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# Summer 2023

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Soaring Psoriasis: Market Trends and Opportunities for Psoriatic Conditions

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Madison Evans, J.D., CEBS Employers Health



Client Spotlight

Interview with Troy Washington from the University of Dayton

### Christopher V. Goff, Esq.

CFO & General Counsel

Christopher 8. Soft

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### MESSAGE

### FROM CHRIS GOFF

A quick Google search of pharmacy benefit managers produces a smattering of headlines covering the PBM industry. A House Oversight Committee hearing on PBMs, a Senate Commerce Committee article titled, "Bringing Transparency and Accountability to Pharmacy Benefit Managers", and another regarding the Federal Trade Commission's vote to withdraw its prior advocacy for PBMs do not bode well for the industry. Transparency, advocacy and accountability are nothing new in the PBM arena. But, what does all this really mean for employers?

It means it is more important than ever that employers have a trusted advocate on their side. Make sure you know your local senator or congressman and ensure he or she knows the importance of laws such as ERISA preemption and preserving an employer plan sponsor's ability to design narrow pharmacy networks and incentivize mail-order prescription deliveries in exchange for lower prescription costs. We encourage you to reach out and share what the proposed changes could mean, not just for your organization, but for your employees and even the community in which they live and work. While these proposed changes are drafted with the intent to lower the costs of prescription drugs, they often limit employer choice and increase the costs of plan administration. Higher costs for employers could mean higher premiums for employees and ultimately less money being put back into the community.

As an added advantage of being an Employers Health client, you have access to a team of benefits professionals; attorneys, clinicians and more to help answer what these changes mean for employers. Madison Evans, our senior vice president of regulatory compliance and external affairs, is upto-date on the latest state and federal legislation pending throughout the U.S. that could affect your plan. She works with our analytics and clinical teams to evaluate how these changes could cost your plan and its participants. As an independent advocate, our team has your best interests in mind and brings the employer voice to the table.

And, as Employers Health grows in client size, our team is also growing. We've added two additional clinical team members bringing the team to a total of 10 pharmacists. As we near 70 employees, our mission remains the same, "to provide resources, tools and advice to help plan sponsors deliver high-quality health care benefits at a sustainable cost."

I hope you think of us as your advocate; we're here for you to help explain what is driving these legislative efforts and how they may affect your plan. If you are interested in reaching out to your local legislative representatives, let us know. We can provide you with resources to help advocate for your plan.



## 2023 Fall Benefits Forum: Health Value and Trends

Wednesday, November 15, 2023 11:00AM-2:30PM

Pro Football Hall of Fame
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Event will be live streamed



### Soaring Psoriasis: Market Trends and Opportunities for Psoriatic Conditions

Patrick Henry, PharmD
Clinical Advisor

Pharmacy benefit plan administrators often see autoimmune conditions, such as rheumatoid arthritis and psoriasis, as large contributors to their spend. Within this class, psoriatic conditions like plaque psoriasis and psoriatic arthritis are leading to higher pharmacy spend than ever before, particularly due to biologics.

By the end of 2023, the total direct health care cost of psoriasis in the United States could be \$60 billion or more, while estimates for indirect costs may be upwards of \$35 billion.¹ When accounting for productivity losses, indirect costs could be at least \$4,000 per person annually.² Biologic therapies account for a large majority of the direct costs, with most of this spend occurring under the pharmacy benefit. Despite the higher pharmacy costs, these products control symptoms effectively and reduce disease progression, which can help control further spend down the road.

Because of their strong track record, biologics have quickly gained notoriety as the best available treatments for psoriatic conditions. Plaque psoriasis, more commonly known as psoriasis, and psoriatic arthritis are closely related as about 30% of people with plaque psoriasis develop psoriatic arthritis.3 Given this close connection, medications used for plaque psoriasis are often effective for psoriatic arthritis as well. This includes Humira, Stelara and most specialty biologics used for psoriasis. Psoriatic arthritis symptoms include uncomfortable skin lesions seen in psoriasis, but these patients also experience joint pain, swollen fingers or toes and reduced mobility. Both conditions increase the risk of developing comorbidities such as diabetes and obesity, but psoriatic arthritis may carry a larger burden to the health care system. Over the last 10 years, all-cause annual health care costs per patient with psoriatic arthritis were almost \$30,000 compared to about \$11,000 for those with plaque psoriasis, highlighting the economic burden of psoriatic arthritis.4 While reviewing claims data, plan sponsors should consider how both conditions are affecting their plan.

