceutical rebate system fostered by PBMs.

Allison Inserro

Specialty Drugs Remain a Costly Concern for Employers With No Easy Answers

Costs remain the top concern of healthcare purchasers of pharmacy benefits, but employers are also concerned with ensuring appropriate use of medication and adherence to medication, according to a new report from the Pharmacy Benefit Management Institute (PBMI).

Laura Joszt

Prescription Benefits Consultant Sees Opportunities for Employers in Debate Over Rebates

Mary Caffrey

Prescription benefits consultant Chris Robbins, chief executive officer of Arxcel, describes the finger-pointing in Congress over lowering drug costs this way: "If it weren't so true, it might be almost humorous."

Pharmaceutical manufacturers blame the pharmacy benefit managers (PBMs); the PBMs blame the manufacturers, and "the manufacturers are almost scared of the PBMs," Robbins said.

From his vantage point, as one who helps employers, unions, health plans, or payers select and contract with a PBM, neither side is blameless. "Historically, PBMs have driven manufacturers to provide rebates," he said. "They always talk about the clinical decision being first on the formulary, but there's been a lot of scrutiny: Are they making clinical decisions, or are they making financial decisions?"

Robbins sees the basic compensation model of the 3 largest PBMs—Express Scripts, CVS Caremark, and Optum—as basically out of alignment with the interests of the group that ultimately pays most of the costs for healthcare: employers.

The American Journal of Managed Care® spoke with Robbins recently about employers' increasing role as a healthcare stakeholder, the possible changes that may come to rebates, and the importance of prevention and wellness in the workplace in holding down healthcare costs.

THE PAYER IS THE EMPLOYER

Robbins said most people do not appreciate that when an insurance company pays a claim, at least half the time it's ultimately an employer paying the cost of the coverage. "The payer is the employer," he said. "They are the ones writing the check."

Thus, as issues arise about the use of rebates in prescription plans, how rebates are distributed, and how they are spent, it's important that employers take seriously their fiduciary responsibility to make sure rebates are spent appropriately, Robbins said.

"Some employers have become used to that big fat rebate check that comes every quarter," he said. "It doesn't always go where it should go."

Arxcel has worked with coalitions of purchasers of healthcare to better understand the options for use of rebates, in light of Optum's decision in March to only accommodate new employer clients that incorporate rebates back to consumers at the point of sale. This move came amid discussions by the Trump administration that it might eliminate rebates entirely, which some said would cause premiums to rise.

LOTS OF PIECES TO THE PUZZLE

It sounds good to say, "let's just get rid of rebates," Robbins said, but it's not that simple. "There's lots of pieces to the puzzle," he said. Pharmaceutical companies entice consumers to use expensive drugs with co-payment assistance programs. There's more money going back and forth than just rebates, he said; there are administrative and data integration fees, and if rebates went away, would other costs increase?

A PBM contract may have a page and half about rebates, Robbins said, "and three-quarters of that tells you what a rebate isn't."

WHOSE MONEY IS IT?

The idea of directing rebates to the patient purchasing the high-cost drug is relatively new, but it has merit, Robbins said. In the past, when co-pays were $5 to $10, and before the rise of high-deductible plans, such a concept was unnecessary, but today it makes more sense, even though it presents logistical challenges, since rebates are not paid right away, and some patients eventually reach 100% benefit.

A lot of employers are beginning to realize they have a fiduciary responsibility to make sure the rebate flows the right person, Robbins said. The question is, "Whose money is it?"

"I do think it should be shared with the plan participant who's buying that drug," he said. In any plan, only a very small number of patients account for a disproportionate share of the costs, and a good benefit structure will make sure the patient gets the drug they need. Often, Robbins said, "It becomes more expensive if someone doesn't take their drug."

The issue of point-of-sale rebates has emerged very quickly; they may not happen in all cases, but they may

be appropriate for certain specialty drugs. "That's why coalitions are important—they're empowering employers to take a stand. There are always going to be drugs out there for which there are no competing products."

PREVENTION AND WELLNESS

Employers "are getting smarter" about issues of prevention and wellness, he said. Preventive drug lists need revisions so that more important drugs can get to consumers without a co-pay, but this will require action from Congress.

The challenge is coming up with payment models that make sense for employers, so that it makes sense for an employer or payer to invest in an expensive therapy that prevents a complication 20 years from now, when the employee may be long gone from the company. Payers have already seen this with the cures for hepatitis C virus, but they will see a new wave of challenges with gene therapies now in the pipeline.

