EMPLOYERS HEALTH®

A publication of Employers Health Coalition, Inc.
Fall/Winter 2018

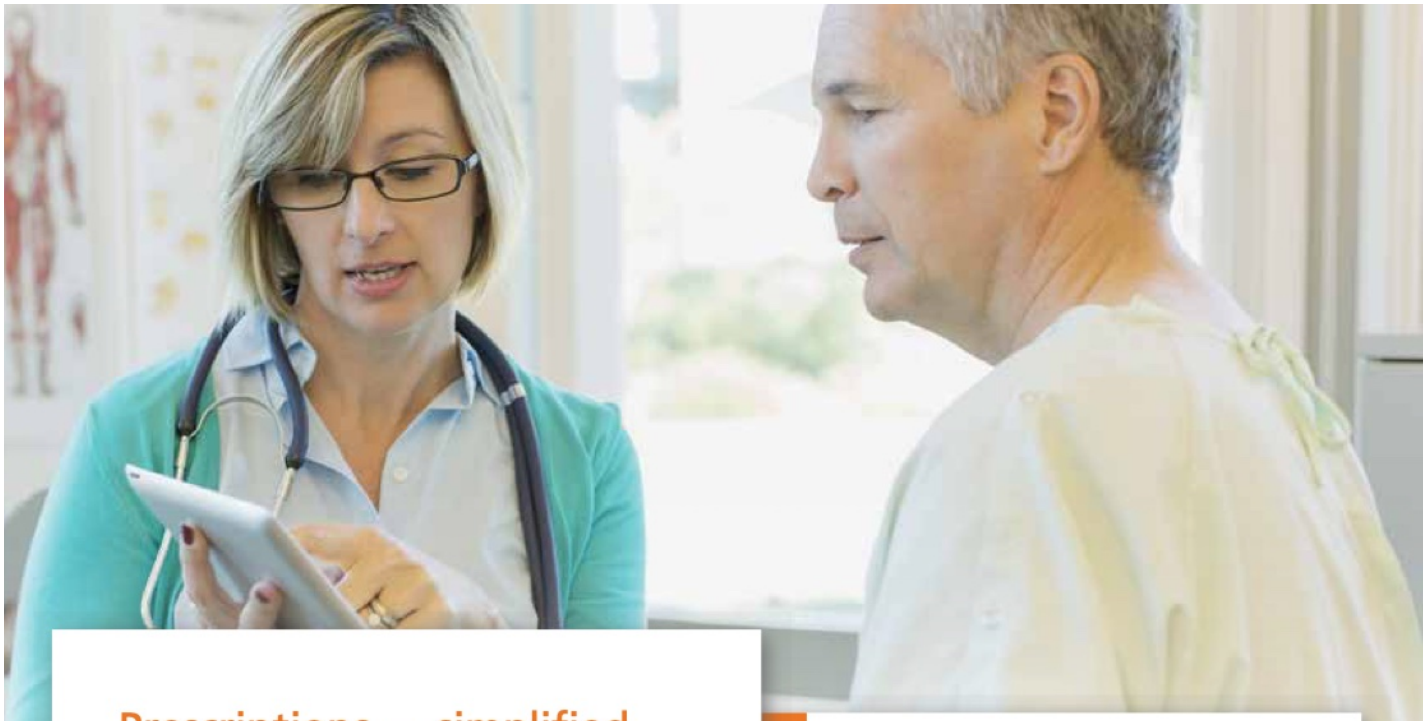
EHconnect

CLAWBACKS, GAG ORDERS... 6

2019 MARKET CHECK 12

Collaboration Spotlight
THE AMERICAN PSYCHIATRIC ASSOCIATION FOUNDATION

Our Q&A with Darcy Gruttadaro
Director of the Center for Workplace Mental Health → 22



Prescriptions — simplified

Providing patient-specific pharmacy information at the point of prescribing.

It happens all the time: After standing in line for a bit, you get to the pharmacy counter only to be told the prescription hasn't been approved yet. Or that it costs more than you expected. Or that your doctor needs to provide more information first.

OptumRx® **PreCheck MyScript™** helps avoid those surprises by giving physicians patient-specific pharmacy-benefit information up front. The tool integrates with any electronic medical record (EMR) system, making it easy for physicians to see, in real time:

- A medication's formulary placement
- The patient's cost share
- Prior authorization requirements and, often, on-the-spot approvals
- Clinical alerts such as duplication or potential interactions

It all adds up to more empowered physicians, smoother plan performance, and less pharmacy hassle for you.

PreCheck MyScript helped guide physician decisions at the point of prescribing:

>20%
of physicians switched to an alternative drug[1]

>30%
prior authorizations avoided or initiated[2]

OPTUMRx®

1. OptumRx. PreCheck MyScript program results. 2017. 2. Ibid.

INSIDE THIS ISSUE

Contents

Collaboration Spotlight

THE AMERICAN PSYCHIATRIC ASSOCIATION FOUNDATION

22

COVER IMAGE FEATURES *(FROM LEFT)*: DARCY GRUTTADARO, DIRECTOR, CENTER FOR WORKPLACE MENTAL HEALTH; EWURIA DARLEY, ASSOCIATE DIRECTOR, CENTER FOR WORKPLACE MENTAL HEALTH; DANIEL H. GILLISON, JR., EXECUTIVE DIRECTOR

PHOTOGRAPHER: DAVID HATHCOX

Emily Clevenger, Editor

2018 Meetings&Events

Stay ahead with Employers Health and save these dates!
You can always find our events calendar at employershealthco.com/events.
**Employer members only*

EMPLOYERS HEALTH annual meeting

THE LATEST TRENDS IN HEALTH CARE

NOV 28, 2018 8-10 A.M.