Despite the higher spend that biologic products are associated with, treatment options are available that can save costs for members and plan sponsors. Conventional therapies such as methotrexate, topical steroids or vitamin D analogs can control symptoms for mild psoriasis without leading to high costs. Phototherapy is another form of cost-effective treatment whereby patients are exposed to controlled amounts of UV light, which can help reduce inflammation on the skin.



In general, patients will visit the hospital or clinic three times a week to receive phototherapy. However, home phototherapy provides substantial costsavings over time for plan sponsors and reduces the burden of treatment for members. A 2018 study estimated that biologics can cost up to 36 times more than home phototherapy over a three-year period since initial setup is the primary source of phototherapy costs.<sup>5</sup> Before starting biologics, phototherapy could be incorporated into prior authorizations to control unnecessary utilization.

Even with tight plan controls, a small number of utilizers of biologic products can have a large impact on spend. Many biologics are single-source brands that do not have market competition to lower costs, which can help explain this impact. The complexity of biologics



necessitates a different approval process for therapeutically equivalent products, which has led to the development of biosimilars. Biologic manufacturers have been able to prevent competition for several years, but many popular products are losing market exclusivity as patents expire. Amjevita was launched this January as the first biosimilar to the blockbuster autoimmune drug, Humira. We expect up to 11 more biosimilar products to launch for this medication throughout 2023. Another highly utilized psoriasis product, Stelara, is expected to lose exclusivity this September. No biosimilars to Stelara have been approved yet, but recent patent settlement agreements make the launches unlikely until January 2025. Loss of exclusivity may also occur for Cimzia in 2024, further expanding the potential biosimilar market for psoriatic conditions. Cost savings will depend on formulary status and market competition, which will take time to produce a significant impact.

Manufacturers are also continuing to invest in the research and development of products for these psoriatic conditions. At the end of 2022, we saw

the launch of a new oral treatment option for psoriasis called Sotyktu that showed favorable results when compared to a common oral product, Otezla. Improved topical treatments for plaque psoriasis have also been a priority for manufacturers as two new topical products were launched in 2022. These products are Vtama and Zoryve, which will compete for formulary placement going forward. Beyond oral and topical products, a new injectable product called Bimzelx (bimekizumab) may see market entry in 2023, but approval has been delayed due to manufacturing concerns. Bimzelx provides a novel mechanism of action, although market uptake may be limited as a result of delayed approval and strong competition. Lastly, Spevigo is a recently approved injectable product for a rare, potentially life-threatening form of psoriasis called generalized pustular psoriasis. FDA approved medications for this condition did not exist prior to Spevigo, which applies to several other dermatological conditions with recent approvals. Novel products often have limited indications and higher costs, making them ideal targets for prior authorization with step therapy and controls to prevent off-label utilization.

Psoriatic conditions can bring high utilization and spend to pharmacy and medical benefit plans due to their health care burden. Members with psoriatic conditions often require biologic medications and increased medical support for their underlying condition and comorbidities. Biologics are effective treatment options, but as large contributors to spend, they are also primary targets for pharmacy utilization management. Incorporating step therapies with conventional medications and phototherapy are great opportunities to mitigate biologic utilization and spend. Biosimilars represent another opportunity to save costs as the first Humira biosimilar was launched in January, while Stelara and Cimzia may see biosimilar competition in late 2024 and 2025. Although biosimilars are expected to bring significant savings for psoriasis and other autoimmune conditions, market competition and formulary placement will determine when those savings can be realized by plan sponsors.

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Patrick Henry, PharmD phenry@employershealthco.com





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# Mental Health Parity Reminders: Are You Prepared for a DOL Audit?

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



Employers have more progress to make in demonstrating that mental and behavioral health benefits are offered in parity with medical and surgical benefits. A January 2022 report to Congress from the Department of Labor (DOL), the Department of Health and Human Services and the Department of the Treasury found that none of the more than 1,000 plans reviewed provided sufficient analyses showing that their mental health coverage was no more restrictive than medical and surgical coverage. In response to this finding, on July 25 the DOL announced proposed regulations to strengthen the Mental Health Parity and Addiction Equity Act (MHPAEA).