Robbins said he supports fair compensation for pharmaceutical companies to support research and development; he hopes industry reform comes from within. "They'd better police themselves before government gets involved."

Employers, he said, "need to put their foot down," and make clear what they will and will not do. "Employers need to hold pharma and PBMs responsible."

Rule Eliminating Rebates Leaves Plenty of Uncertainty

Laura Joszt

A policy from the Trump administration to benefit patients and alleviate the high cost of prescription drugs would eliminate rebates from pharmaceutical companies to pharmacy benefit managers (PBMs). However, there is still a lot of uncertainty around the rule, how it might actually benefit patients, how others in the industry might change behavior, and if January 1, 2020, is enough time to make these changes go live.

At Asembia's 15th annual Specialty Pharmacy Summit, held April 30 to May 2 in Las Vegas, Nevada, 2 speakers from Deloitte Consulting LLP outlined what models are expected to result from the changes to rebates and how they will affect various stakeholders in healthcare.

The proposed rule would do away with retrospective rebates and require that they happen at the point of sale (POS), so patients benefit, explained George Van Antwerp, managing director at Deloitte. There are 2 models being discussed that would replace the current rebate system: a POS rebate model and an upfront negotiated discount price (NDP) model.

Van Antwerp and his colleague, Joseph M. Coppola, also a managing director at Deloitte, focused on the NDP model. Under this model, the manufacturer and PBM still agree on a formulary position, but it is based on the NDP instead of a rebate, like it is today. The pharmacy is reimbursed at NDP plus a dispensing fee, and the out-of-pocket cost to the patient is based on the NDP instead of the wholesale acquisition cost (WAC).

However, as part of that model, the pharmacy is out money, Coppola noted, because it is still acquiring the product at WAC.

"So, there needs to be some making the pharmacy whole," he said. "But the mechanism by which they would be made whole is still unknown."

He said the transaction processor who could fill that role might be played by PBMs or a wholesaler or Amazon—no one knows just yet.

According to Coppola, they expect that the new NDP model will accelerate biosimilars to the market because of the focus on the lowest price. Innovative therapies will also have an easier time getting access to patients.

"If you think about this rebate wall that exists today…if that goes away…the implications of that is that it opens the door, it levels the playing field for more innovative therapies to gain access to formulary," he said.

For the PBMs, there is going to be a shift in business model as pools of revenue and profit from rebates disappear, said Van Antwerp.

While the government policy to eliminate rebates would only affect Medicare, there is the very real possibility that it could spill over into the commercial space or into Medicaid, he added. Without those rebates, there could be an increase in premiums from as little as 1% to as much as 25%, depending on which study you look at and what assumptions are used.

"The point is there will be some impact," he said. "Rebates have been used to keep everybody's cost, even the healthy people, down. Now you're going to see only the people that have high brand usage [or] high specialty usage really be the people who see the benefit of the rebate, because they're going to go directly to that patient…"

Already, there is proposed legislation in the House about eliminating rebates in the commercial space, and states will look to drive that change even faster than the federal government, Van Antwerp said. He expects to see more adoption of POS programs in the commercial world.

There remains a lot of uncertainty around the policy, such as that January 1, 2020, start date; who can administer chargebacks to pharmacies; and whether or not pricing will come down. Van Antwerp also noted that this rule might be the end of value-based contracting as we know it because those contracts are very retrospective and tied to outcomes. There might need to be a caveat that those contracts are not part of the change.

"I think it's an exciting time for those of you who like disruption and like being able to take advantage of the market changes," Van Antwerp said. "What exactly will happen, how fast it will happen…is still up in the air."

Cigna, Express Scripts Capping Insulin Co-Pays at $25 for Participating Commercial Members

Allison Inserro

A day after stakeholders told a House of Representatives subcommittee about problems accessing and paying for insulin, Cigna and its pharmacy benefit manager Express Scripts said they are launching a program for patients with diabetes in their commercial plans so that they pay no more than $25 for a 30-day supply of insulin.

In a statement, the companies said Wednesday the average out-of-pocket (OOP) cost for insulin was $41.50 for a 30-day supply last year; under the new program, eligible patients will save approximately 40%.

"We are planning to have all forms of insulin available (short acting, basal, and intermediate). A full list of products is not yet available," Jennifer l. Luddy, an Express Scripts spokeswoman, told *The American Journal of Managed Care*®. "In most cases, people who use insulin will see lower out-of-pocket costs without any increased cost to the plan," the companies said.

The program is not available to people enrolled in government health plans.