BREAKFAST & REGISTRATION 8-8:30 A.M.
KENT STATE UNIVERSITY
STARK CONFERENCE CENTER

EMPLOYER ROUNDTABLE: PBM trends

PHARMACY BENEFITS & MENTAL HEALTH TRENDS

DEC 13, 2018 8-11 A.M.

BREAKFAST & REGISTRATION 8-8:30 A.M.
CINCINNATI, OH

CINCINNATI OHIO PBM CONFERENCE

SAVE THE DATE
MAR 20, 2019
CINCINNATI, OH
MARRIOTT WEST CHESTER

ANNUAL INNOVATIONS IN BENEFITS CONFERENCE

SAVE THE DATE
MAY 15, 2019
CANTON, OH
KENT STATE UNIVERSITY AT STARK

HOLIDAY LUNCHES

Lunches are from 12-1 p.m.

DEC 04 | **TOLEDO**
HOLIDAY LUNCH*
BIAGGI'S RISTORANTE ITALIANO

DEC 05 | **CANTON**
HOLIDAY LUNCH*
BENDERS TAVERN

DEC 11 | **CINCINNATI**
HOLIDAY LUNCH*
STONECREEK DINING COMPANY

DEC 12 | **AKRON**
HOLIDAY LUNCH*
KEN STEWART'S

DEC 13 | **COLUMBUS**
HOLIDAY LUNCH*
CAP CITY DINER

NOV 30 | **CHICAGO**
HOLIDAY LUNCH*
GIBSON'S BAR AND STEAKHOUSE

**Employer members only*

Message from Chris

You'll see a common theme throughout this issue of EH Connect: heightened scrutiny of the pharmacy benefits industry. While we don't aim for a theme with each edition of EH Connect, it's hard to talk about pharmacy benefits today without mention of the countless news stories critiquing the pharmaceutical industry. As with most news stories, it's important for plan sponsors to keep in mind that there are multiple sides to every story.

While these industry critics frequently focus their scrutiny on one drug or one pricing mechanism, it is important for plan sponsors to concentrate on the total cost of the pharmacy benefit plan.

Associate Counsel Bryce Horomanski's article, "In the News: Clawbacks, Gag Orders and Other Painful Sounding PBM News," is an excellent primer on all of the PBM buzzwords that find their way into news stories and opinion pieces.

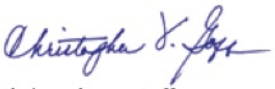
The 2019 Market Check article, written by Vice President of PBM Contracting and Strategy, Dave Uldricks, helps explain the bigger picture of PBM contracting and the importance and benefits of an annual market check.

Finally, on page 14, Employers Health pharmacists, Matt Harman and Kevin Wenceslao, detail the newest non-specialty condition, nonalcoholic steatohepatitis, or NASH.

The price a plan participant pays for a drug is an important factor in the pharmacy benefits industry, but as you will learn from the articles in this issue, it is not the only factor. Proper clinical management, an aggressively priced contract and sound definitions are all essential to providing a sustainable pharmacy benefit. As employers continue to recognize the benefit of a comprehensive group purchasing program for pharmacy benefits, the organization continues to grow stronger. So far this year, we have added more than 25 new employer members accounting for more than $175 million in pharmacy spend.

With this growth comes the responsibility to deliver exceptional service to our member organizations. We continue to add new team members to ensure the highest possible member satisfaction rate.