### Requirements summary

The MHPAEA generally requires that group health plans and health insurance issuers offering group or individual health insurance coverage ensure that the financial requirements and treatment limitations on mental health or substance use disorder (MH/SUD) benefits they provide are no more restrictive than those placed on medical or surgical benefits. This is commonly referred to as providing MH/SUD benefits in parity with medical and surgical benefits.

Plans must perform an analysis demonstrating parity in each of these six benefits classifications:

Inpatient, in-network benefits

Inpatient, out-of-network benefits

Outpatient, in-network benefits

Outpatient, out-of-network benefits

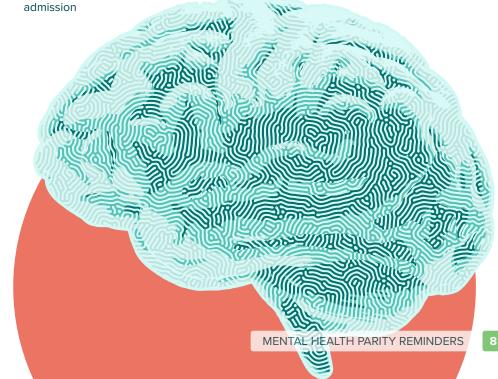
Emergency care benefits

Prescription drug benefits

Plans must show parity for both quantitative standards and nonquantitative treatment limits. Quantitative standards include financial requirements and quantitative treatment limits; plans cannot place financial requirements, such as copays or coinsurance, and quantitative treatment limits, such as day and visit limits, on MH/SUD benefits that are more restrictive than the limits applied to substantially all medical and surgical benefits. Behavioral health and medical/surgical benefits must count toward the same deductible, out-ofpocket maximum and visit cap. Nonquantitative treatment limits (NQTLs) include any limitation on coverage that is not numerical. MHPAEA regulations include a non-exhaustive list of common NQTLs such as: prior authorization, limitations based on medical necessity, formulary design for prescription drugs, standards for provider

to participate in a network and network tier design. Because it is far easier to determine parity based on quantitative standards, almost all agency efforts and enforcement occur in the NQTL category.

The 2021 Consolidated Appropriations Act (CAA) introduced a new requirement for health plans to conduct and document an analysis that compares the NQTLs that apply to MH/SUD benefits to the NQTLs applied to medical and surgical benefits. Plans must be prepared to provide an NQTL comparative analysis upon request from the DOL. Prior to the enactment of the CAA, the Departments recommended that plans analyze the NQTLs and maintain documentation as a best practice. It is now a requirement for plans to do so.



### Each comparative analysis must show:

O1 The specific plan or coverage terms regarding the NQTL and a description of benefits to which the term applies in each respective benefits classification.

O2 The factors used to determine that the NQTLs will apply to behavioral health benefits and medical benefits.

O3 The evidentiary standards used for the factors identified.

O4 The comparative analyses demonstrate that the processes, strategies and factors used to apply NQTLs to MH/SUD benefits are comparable to and applied no more stringently than the processes, strategies and factors used to apply the NQTLs to medical/surgical benefits.

O5 The specific findings and conclusions reached by the plan, including results of the analyses that indicate the plan is or is not in compliance with the MHPAEA requirements.

The departments have provided that their main areas of focus and testing will be prior authorization requirements for in-network and out-of-network inpatient services, concurrent review for in-network and out-of-network inpatient and outpatient services, standards for provider admission to participate in a network, including reimbursement rates and out-of-network reimbursement rates (plan methods for determining usual, customary and reasonable charges).

### Audit process and procedure

The CAA requires government auditors to request NQTL comparative analyses from at least 20 different plans each year. If auditors find the documentation of a comparative analysis to be insufficient, they will specify what additional information must be provided. If the auditors find noncompliance, they will specify actions that need to be taken. Plans will generally have 45 days to respond with additional comparative analyses that demonstrate compliance. The auditors may then issue a final determination. If that determination concludes that the plan remains out of compliance, the plan will need to notify all participants of that determination within seven days.

Although documents provided in the exchange with auditors will not be subject to public disclosure, certain information may be shared. The agencies will report their audit findings to state regulators and Congress. Further, the annual report to Congress will identify plans that did not provide adequate information or are found to be noncompliant. Plans and insurers are also required to provide documentation of their comparative analyses to state regulators and plan participants on request.

