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Christopher V. Goff, Esq.
President & CEO

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2023 was a year of tremendous growth for Employers Health. What started in 1983 to contain health care costs for local employers has evolved into more than 70 employees serving over 350 clients throughout the country, all working toward that goal to help employers manage health care spend. Just 10 years ago, we had 21 team members serving clients domiciled in 29 states; today we're supporting clients domiciled in 40 states, covering more than 1.6 million lives and spending $3.5 billion on pharmacy.

This growth of our client base necessitates the growth of our organization. With that, a tradition of more than 20 years concludes as we combine our annual Canton, Ohio employee benefits conference (or what many of us still refer to as our annual symposium) with our Columbus, Ohio pharmacy benefits conference. Our new event, now named the Annual Benefits Forum, will take place March 5 and 6 in Columbus, Ohio. This two-day event will feature seasoned pharmacy consultants, benefits professionals, clinical management specialists and other industry experts covering the latest in employee and pharmacy benefit trends. Attendees will network with industry professionals and meet leading solutions providers all while discovering real-life solutions to today's benefits issues. As always, this event is complimentary for Employers Health clients. I encourage you to learn more and register at employershealthco.com/abf24.

Our organizational growth has also facilitated record-setting growth in our team. Since 2022, we have added 29 team members. We always strive to provide you and your plan exceptional service while also working to meet your plan's performance goals and we do this through a talented team of client executives, clinical pharmacists, data analytics specialists and more. Each client executive maintains a smaller book of business with approximately 15 clients so we can ensure that you always receive exceptional service and a dedicated advocate for your plan. To that end, I'm happy to share that our clients scored us a 4.8 on a 5-point scale on our recent client satisfaction survey.

This positive change would not be possible without the confidence and support of our clients and their consultants who strive to provide affordable prescription benefits for both the plan and its participants. As we all work together to achieve this common goal, we expand our purchasing power, directly aiding your organization in reducing its pharmacy spend. On behalf of the entire Employers Health team and its board of directors, I thank you for your continued trust in our organization and collaboration over the past year.

Best wishes for a great year.

The Inflation Reduction Act's Medicare Drug Price Negotiation Program

Madison Connor, J.D., CEBS
Senior Vice President, Regulatory Compliance and External Affairs

Background

On August 16, 2022, President Biden signed into law landmark legislation aimed at curbing inflation by possibly reducing the federal government budget deficit. The law, known as the Inflation Reduction Act, includes several provisions impacting prescription drugs and, most notably, requires the Secretary of Health and Human Services to directly negotiate prices with drug manufacturers for certain drugs covered under Medicare Part D. To be eligible for negotiation, a drug must be a single source brand-name drug or biological product, without a therapeutically equivalent generic or biosimilar. Additionally, it must have been approved or licensed by the Food and Drug Administration for either seven years in the case of small molecule drugs or 11 years in the case of biologics.

For over a decade, legislators have debated whether to grant the federal government the authority to negotiate prices for drugs covered by Medicare. When Medicare Part D was originally established in 2003, Congress left Medicare drug pricing to the drug manufacturers, PBMs and insurers to determine and expressly prohibited the government from interfering in these private negotiations under the program's "noninterference clause."

A summary of the Medicare Drug Price Negotiation Program follows.

10 drugs selected for negotiation for initial price applicability in year 2026:

Eliquis for preventing strokes and blood clots, from Bristol Myers Squibb and Pfizer	**Jardiance** for diabetes and heart failure, from Boehringer Ingelheim and Eli Lilly	**Xarelto** for preventing strokes and blood clots, from Johnson & Johnson	**Januvia** for diabetes, from Merck	**Farxiga** for diabetes, heart failure and chronic kidney disease, from AstraZeneca
Entresto for heart failure, from Novartis	**Enbrel** for arthritis and other autoimmune conditions, from Amgen	**Imbruvica** for blood cancers, from AbbVie and Johnson & Johnson	**Stelara** for Crohn's disease, from Johnson & Johnson	**Fiasp and NovoLog** insulin products, for diabetes, from Novo Nordisk

FIGURE 1

Negotiation Program Details

In creating Medicare's Drug Price Negotiation Program (the Program), Congress directed the Centers for Medicare and Medicaid Services (CMS) to select the top spend drugs under Medicare and negotiate with the manufacturers of those drugs to determine a "maximum fair price." To identify drugs selected for negotiations, CMS determined a list of eligible drugs (qualifying single source drugs without a generic or biosimilar alternative) and then looked at total expenditures for each based on spending data for the 12-month period June 1, 2022 to May 31, 2023. Late last summer, CMS announced its initial list of 10 drugs that will be negotiated for price applicability in 2026, see FIGURE 1.