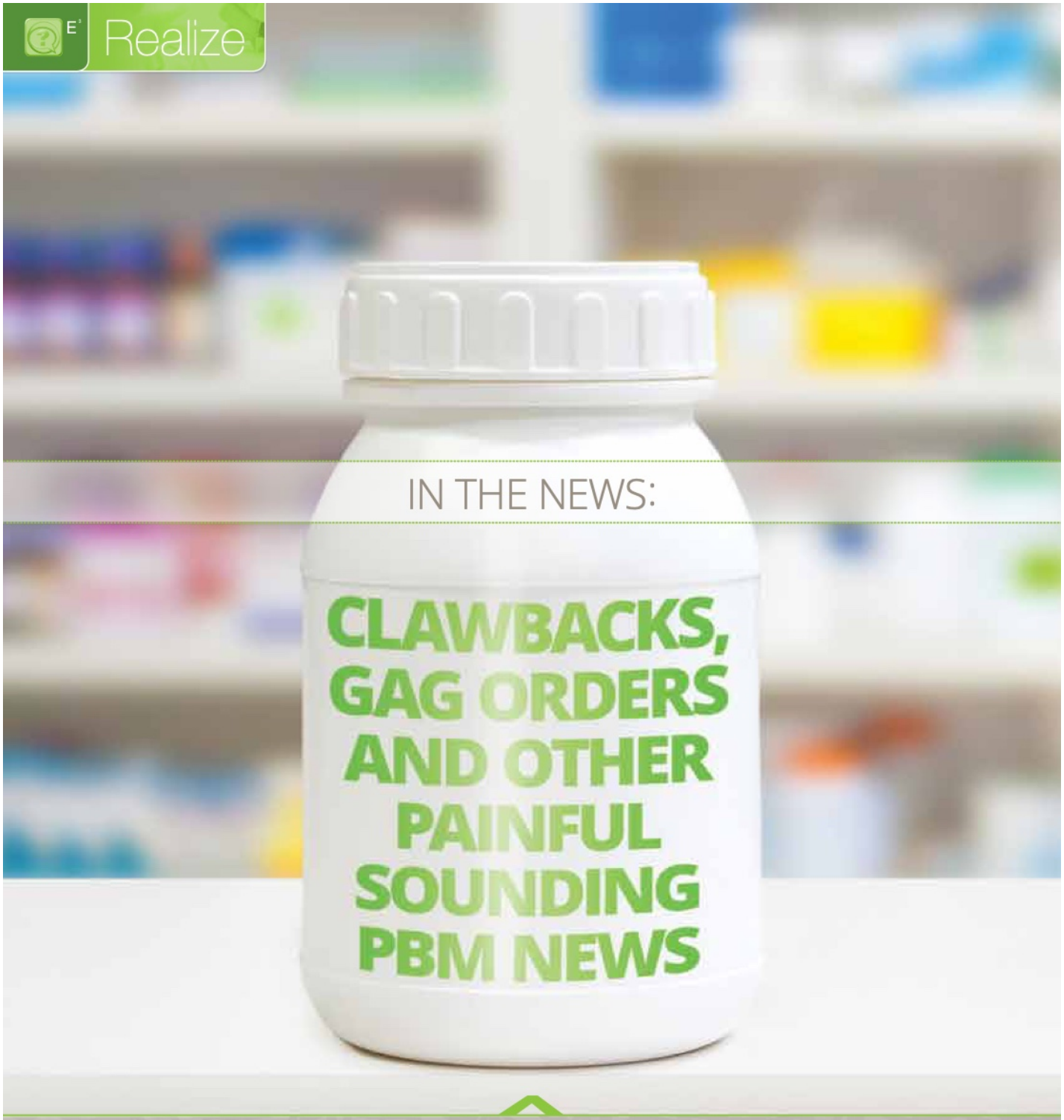
In June, Brooke Knollman, Madison Simmons and Kendall Nelson joined Employers Health and are based in our Cincinnati office. They will work as account management specialists to service our growing book of business. As an extension of your benefits team, it is important to have the best and brightest working alongside you to deliver the best experience possible. We value your continued relationship and engagement with Employers Health as we continue to navigate the challenges and opportunities that lie ahead.



Christopher V. Goff, Esq.
CEO & GENERAL COUNSEL

Welcome to our newest members!

- Catholic Diocese of Savannah
- Dolese Bros. Co
- Essity
- Georgetown University
- Lundbeck
- Morningstar
- St. Johns County, FL
- Terracon
- Total Quality Logistics, LLC
- Vertiv



IN THE NEWS:

CLAWBACKS, GAG ORDERS AND OTHER PAINFUL SOUNDING PBM NEWS

WRITTEN BY: **BRYCE HOROMANSKI, J.D.** *// Associate Counsel*

It seems on a weekly basis that publications introduce us to some new term that describes an unruly practice within the pharmacy benefit landscape. Clawbacks, spread, gag clauses and others dominate the headlines, with advocates for the many stakeholders in the pharmacy supply chain lining up to either launch an assault or defend their turf. Since the "purchaser" voice is usually absent from these national discussions, we have provided a high-level overview below.

CLAWBACKS

Clawbacks can arise in multiple scenarios, but most often occur when a patient is on a benefit plan that requires a minimum copayment regardless of the actual cost of the drug. While processing a prescription, the retail pharmacy sends information about the prescription to the individual's PBM. The PBM then tells the pharmacy the amount of the copay or cost sharing that it must collect from the patient. When the collected copay is more than the pharmacy's contracted reimbursement, the PBM reduces the pharmacy reimbursement by this difference. This reduction is referred to as the clawback. In some scenarios the PBM may keep these funds. In others, they are passed back to the insurance company or plan sponsor. Regardless, in most cases the patient is paying more than he/she would if the insurance plan was not being utilized.

GAG CLAUSES

On October 10, 2018, President Trump signed into law the Patient Right to Know Drug Prices Act. The act removes the ability for a PBM to enforce a contractual clause prohibiting a pharmacy from telling a covered individual the difference between his/her out-of-pocket cost for a medication and what the cost of the medication would be without insurance coverage. These clauses are better known as "gag" clauses.

Community pharmacists argue that gag clauses allow PBMs and insurance companies to overcharge patients. PBMs acknowledge that there is confidentiality language in its contracts but argue that the practice of charging minimum copays when the cash price is lower is a plan design decision made by the plan sponsor and is rare due to lowest of logic provisions. One recent study showed that patients are charged more than the cash price of the

drug approximately 25 percent of the time, but it is unknown how much of that study's data were from fully-insured plan designs that required a minimum copay.