On Tuesday, patients and diabetes experts testified before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce about a number of issues related to the rising costs of insulin, including rationing, despite the risk of fatal and near-fatal complications.

Last month, Eli Lilly said it was lowering the cost of Humalog (insulin lispro) by creating an "authorized generic" version. The price of the new generic will be $137.35 per vial, or 50% of the cost of the branded version. Humalog is a fast-acting insulin that people with diabetes use to control blood glucose spikes that occur with meals.

But as happened when Eli Lilly announced its price cut, many on Twitter responded that the co-pay is still difficult for people without health insurance, and that in other countries, insulin is free for some.

At the hearing on Tuesday, Kasia J. Lipska, MD, of the Yale-New Haven Hospital Center for Outcomes Research and Evaluation at the Yale University School of Medicine, said 1 in 4 patients ration their insulin. In a survey of 199 patients at the Yale Diabetes Center, rationing affected patients across all different prescription coverage plans as well as across most demographic factors, although those with incomes below $100,000 were more likely to ration insulin, she said.

She also pointed out that Eli Lilly's price cut still places Humalog much higher than its $21 cost in 1996, even though nothing has changed about the drug.

Current and Future Status of Drug Pricing Reform as the Blueprint Approaches the 1-Year Mark

Christina Mattina

Several efforts are underway nearly a year after the Trump administration released its blueprint to lower drug prices in May 2018, but tracking their outcomes depends on what metric is used to define drug prices, according to a session at the Academy of Managed Care Pharmacy Managed Care & Specialty Pharmacy Annual Meeting, held March 25-28 in San Diego, California.

Melissa Andel, MPP, vice president of health policy, Applied Policy, started her talk by providing what she called an "oversimplified explanation of drug prices." It's essential to understand what kind of drug prices policy makers are talking about—published list prices, net costs to plans or pharmacy benefits managers (PBMs) after rebates, the price paid by the patient at the pharmacy counter, or other measurements of price—before observers can assess the results of drug pricing efforts.

Rebates garner a lot of negative attention in these efforts, because the process is opaque and doesn't reveal whether the discounts are being passed through to patients. As patients have increased cost liability through higher co-payments and deductibles, it's more difficult to determine which price should be used to calculate their cost sharing. Andel noted that reasonable people disagree on the answer.

Because patients think that drug prices are those they hear about in the news or what they pay at the pharmacy counter, politicians need to carefully consider which mechanisms will actually address those costs. For example, pressuring manufacturers to lower list prices could drive them to get rid of rebates, resulting in no net reduction in spending. Lowering out-of-pocket (OOP) costs through changes to the benefit structure could result in higher premiums, which could be considered unfair by Americans who do not use prescription drugs but must still pay those premiums.

> *Drug costs are one of the top, if not the top issue for many Americans, so we're going to continue to hear a lot about it and we're going to see changes*

Regardless of the measures used to define drug pricing, the topic will remain at the forefront of political priorities in the foreseeable future, Andel said.

"Drug costs are one of the top, if not the top issue for many Americans, so we're going to continue to hear a lot about it and we're going to see changes," she predicted. "Changes are coming; it's really just a matter of what those changes look like."

Next, Andel moved into discussing the blueprint released by the Trump administration in May 2018. The document is a comprehensive overview of various proposals and ideas that the administration is considering, and it has been a fairly accurate predictor of the steps that have been seen so far. It focuses on 4 problems considered the pillars of drug pricing: high list prices, rising OOP costs, foreign free-riding, and overpaying due to lack of negotiation.

Some of the proposals related to list prices include removal of the rebate safe harbors and establishing 2 new safe harbors protecting point-of-sale discounts. Comments on this proposal are open, and HHS says the rule will be in effect January 1, 2020, but Andel noted that the comment period may close in June, after 2020 plan bids must be submitted to CMS.

Rebate change agreements will come with tradeoffs, she warned. With the loss of rebate revenue, customers may face higher premiums and fewer plan choices, and these consequences could hit around the time of the 2020 election when beneficiaries shop for Part D plans in late October and early November. Additionally, lower list prices would slow beneficiaries' progression through their benefits and could lead to longer times spent in the coverage gap.

Andel discussed 2 other proposals with uncertain prospects. It is unclear whether CMS has the authority to mandate drug makers to disclose list prices in direct-to-consumer ads, so she would be "shocked" to see this rule finalized without a legal battle, but some manufacturers have moved to voluntarily disclose prices. Similarly, if

CMS moves to revoke protected status for drugs in 6 classes, plans would no longer have to cover drugs in these classes that are priced above a certain threshold, but lawsuits or Congressional action might prevent this from going into effect.