Together the selected 10 drugs accounted for $50.5 billion in Part D gross costs or 20% of Medicare Part D spending over the pricing reference period. In future years, CMS will select for negotiation up to 15 additional drugs covered under Part D for 2027, up to 15 additional drugs for 2028 (including drugs covered under Part B and Part D) and up to 20 additional drugs each year thereafter.

Next, CMS will determine the maximum fair price by considering a list of statutory factors including the manufacturer's research and development costs, the extent to which these costs have been recouped, current unit costs of production and distribution, etc. The Program also establishes an upper limit for the maximum fair price of a given drug. That limit is the lower of a fixed percentage discount (between 25% and 60% based on the drug's approval date) off the pre-rebate non-federal average manufacturer price, or the prior year's net price negotiated by Medicare Part D plan sponsors after rebates. A manufacturer of a drug selected for the Program may choose not to participate in the negotiation process, in which case the manufacturer should not sign the voluntary agreement to negotiate maximum fair price and must then withdraw its drugs from coverage under Medicare and Medicaid. The manufacturers of all ten drugs selected for negotiation have signed agreements to participate in the Program.

Potential Impact

The Congressional Budget Office projects that the Program will save the government $98.5 billion over the years 2022 to 2031. The savings will offset approximately $1.9 trillion in expected Part D drug spend over that same time. As the prices negotiated for selected drugs are only applicable to Medicare beneficiaries, any direct savings related to the Program will not apply to the commercial market. Some experts suggest that the published negotiated prices will provide the commercial market with benchmark pricing to leverage in drug purchasing. But, given the small number of drugs being negotiated and the fact that negotiations will occur three years in advance of the applicable pricing year, the impact is likely to be small. Another possibility is that these negotiations have the opposite effect; reducing Medicare prices could lead to cost shifting and an increase in prices for the privately insured market.

Another dynamic to keep in mind is that the 10 negotiation-eligible drugs were chosen without accounting for rebates that are already negotiated by Part D plans and/or pharmacy benefit managers. In other words, a selection of highly-rebateable drugs may skew the projected savings and CMS's negotiated prices may not ultimately end up lower than what the government currently pays after factoring in rebate payments.

Patent expirations and brand competition will also factor into the Program's impact.

Key Negotiation Deadlines:

OCT 2023

The deadline for manufacturers to sign agreements to participate in the negotiations for 2026.

FEB 2024

CMS will make its initial offer of the maximum fair price for a chosen drug.

AUG 2024

The parties must reach an agreement on a negotiated price.

SEPT 2024

Final negotiated prices for the first 10 drugs will be released to the public.

MAR 2025

CMS to release a public explanation of the negotiated prices.

JAN 2026

Maximum fair prices will go into effect for Part D plans.

For example, Merck's Januvia could lose exclusivity mid-2026 and AstraZeneca's Farxiga patent for cardiovascular risk is set to expire in 2025. Thus, it is entirely possible that we will only feel the impact of negotiations for a year before generic competition minimizes the effects of the negotiated price or even that a drug may "drop off" the negotiations list prior to 2026 due to the drug no longer technically being single source. The Program does include a mechanism to grant a delay in selecting drugs that have a high likelihood of biosimilar market entry within two years of publication of the initial drug list. To qualify for this delay, the manufacturer of the biosimilar product for a given negotiation-eligible reference product must submit a delay request to CMS prior to the drug list publication date, and there must be a high likelihood of biosimilar market entry within two years after publication of the list.