The likely impact to self-funded plan sponsors is minimal if any. Since Walmart's introduction of its $4 generic drug program in 2006, most PBM contracts have included a "lowest of" provision where the plan is billed the lowest of the drug's discounted cost or the pharmacy's usual and customary price (U&C). In addition, many plan sponsors apply lowest-of logic to the application of a participant's cost share in its plan design. In many retail pharmacy agreements with PBMs, the U&C is defined as, "the price the pharmacy would charge a cash-paying customer for the same prescription."

The "Patient Right to Know Drug Prices was approved by a near unanimous vote in Congress and all stakeholders, including PBMs, supported the legislation.

LOWEST OF LOGIC

Lowest of logic is both a contractual clause and a plan design decision. The contractual clause requires a PBM to invoice the plan sponsor the lowest price among the discounted average wholesale price (AWP), the pharmacy's usual and customary price (U&C) or the maximum allowable cost (MAC). Plan design setup determines what cost is paid by the participant at the point of sale. When lowest of logic is implemented, a plan participant will be charged the invoiced cost to the plan or the participant's cost share, whichever is lower. When this clause exists in the PBM contract and the plan design, and when retail pharmacies are submitting their cash price as required by their network agreements, the participant should not pay more than the price he/she would otherwise pay without using insurance. This does not include prices associated with retail pharmacy membership programs or drug discount cards like GoodRx, which is an entirely separate conversation.

SPREAD

It is important to remember that the PBM determines the price it will reimburse a retail network pharmacy and the price it will invoice a plan sponsor on any given transaction, so long as it stays within the confines of its contractual arrangements. Retail spread occurs when the amount the PBM reimburses the retail pharmacy is less than the amount the PBM charges the plan sponsor. Certainly, this spread on retail claims is not the only place that a PBM can produce margin, but it is a common practice.

Under a traditional deal, negotiated discount guarantees are set forth in the contract, regardless of which pharmacy fills the prescription for participants. This benefits the plan sponsor because it provides a level of stability and certainty around its drug costs by taking channel and drug mix out of the pricing equation. The PBM puts itself at risk to hit the contracted guarantees. While the PBM is at risk for not hitting its guarantees, it benefits in circumstances when its payment to the pharmacy is less than the price it has guaranteed in its contract with the employer.

Under a basic pass-through deal, the PBM invoices the plan sponsor whatever it reimbursed the pharmacy. As the PBM cannot derive revenue from spread, it charges an administrative fee to the plan to cover the cost of its services. While there may be overall discount guarantees in the contract, they are typically lower than those set in a traditional deal, so the plan sponsor is at risk for its participants utilizing high cost versus low cost pharmacies.

It is possible to manage a traditional model with spread so that the total costs to the plan are less than a pass-through model. It is also possible for a pass-through model to generate savings, particularly for plans with limited networks, on-site pharmacies or who wish to direct contract with local pharmacies. Regardless, the model should be aligned with delivering the lowest net cost to the plan and its participants.

REBATES

Rebates are produced through a mechanism that allow PBMs, on behalf of their plan sponsor clients, to negotiate directly with drug manufacturers to reduce the price of brand name drugs. Without this ability to negotiate directly with manufacturers, PBMs would be required to negotiate with retail pharmacies to lower their prices, who would then have to negotiate with drug wholesalers, who would then negotiate with the drug manufacturers. Historical performance and an underlying knowledge of the supply chain would suggest that these intermediate entities are not interested in lowering drug prices under the current system.

While plan sponsors should want to preserve the mechanism of negotiating directly with manufacturers for additional discounts, there is no debate that the inflation of list prices and their corresponding rebates has risen to a level of absurdness. Complicating the issue is the practice of PBMs and health insurance companies of keeping all or part of the rebates tied to a plan sponsor's utilization. In these cases, the PBM directly benefits as rebates grow.

Further complicating the matter are contractual rebate guarantees that PBMs have with plan sponsors, particularly those guarantees for future years of the contract term. Under these arrangements, the PBM has set the guarantees based on its expectation of the plan's rebate yield, both in the short and long term. As new drugs come to market in established therapeutic classes with lower list prices and lower rebate values, it is difficult for a PBM to add these drugs to its formulary without renegotiating the rebate guarantees in its contracts with plan sponsors. Without adequate transparency of the drug-level rebates and appropriate analytics, many plan sponsors see taking a reduction in rebate guarantees as a negative.

A final topic under the rebate category is the implementation of point-of-sale rebates. Point-of-sale rebate models apply an estimate of the drug-level rebate at the time the claim is processed. Since the value of the rebate is typically applied before a participant's cost share is calculated, it can result in a reduction of a participant's out-of-pocket costs.