In terms of rising OOP costs, a successful step is that Part D plans now can immediately drop coverage or increase cost sharing for a branded drug once a generic becomes available, and there is more flexibility for midyear formulary changes when therapeutic alternatives are launched. However, not all steps will be so impactful: Andel's slide about the banning of pharmacy gag clauses featured an image of Bigfoot, because she's "never actually met someone who can prove that these things actually exist."

One idea in the administration's plan to end foreign free-riding is an International Pricing Index (IPI) that ties the amount paid for drugs to that in foreign countries. However, Andel noted that this idea is not an actual proposal yet, yet alone a final rule, and the document released by CMS lacks detail on the methodology that would be used. For instance, would CMS calculate a single IPI for all drugs or an individual IPI for each drug? How would the physician add-on payment be calculated?

"We're talking about a wholesale change in the way that physicians who administer these drugs would be doing business. They would lose a major revenue stream, and so far we haven't really talked about how that would impact them," said Andel.

More concrete steps have been taken in the realm of negotiation, where Medicare Advantage (MA) and Part D are being run more like a commercial plan. Step therapy in MA began in 2019, and CMS will allow indication-based formulary design in Medicare Part D starting in 2020.

As a resident of Washington, DC, where "it's always election season," Andel discussed potential future policy changes surrounding drug pricing. There are some areas where the 2 parties may be able to agree, such as allowing drug importation, increasing generic drug access, and ramping up scrutiny on insurers and PBMs, but they are unlikely to reach a compromise on issues like federal negotiation of prescription drug prices or international reference pricing.

If in 2020 the Democrats win the White House and Senate and keep control of the House, Andel still did not think "Medicaid for all" would be enacted. Public polling is against it, especially when respondents are told it will require higher taxes, and the candidates' promises don't match up with what Medicare actually delivers. For instance, candidates say their plans would eliminate co-pays and deductibles, which do exist in Medicare, and aim to prohibit private insurance, even though MA plans cover more than one-third of Medicare enrollees.

Andel offered words of comfort for those in the audience who may be worried about the prospect of a single-payer plan. "For those of you in the audience who break out into sweats when you think about Medicare for all, I think you can probably sleep at night," she said.

Instead, Andel predicted that some more incremental reforms could be enacted if 2020 brings a Democratic president. We could see Medicaid expansion extended to all states, Medicare buy-in options for those older than 50 or for all Americans, or changes addressing the current Affordable Care Act subsidy cliff for individuals making 401% of the federal poverty level. These steps are "more realistic than straight-up single payer Medicare for all," Andel concluded.

Is There an Alternative to PBM Rebates? ICER Paper Examines 3 Options

Allison Inserro

With discussion and debate happening for months in Washington, DC, over drug pricing and the role of pharmacy benefit managers (PBMs), the Institute for Clinical and Economic Review (ICER) published a white paper this week that analyzes 3 possible alternatives to the pharmaceutical rebate system fostered by PBMs.

The paper, "Value, Access, and Incentives for Innovation: Policy Perspectives on Alternative Models for Pharmaceutical

Rebates," cautions that abrupt change could have unintended consequences, even as nearly all players understand that change is coming. For instance, this week, UnitedHealthcare said it will expand its drug rebate program that passes rebates from drug makers directly to patients.

In January, HHS proposed a rule to exclude rebates from safe harbor protections that currently shelter drug makers' rebates from federal kickback penalties and reduce patients' out-of-pocket costs for prescription drugs; instead, the rule suggests that discounts be directly turned over to patients enrolled in Medicare and Medicaid. That idea is one of the options ICER examined.

ICER evaluated all 3 options against 7 criteria:

- Impact on patients' affordability, access to care, and clinical outcomes (via improved adherence)
- Impact on overall cost of pharmaceuticals and medical spending
- Impact on competitive outlook for innovative new medicines
- Ability to support outcomes-based contracting and indication-specific pricing agreements
- Impact on efforts to design formularies based on cost-effectiveness of pharmaceuticals
- Feasibility of implementation
- Ability to improve transparency of costs to support public dialogue on value and affordability

The first 2 options—passing all rebates on to insurers, or sending them all to the patient at the point of sale (POS)—could be used alone or together, ICER said. They also represent the least drastic of the 3 options.

Under the first option, insurers would pay fees to PBMs in an attempt to end the current incentive for PBMs to develop restrictive formularies that include highly rebated drugs despite higher net costs for payers.