Ongoing Stakeholder Challenges

So far, drug makers and trade associations (including Merck, Bristol-Myers Squibb, PhRMA, AstraZeneca, Boehringer Ingelheim, Johnson & Johnson, the National Infusion Center Association and the U.S. Chamber of Commerce) have filed at least 10 lawsuits challenging the Program. The suits bring a variety of claims alleging that the Program violates the First, Fifth and Eighth Amendments of the Constitution for free speech, takings and excessive fines. Some suits also raise administrative law claims that the Biden administration violated the Administrative Procedure Act by trying to implement the Program via agency guidance rather than the formal regulatory process. However, these lawsuits will face an uphill battle to overcome the argument that Medicare is a voluntary program and that if manufacturers desire to participate in Medicare drug coverage, then they must agree to participate in the negotiations Program. Unsurprisingly, the lawsuits are strategically spread across six different circuits. Any split judicial opinions regarding the viability of the Program would serve as a prime vehicle for consideration by the U.S. Supreme Court.

Closing Thoughts

The Program faces substantial uncertainty in the coming months due to ongoing litigation. Even assuming that none of the lawsuits are successful at blocking the provisions or delaying the first round of negotiations, the Program's first year of price applicability is likely to have a muted impact. Generic competition may even lead to pricing for fewer than 10 drugs ultimately being negotiated. Overall, the potential for greatest savings will be when a substantial amount of high-cost drugs are phased into the Program and when the government strategically negotiates the prices of high-cost drugs with lower-rebate yields.

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Navigating the GLP-1 Landscape: *Understanding the Buzz and Price Increases*

Dave Uldricks, J.D., LL.M.
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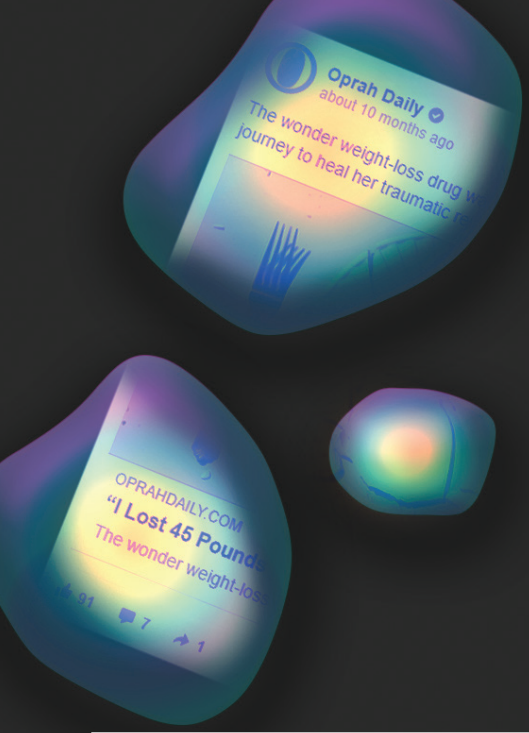

Over the past few months, I have seen more commercials for Ozempic than I can count, and every morning during my drive to work I hear a radio commercial from a men's health clinic touting the effectiveness of a combination therapy of testosterone plus semaglutide (the active ingredient in Ozempic and Wegovy) for body recomposition. There are more than 4,000 reported semaglutide advertisements between Instagram and Facebook, #wegovy has been posted more than 50,000 times on Instagram, #ozempic has been posted 134,00 times on Instagram and everyone from Elon Musk to Chelsea Handler have endorsed semaglutide products. All the media attention on Ozempic, Wegovy and similar medications has contributed to an untapped demand for these products which, in turn, has driven increased overall total drug spend.

Over the first half of 2023, no product contributed more to the gross cost trend across the Employers Health book of business than Ozempic. Ozempic belongs to a class of drugs known as glucagon-like peptide analogues (GLP-1), and the contribution to total drug spend generated by this class is on the rise. GLP-1s are indicated for the treatment of Type 2 diabetes and obesity. In 2021, GLP-1s comprised 6.3% of total gross cost across the Employers Health book of business. In 2022, that figure increased to 8.7%, and over the first half of 2023, GLP-1s contributed 13.6% to total gross cost.

Whether evaluating it in the aggregate or at the therapeutic class level, drug spend is dependent upon three factors:

01 the prices of the drugs,

02 which drugs are being used (aka drug mix) and

03 how much of the drugs are being used (aka utilization).