There are pros and cons to this approach. The obvious pro is that applying the rebate and lowering participant out-of-pocket costs for expensive chronic medications may result in greater adherence levels and lower overall health care costs. An obvious con is that sharing rebate dollars with participants at the time of a claim can increase a plan's overall cost, thereby resulting in higher premium contributions or higher deductibles and max-out-of-pocket (MOOPs) to offset these additional costs. While the approach seems very logical, there are a host of other considerations for plan sponsors. Mike Stull's recent article, Now or Later: Rebate Considerations for Plan Sponsors, covers this topic in more depth. *This article can be found at employershealthco.com/benefits_insights/now-or-later-rebate-considerations-for-plan-sponsors-2.*

PRO

APPLYING THE REBATE AND LOWERING PARTICIPANT OUT-OF-POCKET COSTS FOR EXPENSIVE CHRONIC MEDICATIONS MAY RESULT IN GREATER ADHERENCE LEVELS AND LOWER OVERALL HEALTH CARE COSTS

CON

SHARING REBATE DOLLARS WITH PARTICIPANTS AT THE TIME OF A CLAIM CAN INCREASE A PLAN'S OVERALL COST, THEREBY RESULTING IN HIGHER PREMIUM CONTRIBUTIONS OR HIGHER DEDUCTIBLES AND MAX-OUT-OF-POCKET (MOOPS) TO OFFSET THESE ADDITIONAL COSTS

To summarize, rebates are an important part of the drug pricing model. Plan sponsors should balance the desire for additional rebates with sound clinical and formulary management that ensures the plan and its participants are achieving lowest net cost.

INDEPENDENT/COMMUNITY PHARMACY ASSOCIATIONS

Independent and community pharmacies have served an important role in the delivery of medications and trusted advice to patients. They also have an active voice in local, state and national politics, seeking to enact policies that allow them to better compete against the national chains. Typically, these policies call for increased reimbursement for the pharmacies and lower earnings for the PBMs. The impact of these policies on prices to plans and patients is relatively unknown, but one could guess that prices would likely increase over time.

Articles written by or in conjunction with the pharmacy associations should be read within the context of their bias and ultimate goal of higher reimbursements. Within a state, these organizations tend to have strong voices with media outlets and state legislators. From a state legislator's perspective, defending the "little guy" against a large, out-of-state competitor using new regulations claiming to protect consumers/taxpayers plays well on both sides of the aisle. Thus, this creates the opportunity for legislation to be passed and allows legislators to show superficial accomplishment. Whether these regulations ultimately lead to lower prices for patients is yet to be conclusively proven.

As with many public policy debates, the underlying issue is much more complex than the headlines or talking points. To be clear, retail pharmacy associations are not advocating for plan sponsors, and it has been shown that in some cases these independent pharmacies are actually reimbursed more than national retail chains, particularly those owned by the PBM. This becomes confusing when the independent pharmacy claims it's not being reimbursed enough to cover its acquisition costs, which seems to imply a procurement challenge in addition to the reimbursement challenge.

Thus, while a news article may evoke sympathy for the challenges (and there are many) independent pharmacies face, plan sponsors must evaluate reimbursement in a much larger context.

THE EMPLOYERS HEALTH **APPROACH**

The Employers Health approach is focused on helping plan sponsors minimize risk and maximize value by

finding balance

among pricing model, participant affordability and disruption and sound clinical management. Employers Health offers multiple pricing models based on the unique needs of each plan sponsor. Participating groups benefit from an annual market check negotiated by Employers Health to refresh and update pricing and contractual terms as the market changes. Participating groups also benefit from audits that verify the PBM contracts are performing as they should. While the PBMs have the opportunity to generate revenue in certain areas, the contract is negotiated and managed in a manner to yield the lowest overall net cost to the plan and its participants.

2019 MARKET CHECK

WRITTEN BY:
DAVID ULDRICKS, J.D., LL.M.
Vice President,
PBM Contracting and Strategy

The pharmacy benefit management marketplace is facing more public scrutiny than ever. Over the past several months, the news media exploded with stories concerning the business practices of pharmacy benefit managers (PBMs). Some stories focus on the rebates PBMs receive from drug manufacturers or the unexplained spikes in the list price of certain drugs. Other stories focus on PBMs requiring pharmacies to collect from patients the full amount of a patient's cost share, even when the actual cost of the drug is less than the patient's full cost share. And, to be sure, there are many other stories that question other PBM business practices.

These stories often assert that certain PBM business practices allow the PBM to profit in an underhanded way at the expense of pharmacy benefit plan sponsors and patients. At the minimum, these stories at least imply that these practices increase overall pharmaceutical costs, and they cast doubt on whether PBMs provide any value.

The truth of the matter is, there is at least some element of truth in these stories. The PBM industry is one that sounds like it should be very straightforward, but in reality, is extremely complex. Unfortunately, this dichotomy leaves many pharmacy benefit plan sponsors vulnerable to business practices that may have a significant impact on the amounts they and their plan enrollees pay for drugs, whether they know it or not.

Of course, PBMs have their side of the story. PBMs generally contend that they have nothing to do with the list price of any drug. Rather, they say, it is their job to reduce the cost of drugs, to the extent possible, through efficiencies, clinical oversight and purchasing power given the plan design they are asked to administer. The reality is, there is at least some element of truth in the PBM stories as well.

The press generated by PBM business practices has spurned a number of proposals for new regulations and legislation concerning some PBM business practices. For example, the U.S. Department of Health and Human Services recently proposed regulation changes governing the safe harbors for rebates paid to PBMs and health plans, and a bill is working its way through the U.S. Senate entitled the "Patient Right to Know Drug Prices Act" (S. 2554) to address the amount a patient should pay at the pharmacy counter. Whether either of these efforts will come to fruition, whether they truly address the issues, and whether they are even a good idea in the first place is still a subject of debate. More importantly, the result of these efforts is largely outside of the control of a pharmacy benefit plan sponsor.