## DOL seeking comments on proposed rule

On July 25, 2023, the Departments released a highly anticipated annual report to Congress, which for the first time, identified health plans by name that had been issued final determinations of noncompliance with the MHPAEA. Along with this report came a long overdue regulatory proposal that the Departments are seeking public commentary on. The proposed rules touch on a number of aspects of the MHPAEA including-data collection requirements and new and expanded examples to address medical management techniques and provider network standards for MH/SUD benefits. Comments are due by October 1, 2023.



In the proposed rules, employers are seeking guidance spelling out specific examples of what the agencies consider to be adequate analyses on why some mental health coverage limits may differ from coverage for medical and surgical benefits. Another issue that complicates these analyses is that plans are often unable to get the information necessary to complete the reporting from third-party vendors that administer their plan.

In the January 2022 report, the DOL recommended that Congress amend the **Employee Retirement Income Security** Act (ERISA) "to expressly provide the agency with the authority to directly pursue parity violations by entities that provide administrative services to ERISA group health plans (including health insurance issuers that provide administrative services to ERISA plans and TPAs)," or third-party administrators. It remains unclear how much the DOL can push vendors to provide these analyses as the regulations are likely unable to mandate conduct by thirdparty service providers.

At a minimum, employers have requested that the departments create a model NQTL template with instructions and provide further clarity on each category of NQTL. They have additionally requested, adoption of a safe harbor regarding widely accepted practices that do not pose a material risk of violating parity. Finally, updates need to be made to the departments' MHPAEA self-compliance tool in order to provide employers with more structured guidance.

### Employer considerations

Sponsors of self-funded health plans should consult with their benefit plan vendors. Those vendors must be prepared to comply with the NQTL requirements for their fully-insured lines of business. Even if a vendor is unwilling to perform the analysis and prepare a report, a plan sponsor will need to obtain information from the vendor regarding subjects such as network development, procedures and controls and operational compliance and may seek documentation that the vendor has prepared for the analysis of its own insurance products. Plan sponsors might even consider contracting with a third-party vendor to complete the plan's comparative analysis documentation for a DOL audit.

### Resources for plan administrators

O1 Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act: https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/self-compliance-tool.pdf

O2 2023 Mental Health Parity and Addiction Equity Act Report to Congress: https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf

O3 2023 Proposed Rules: https://www.govinfo.gov/content/pkg/FR-2023-08-03/pdf/2023-15945.pdf





United Way of Greater Stark County recently recognized Employers Health as a Leading the Way award recipient. This award is the highest honor to those with existing employee campaigns.

[Pictured above Garrett Brown, senior vice president, legal, with Carrie Clemens, vice president of resource development at United Way.]

Vice President of Client Solutions, Travis Johns, is serving as chair of the National Alliance on Mental Illness (NAMI) Stark County 5th Annual Golf Outing raising funds for those impacted by mental illness.

Lisa Oesch, controller, recently joined the board of directors of RAHAB, an organization providing transformational services to those affected by sex trafficking in Northeast Ohio.

Clinical Advisor, Courtney Keefe, recently served as part of an Obesity Advisory Board hosted by one of the world's largest pharmaceutical companies.

Travis Johns graduated from Leadership Stark County's Signature Program as a member of the 36th Class.

Emily Clevenger, director, marketing, was recently voted in as a member of the Stark County Library Foundation Board. The organization works to financially support the mission of the library in order to grow programming and services.

### BEST EMPLOYERS IN OHIO 2023 CRAIN'S CLEVELAND BUSINESS

Employers Health was recently named as one of the 2023 Best Employers in Ohio by Best Companies Group in partnership with Crain's Cleveland Business and Crain's Content Studio-Cleveland.

Senior Vice President, Regulatory
Compliance and External Affairs,
Madison Evans, was selected to join
the board of directors for CommQuest,
an organization which provides
collaborative care and advocacy through:
mental health, addiction recovery and
social support.