In January 2023, all GLP-1 products indicated for the treatment of Type 2 diabetes experienced a price increase. The average wholesale price (AWP) for Bydureon BCise and Byetta increased by 3.0%. The AWP for Ozempic, Rebelsus and Victoza increased by 4.9%. And the AWP for Mounjaro and Trulicity increased by 5.0%. The AWP for Saxenda and Wegovy, GLP-1s used for weight loss management, remained unchanged for 2023; however, the price of Wegovy continues to remain at a significantly higher level than GLP-1s indicated for the treatment of Type 2 diabetes. The increase in drug spend attributable to drug mix over the first half of 2023 was driven primarily by a comparative increase in the use of Wegovy. In 2022, Wegovy accounted for 2.73% of days' supply dispensed, whereas in the first half of 2023 Wegovy accounted for 8.63%. However, increasing price and drug mix changes account for a small part of the increase in total drug spend within the GLP-1 class. As shown in **FIGURE 1**, from 2022 to the first half of 2023 utilization of GLP-1 products grew by a factor of 2.5, driving a 171% increase in gross cost per member over the same period. From 2021 to the first half of 2023 utilization grew by a factor of 3.9, and gross cost per member increased by 258%.

	2021	2022	2023
GLP-1 Utilization per 1,000 Members	1.6	2.5	6.3
GLP-1 Gross Cost per Member	$8.99	$13.56	$23.16
GLP-1 Contribution to Total Gross Cost	6.3%	8.7%	13.6%

FIGURE 1

A Quick Background on GLP-1s

GLP-1s were first studied and approved to treat Type 2 diabetes. This class of drugs stimulates glucose-dependent insulin release, slows gastric emptying, increases satiety and reduces food intake. In clinical trials, GLP-1s demonstrated clinically significant decreases in A1C, and during the studies it was observed that certain portions of the study population experienced significant weight loss. This led drug manufacturers to pursue clinical trials specific to weight loss management and in June 2021, the Food and Drug Administration (FDA) approved Wegovy for this indication. Semaglutide is the active ingredient in Wegovy, and it is the same active ingredient in Ozempic. The differences between Wegovy and Ozempic are: Ozempic has an FDA indication for the treatment of Type 2 diabetes, while Wegovy has an FDA indication for weight loss management, is prescribed at comparatively higher doses and cost on a per therapeutic unit basis.

Although Saxenda and other medications were on the market for weight loss management prior to the launch of Wegovy, Wegovy's safety profile and labeling showing 15% weight loss from baseline was a game changer. The launch of a medication with those levels of safety and effectiveness for weight loss management triggered tremendous demand for the medication and a wave of media attention. By December 2021, NovoNordisk, the manufacturer of Wegovy, announced that it was in short supply due to underestimating demand and a host of other supply chain issues. With demand for Wegovy already outpacing supply, in January 2022, the American Diabetes Association (ADA) released new clinical guidelines outlining GLP-1 agents as a first-line treatment option in addition, or as an alternative to metformin in patients with Type 2 diabetes. The guideline updates also specifically recommended Wegovy use for overweight or obesity therapy in those with Type 2 diabetes. The news of these guideline changes added fuel to what was already explosive demand. And with that demand, by August 2022 the FDA announced that Ozempic was in short supply.

Despite the supply issues eventually experienced by both Wegovy and Ozempic, utilization of these drugs grew tremendously over the past year. The growth of this utilization was certainly caused by the effectiveness of the medications, the change in ADA guidelines and the notoriety these drugs have garnered through social media and other media outposts.

Increasing the Utilization of GLP-1s is a Veritable Certainty for Several Reasons:

- With the change in ADA guidelines placing GLP-1s in primary position for the treatment of Type 2 diabetes, the likelihood of newly diagnosed patients beginning therapy on a GLP-1 increases dramatically.
- The prevalence of Type 2 diabetes and obesity continues to grow significantly year over year.
- NovoNordisk has already improved some of its supply chain issues which will increase access to Wegovy and Ozempic.
- Newer GLP-1 products with more impressive clinical profiles have entered or will soon enter the market.
- Research is being conducted to determine whether GLP-1s may prove beneficial for the treatment of numerous other conditions including cardiovascular disease, Parkinson's disease, sleep apnea, addiction and pre-diabetes.

Whether any GLP-1 will expand indications beyond the treatment of Type 2 diabetes and obesity remains to be seen. Regardless, it is clear that GLP-1 utilization will continue to increase, even if indications for these drugs do not expand beyond their present state.

What Can Plan Sponsors do to Proactively Manage This Expected Increase in Utilization?