What a pharmacy benefit plan sponsor can do

to help ensure that its overall drug spend is being managed appropriately is align itself with a PBM program that rigorously monitors market dynamics and proactively adjusts for them. For years, **Employers Health has used its collective purchasing power** to avoid PBM gamesmanship through a process called a "market check".

A market check is a process through which Employers Health, on an annual basis, renegotiates the terms and conditions related to the PBM services provided to its members. Much of this process involves renegotiating pricing terms to ensure that Employers Health members enjoy the lowest possible drug cost while maintaining high-quality patient care. But, the process also includes amending contract provisions to avoid PBM gamesmanship.

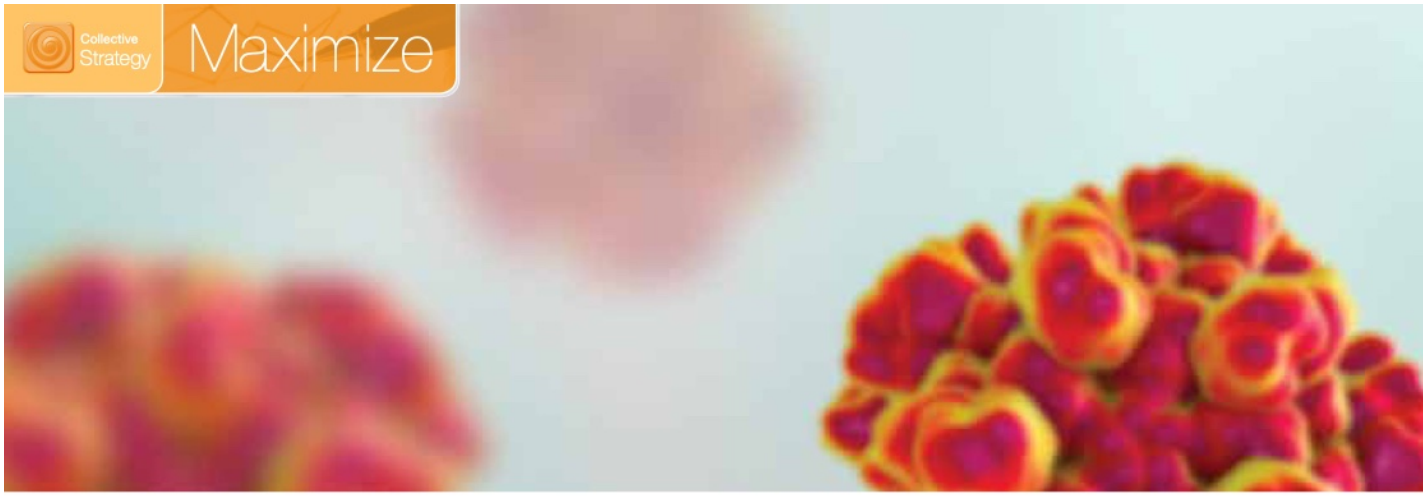
As an example, over a decade ago, Employers Health incorporated terms into its PBM agreements that required pharmacies to collect from patients no more than the lowest of the patient's cost share, or the pharmacy's cash price, or what the pharmacy's cash price should be (a.k.a. Maximum Allowable Cost, or MAC). Until recently, this provision got little attention. But over the years, collectively, it has saved plan enrollees countless dollars that otherwise would have been unknowingly spent.

A more recent example concerns rebates. Since its inception, Employers Health has had a keen focus on ensuring that its member organizations receive the maximum possible rebates. In the past, rebates were relatively straightforward and easy to administer, but over the years, payments from drug manufacturers started to take different forms. Employers Health has stayed abreast of these industry dynamics. Through the market check process, Employers Health has ensured that its members benefit from drug manufacturer payments to the greatest extent possible. As a result, since 2014, the rebate guarantee for a retail brand prescription has increased over 600 percent, and Employers Health is generally known for having industry leading rebate guarantees. This, in turn, helps our member organizations combat out of control increases in the list price of many drugs.

Turning our eyes toward the future, much has been done already in anticipation of 2019. The pricing terms for 2019 have been renegotiated to maintain our industry leading standard. In addition, Employers Health has taken steps to ensure that specialty drugs are priced appropriately as more and more generics are given a specialty designation, and the specialty class continues to grow in importance. For most Employers Health members, these efforts will result in significant improvements compared with their current industry-leading terms.

As the complexity of the PBM marketplace continues to increase, the need for pharmacy benefit plan sponsors to be market savvy is greater than ever. As the buzz grows louder on certain PBM business practices, Employers Health is proud to have addressed many of these issues years ago and looks forward to continuing to serve its membership into the future.

A MARKET CHECK
IS A PROCESS THROUGH WHICH EMPLOYERS HEALTH, ON AN ANNUAL BASIS, RENEGOTIATES THE TERMS AND CONDITIONS RELATED TO THE PBM SERVICES PROVIDED TO ITS MEMBERS.