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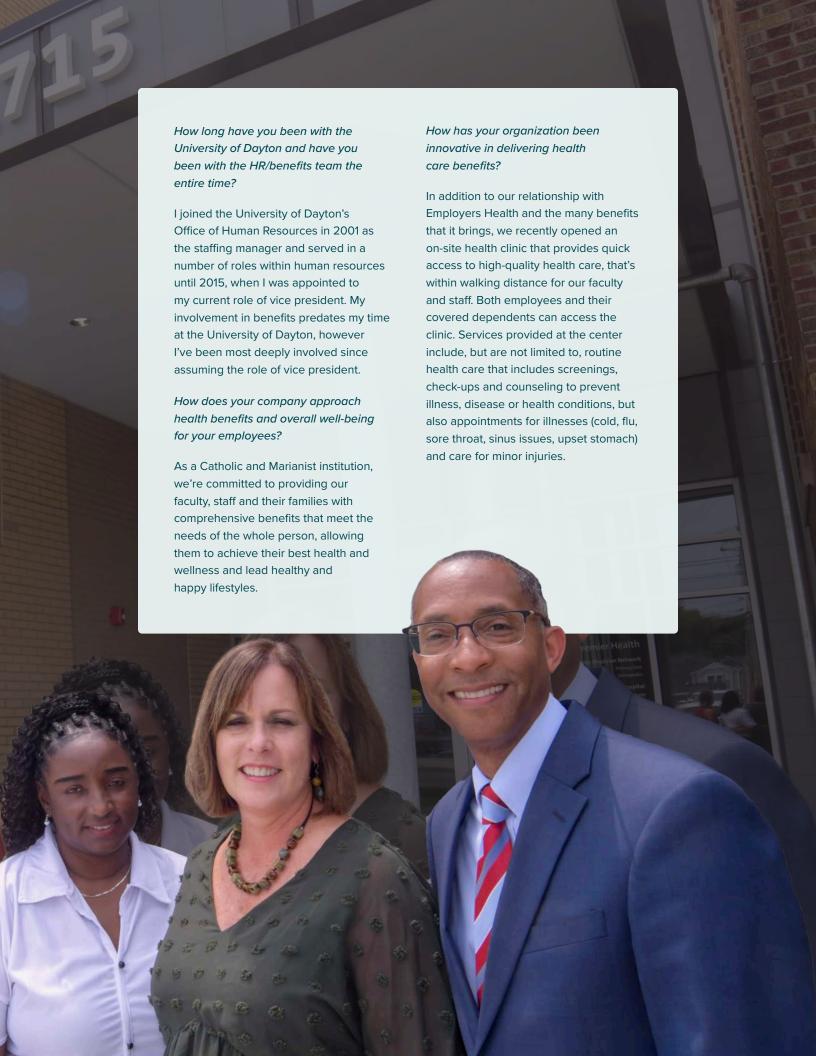
Troy Washington

Vice President for Human Resources



Founded in 1850, the University of Dayton is a Catholic research university located in southwest Ohio. With more than 80 undergraduate programs and 50 graduate and doctoral programs, it employs nearly 5,000 while more than 10,000 graduate and undergraduate students attend the school.

We recently sat down with the university's Vice President for Human Resources, Troy Washington to hear how he got his start in HR and benefits, how he and the team work to keep health care costs low while still providing competitive benefits, and how the university's on-site child care facility and new on-site clinic set it apart.



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

In addition to offering on-site care, our wellness programming is one of the hallmarks of our benefits offerings. At the University of Dayton, our approach is to provide wellness opportunities to meet the needs of the whole person, extending beyond physical wellness and including financial, spiritual and mental wellness. This approach, in addition to our experienced, dedicated and passionate team has led to the University being recognized as one of the healthiest employers in the region on numerous occasions.

### What are your thoughts on the future of employee benefits?

Like many other aspects of human resources, digital transformation and the enhancement of digital platforms will continue to have a significant impact on the access to and management of employee benefits. In an environment where the prevalence of hybrid and remote work continues to increase, having systems in place that offer employees quick, convenient and affordable access to high-quality information and care will be paramount for the future.

### How long have you been engaged with Employers Health?

We joined Employers Health in 2011, so 12 years! We began purchasing pharmacy benefits through Employers Health in 2018.

Previously, your pharmacy benefits were carved in through your medical provider. Can you tell us the differences you've experienced carving out through the Employers Health CVS deal?

Since carving out the pharmacy benefits and moving them to CVS, the relationship and consultation have provided consistent analysis and discussion around any initiatives and cost-saving measures. Subsequently, those analyses have resulted in the ability to add further cost savings and to better manage pharmacy costs and drive appropriate use of medications.

#### What value do you derive by being part of an organization like Employers Health?

Our relationship with Employers Health has positioned us well, to benefit from economies of scale that we would not otherwise be able to leverage, helping both the university and our faculty, staff and their dependents manage health care costs.

Have a story to share?

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