Because of the certainty of increased utilization of GLP-1s, now more than ever, pharmacy benefit plan sponsors should review their coverage and management strategies associated with GLP-1s to ensure they align with benefit plan philosophies. For most pharmacy benefit plans, agents to treat Type 2 diabetes are covered. The question then, for most plans, is how to manage GLP-1 utilization. The answer depends, in part, on whether the pharmacy benefit plan covers medications for weight loss management.

While there is a growing trend to cover medications for weight loss management among Employers Health's pharmacy benefit management (PBM) clients, there are also many that do not.

For those that do not, part of the strategy to manage GLP-1s for the treatment of Type 2 diabetes must include strategies to limit off-label use of GLP-1s for weight loss management by limiting access to GLP-1s indicated for diabetes management. Whether the pharmacy benefit plan covers medications for weight loss management or not, at the minimum, a sound management strategy should include clinical edits to confirm diabetes diagnosis and history of use of medications for the treatment of diabetes. Beyond that, plans should consider implementing prior authorizations that align with product labeling and require confirmation of at least one comorbidity through attestation or documentation along with active participation in a diet and/or exercise program.

For plans that cover medications for weight loss management, a sound strategy for managing GLP-1 utilization includes a minimum body mass index (BMI) and/or a minimum waist circumference. Beyond that, similar to prior authorizations for utilization management for Type 2 diabetes, plans should consider implementing prior authorizations that align with product labeling and require confirmation of at least one comorbidity through attestation or documentation, in conjunction with active participation in a diet and/or exercise program.

GLP-1s can be highly effective agents for the treatment of Type 2 diabetes and obesity; however, they are costly and have a high discontinuation rate. Whether the plan covers medications for weight loss management or not, prior authorizations for GLP-1s should allow ongoing monitoring of the ability of the patient to tolerate the GLP-1 product, to ensure that the patient is compliant with the medication regimen and to make certain that the GLP-1 product is helping the patient to achieve treatment goals.

Should Your Plan Cover GLP-1s for Weight Loss?

While no study exists that can definitively state whether the cost of covering GLP-1 therapies for weight loss is outweighed by the savings associated with halting the progression of comorbidities, certain criteria can help inform a decision on whether a plan should adopt or maintain weight loss management medication coverage. Coverage of medications for weight loss management is an investment in long-term health; therefore, providing such coverage by organizations with a high-turnover rate may not be appealing.

For plan sponsors that elect weight loss coverage under the pharmacy benefit, it is highly recommended to adopt utilization management around GLP-1 products. This is crucial to ensure appropriate use and minimize an increase in spend that may follow this coverage decision. These controls often include prior authorizations and quantity limits to verify medication eligibility, therapy results and to prevent discontinuation waste. With significant discontinuation rates, limiting the days' supply of these products is a sound solution, in addition to prior authorizations, that can reduce medication waste and protect plans from unnecessary expenses.

Because of the cost and potential efficacy and waste associated with GLP-1s, there are many factors to consider when evaluating coverage and management options. Employers Health's team of clinical advisors and benefits professionals can help tailor GLP-1 coverage and management strategies to conform with your plan's benefit philosophy. If you have questions about GLP-1 coverage or other plan design questions, we encourage you to contact us.

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Client Spotlight

Aileen Espiritu

Benefits Manager

essity

Essity is a leading global hygiene and health company, producing and marketing consumer goods and services with roughly 3,000 employees in the United States and 48,000 global employees. Dedicated to improving the well-being of consumers through hygiene and health solutions, Essity encourages people to live happier, healthier lives. We recently spoke with Essity's benefits manager, Aileen Espiritu to hear about her approach to benefits and some of the unique philosophies this Swedish-based company incorporates in its benefits.

How long have you been at Essity and have you been with the HR/ benefits team the entire time?

I have been with the Essity benefits team for five years, going on six. Before joining Essity, I was a benefits consultant and was actually Essity's consultant for over 10 years.

How does your company approach health benefits and overall well-being for your employees?

The name Essity is a combination of "essentials" and "necessity," so our overall approach to health benefits and well-being is rooted in our commitment to keeping people healthy. We review our plans annually, benchmarking them for competitiveness and actively listening to employees to understand their evolving needs. Additionally, we know 85% of U.S. employees obtain their health insurance coverage through their employer, so it's important that we focus on total rewards and not just salary.