The Countdown to NASH:

Employers Brace for the New Non-Specialty Condition

WRITTEN BY:
MATTHEW HARMAN, PHARMD, M.P.H. // *Director of Pharmacy* AND **KEVIN WENCESLAO, PHARMD, RPH** // *Pharmacy Resident*

In recent years, the health care world was heavily focused on developing and finding a cure for hepatitis C, a bloodborne infection affecting nearly 3.9 million people in the U.S.[1] With the advent of therapies with cure rates more than 90 percent for hepatitis C, medical professionals now predict a shift in industry focus to the leading cause of liver disease in Americans, nonalcoholic steatohepatitis, or NASH.[1,2]

What is NASH?

NASH is a subcategory of a larger condition called nonalcoholic fatty liver disease (NAFLD), which involves excess fat buildup in the liver. Unlike NAFLD, NASH patients also experience liver tissue inflammation which can lead to scarring or fibrosis.[3]

Damage to liver cells from prolonged exposure to a disease or a substance can lead to impaired function, cancer or liver failure. Cirrhosis is a severe condition where normal healthy liver tissue is permanently replaced by damaged scar tissue thereby preventing proper function. This can be caused by a variety of things including alcohol, medications and infections.[4]

As the name suggests, both NAFLD and NASH are not caused by alcohol, but instead, are closely associated with obesity, diabetes, high blood pressure and high cholesterol. It is estimated about 3-to-12 percent of adult Americans are diagnosed with NASH.

Patients with NASH often experience little to no symptoms with the most common being discomfort or pain in the upper right abdomen. Due to the silent nature of the disease, NASH is difficult to screen and diagnose. Diagnosing NASH often requires a hepatic specialist. The gold standard for diagnosis is a liver biopsy which can be both invasive and expensive for a patient who may not be necessarily experiencing significant symptoms. Unfortunately, if NASH is left untreated, the scarring can progress to more severe cirrhosis which can develop into liver cancer or liver failure.[3]

How do we treat NASH?

Despite the extensive history of this disease, there are no FDA-approved NASH drug treatments currently. According to guidelines by the American Association for the Study of Liver Diseases (AASLD), dietary and lifestyle modifications remain the mainstay of both prevention and treatment of NASH.

Some pharmacological agents such as Vitamin E and the diabetes treatment, pioglitazone (Actos®), have shown some benefit in NASH patients by reducing inflammation and fat buildup.[5] However, neither treatments have been properly tested for long term safety and efficacy in NASH. As the focus on NASH grows, a better understanding of the disease pathways has led to a surge of development for drugs that will target these various mechanisms.

As of May 2018, there are roughly 48 NASH drugs undergoing clinical trials with about a dozen likely to enter the market in the next couple of years.[6] As these products are approved, marketing of these drugs will cause a heightened awareness of the disease, which will lead to increased demand of these novel drugs. The challenge lies in determining who to treat and how to properly use these different medications, which will be greatly impacted by the yet-to-be-determined price of the therapies as well.

To discuss further, please contact:

Matt Harman at
mharman@employershealthco.com

Kevin Wenceslao at
kwenceslao@employershealthco.com.

References:

[1] https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm

[2] https://labblog.uofmhealth.org/rounds/nash-may-overtake-hepatitis-c-as-top-liver-transplant-cause

[3] https://www.niddk.nih.gov/health-information/liver-disease/nafld-nash/definition-facts

[4] https://liverfoundation.org/for-patients/about-the-liver/diseases-of-the-liver/cirrhosis/

[5] https://www.aasld.org/sites/default/files/NAFLD%20Guidance%202018.pdf

[6] https://www.biopharmadive.com/news/nash-drug-pipeline-market-liver-disease/523492/

How do we manage new therapies?

While the specific strategies for NASH will depend on what products are approved, ensuring appropriate use via formulary placement and access management will be critical in regulating trend.

> **Due to the large number of products in** the pipeline, PBMs should be able to leverage competition in negotiations for rebates to reduce the overall net cost to the payer, similar to how brand drugs used for diabetes are managed today.