However, a possible problem is that new "fees" could be developed that would create the same effect. Therefore, ICER said, real change would take place only if this option were implemented alongside transparent contracting.

Some states have started demanding this type of transparency, for example, in their Medicaid pharmacy contracts.

The second option would require some part of the rebates to be shared with patients at the POS, as UnitedHealthcare plans to do. However, providing POS rebates would require releasing confidential information to patients that inadvertently discloses the gross-to-net price gap, thus eliminating confidentiality of the rebate level and undermining the negotiating power held by payers through their ability to get confidential rebates.

The first option, the pass-through model, could be combined with the second option. ICER noted that a 100% pass-through model will be most effective; patients might see the most benefit from this model if their cost sharing is linked to list price (which could lead to better adherence and outcomes), because with less incentive for higher rebates, list prices and the gross-net gap may fall.

In the second model, giving some POS rebates to individual patients that would have otherwise gone back to the insurer means the insurer would not have the option to use those funds to cut premiums. As a result, even if individual costs drop at the pharmacy level, the rest of the country could see higher premiums.

The third option would end rebates altogether, moving exclusively to a system of upfront discounts. This is what the Trump administration is trying to do with its plan to end rebates in Medicare Part D. However, this strategy would require a change to the payment structures for wholesalers and pharmacies, would require technology investments, and it could face legal challenges. A chargeback model would likely have to be implemented, under which manufacturers and wholesalers could coordinate pharmacy reimbursement based on compiled reporting or prescription claims records.

The first 2 options would either have no effect on competition or on the ability to create value-based formularies, or it would be more complicated to do so, the paper said.

ICER put the report together through 10 interviews with various stakeholders, a literature review, and looking at the public comments regarding HHS' drug pricing blueprint. ICER performs analyses on the effectiveness and costs of medical tests, treatments, and delivery systems; develops reports assessing the value of key new drugs; and creates initiatives that use evidence to drive changes to both practice and policy.

Specialty Drugs Remain a Costly Concern for Employers With No Easy Answers

Laura Joszt

Costs remain the top concern of healthcare purchasers of pharmacy benefits, but employers are also concerned with ensuring appropriate use of medication and adherence to medication, according to a new report from the Pharmacy Benefit Management Institute (PBMI).

The eighth *Trends in Specialty Drug Benefits* includes findings from a survey of 306 respondents responsible for managing the drug benefit for their organization.

Specialty drug spend currently accounts for half of the total drug spend, which creates challenges for employers who want to ensure employees have access to medications. However, with costs rising, employers are also interested in evidence that these medications provide value, which can be gained through new reimbursement arrangements.

Outcomes-based contracts provide the ability to track patient outcomes, with 67% of respondents using these arrangements to track total healthcare cost of patients receiving specialty drugs, 63% tracking adherence and persistency, and 27% tracking clinical efficacy. Less than 10% are tracking the impact of medications on employee productivity.

"Timely, accurate, and actionable reporting is key to measuring how a plan is doing in terms of specialty drug benefit management," according to the report. "When done well, reporting can highlight areas of opportunity to improve clinical and financial outcomes."

While nearly all (94%) of respondents said their pharmacy benefit manager (PBM)/healthcare vendor tracks specialty and nonspecialty drug spend under the pharmacy benefit, only half said they are tracked under the medical benefit.

Of respondents whose PBM/healthcare vendor tracks specialty drug spend, 63% of respondents said they can effectively track adherence and persistency, but 34% said they cannot and would like that ability. Furthermore, only 27% can track clinical efficacy and 66% said they cannot and would like the ability.

Respondents were asked an open-ended question of what other outcomes they were interested in tracking, and responses included adverse events and side effects, impact of high-deductible plans and coinsurance on outcomes, long-term cost avoidance by drug, and clinical alternatives and cost impact.

The survey found that respondents are less interested in using formulary exclusions to manage the specialty trend. In the 2018 report, the number of respondents who think exclusions are effective declined 21%. However, this belief does not mean formulary exclusions are going anywhere. Sixty percent of respondents said they use formulary exclusions and 33% are considering adding or increasing their use.

Close to half (42%) of respondents said member dissatisfaction was the number 1 challenge with formulary exclusions, while 27% named it the number 2 challenge.

"Plan sponsors continue to use the traditional drug management levers of utilization management, clinical programs, formulary, and cost-sharing, but remain open and willing to be part of conversations that explore new ways to rein in specialty costs while providing a quality and affordable specialty drug benefit," according to the report.