Our dedication to diversity, equity and inclusion ensures our benefits programs cater to the needs of everyone, enabling all plan members to live healthier and happier lives. Using a DEI perspective, Essity's Benefits Administration Committee reviews and approves changes with a focus on more than just cost. The committee works to ensure that any changes help to improve or enhance a person's well-being.

How has your organization been innovative in delivering health care benefits?

Essity self-funds its medical, pharmacy and dental insurance programs, providing us with greater access to the data we need to understand the unique needs of our population. This empowers us to tailor solutions and programs that can genuinely transform how plan members view their health and wellness. Through this data, we recognized the high prevalence of Type 2 diabetes among our employees and their dependents. Not only is diabetes an expensive disease to manage, but it was also causing disability claims amongst people who didn't have their condition under control. As a result, we identified a vendor and now offer a voluntary program at no cost to participants that is changing lives for the better.

We realize it's not just important to offer the program, but effectively promote it. We received many positive testimonials from plan participants and share many of those on the Essity and vendor websites. As a result of the program not only are employees improving their A1C, but they are improving their overall health and well-being.

Can you share what makes your workplace/benefit plan unique?

Utilizing the data available from our PBM, we have made it a priority to remove cost barriers. Through a value-based plan design for our prescription drug program we've eliminated copays for especially prevalent conditions like diabetes, depression and hyperlipidemia. Our team recognizes that even small financial relief can make a tremendous impact. By eliminating copays for some of these disease states, we've enhanced affordability and support for Essity employees.

What are your thoughts on the future of employee benefits?

When looking at the future of employee benefits, it's crucial to recognize the evolving and diverse needs of employees. As younger generations join the workforce, we need to provide them with benefits that fulfill their needs. While health care will remain a vital component, we know younger workers are also interested in benefits like student loan support and pet insurance. Employers will need to keep up to attract and retain talent.

Additionally, one of the most important things we learned from the pandemic was just how much mental health impacts your physical health and well-being. Future employee benefits will need to provide essential resources for employees and their family members seeking essential support and resources for their mental health.

How long have you been engaged with Employers Health?

We learned about Employers Health through the Greater Philadelphia Business Coalition on Health and later joined in 2019 for its group purchasing programs for pharmacy benefits through CVS Caremark.

How does Employers Health contribute to your organization's overall benefits strategy and your mission?

As I mentioned previously, the data available as a self-insured plan sponsor is invaluable. Employers Health presents us with crucial data that helps our team make important plan decisions. Statistically, a prescription drug plan is a very utilized benefit. With the guidance of Employers Health, we can evaluate and make plan design changes, not just for change's sake but with the knowledge of how it will impact our participants. Through this guidance and impressive annual contract negotiations, Essity can live out its mission of keeping its people healthy through affordable prescription pricing.

How has your relationship with Employers Health evolved?

From regular monthly meetings with the CVS Caremark and Employers Health team, to contract term negotiations that improve every year, the team at Employers Health's unwavering commitment to understanding CVS programs and aligning them with our needs shows how committed they are to our organization. Through our years working together, I know that I can count on Employers Health to live up to its promises.

When Essity moved to Employers Health it went from one of the other big three pharmacy benefit managers to CVS. Can you share a little about that transition and any significant differences the benefits team and employees have experienced?

We were previously purchasing pharmacy benefits directly with one of the big three PBMs and the service was not good, so that was a major factor for us. When we transitioned to CVS through Employers Health, we were able to address issues we had with our previous PBM like low mail-order utilization. The implementation was smooth, and through CVS' Maintenance Choice offering, we provided 90-day fills at CVS retail pharmacies, helping to improve 90-day utilization while achieving better pricing and maintaining a sustainable program.

How has Employers Health demonstrated its proactive and responsiveness to evolving market trends for your plan and employees?

Employers Health continually impresses us with exceptional annual contract negotiations. We find tremendous value in offering a sustainable pharmacy benefit. The overall cost has enabled us to keep a copay program and not move to a co-insurance program. Additionally, its team's active participation as a voice for us with the PBM, insightful advice and information helps us navigate changes, providing a smooth, painless experience for our members. We also value the feedback we receive through other Employers Health clients, so overall, the advice is invaluable. It helps us to mitigate noise and make sound decisions for our members.

Have a story to share?
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