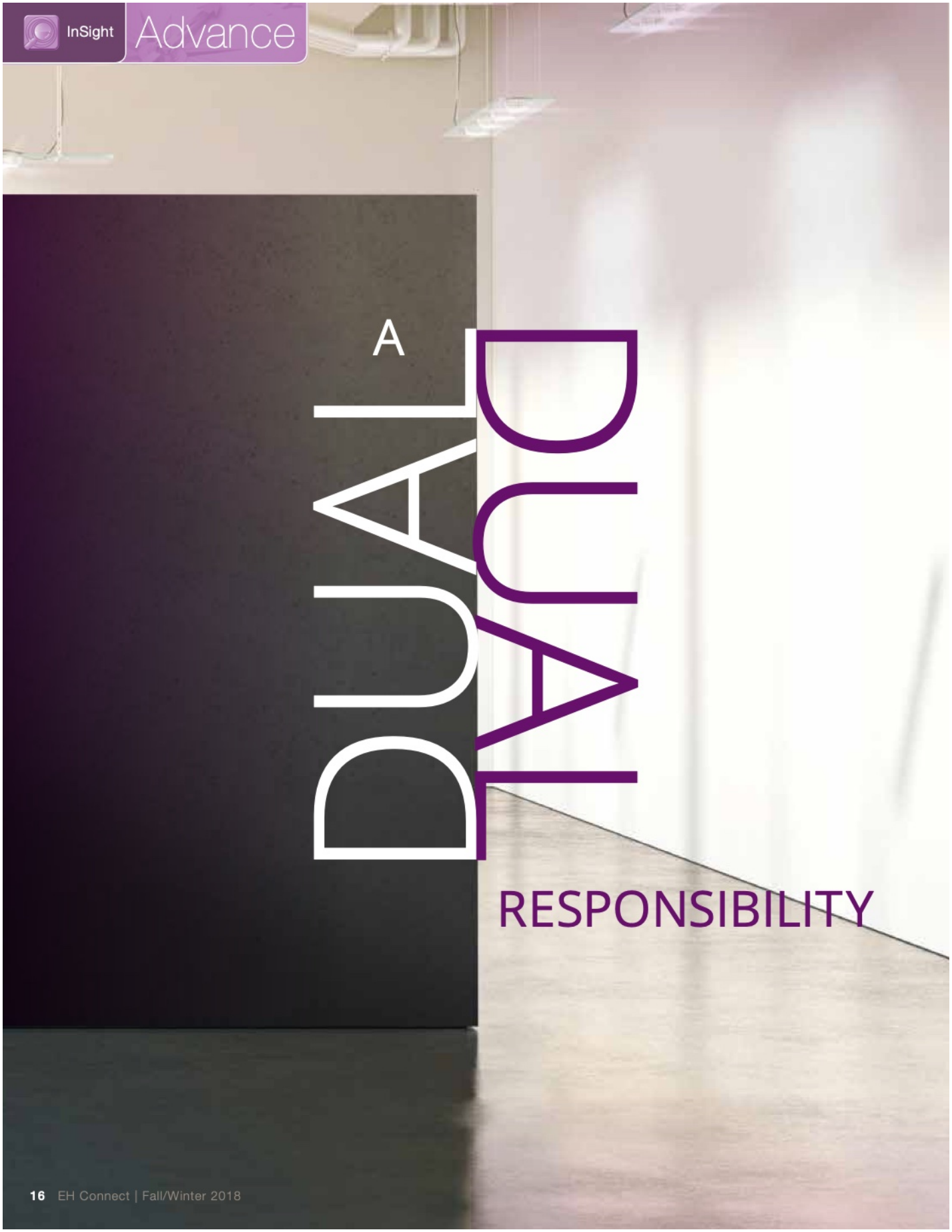
> **Until effective outcomes studies are** published and evaluated, expect prior authorization criteria to be quite restrictive, and include elements of the following:
- Liver biopsy or imaging
- Liver fibrosis score of at least two
- Specialist prescriber, such as a hepatologist
- Lifestyle modification requirement to promote weight loss and limiting alcohol consumption
- Restricting combination use of different NASH treatment mechanisms

> **Quantity limits to the FDA-approved dosing** will be standard as well, especially with the reported deaths in Ocaliva™ trials likely due to higher off-label dosages.

> **Step therapy protocols, based on the AASLD** treatment guidelines, may include patients without diabetes to first try Vitamin E prior to NASH therapy while those with diabetes could be required to fail pioglitazone treatment.

Another key factor in controlling NASH spend will come from disease management programs. Not only can trained professionals aid in adherence to the potential strategies listed above, but they can provide support in patient education of the new condition as well as assist in navigating the various drug dispensing channels. This will be even more critical for patients taking multiple NASH medications, which can vary from intravenous infusion in a specialty setting to the traditional oral medication.

For the past few years, the term NASH has been quietly tossed around as the next big disease state in the health care community. We are quickly approaching the years where it will be loudly discussed by those footing the bill for treatment of this highly prevalent condition, especially by those without sound clinical and financial management.



A DUAL RESPONSIBILITY

Preparing Workforces for Demanding Environments

WRITTEN BY:
SIDDHARTH SHAH, M.D. // *Founder and CEO, Greenleaf Integrative*
NANCY SPANGLER PH.D., OTR/L // *Senior Advisor and Practitioner, Greenleaf Integrative*

Does your industry include workers who operate in highly demanding environments? For example, health care, construction, law enforcement, counseling and social work professions have both predictable *and* unpredictable threats, pressures, and circumstances that create high levels of cumulative stress. Increasingly, one unpredictable concern in a number of settings is the threat of violence.

The highest number of injuries in U.S. workplaces related to violence are directed at health care and social assistance workers (Centers for Disease Control and Prevention, 2018), but industries like education, journalism and others have faced acts of violence in recent years as well.

These acts may include an attack from a person who has a known violent history; attack from someone with no known history, such as a patient or family member; physical assault by a co-worker; or a mass event, such as an active shooter or someone bringing an explosive device in one's facility or community.

More than ever, workplaces are providing protocols and training to reduce the likelihood that personnel will experience violence and are preparing workers in the event violence does occur. Such protocols and training will falter, however, without an understanding of basic neuroscience, resilience and effective leadership.

UNDERSTANDING FEAR OF VIOLENCE

In 2014, the U.S. Agency for International Development (USAID) commissioned Greenleaf Integrative to conduct a gap analysis study of stress exposure that its humanitarian workers face and to recommend ways to close gaps of vulnerability. We uncovered information that is applicable and valuable to many professions.

USAID leads the U.S. government's international development and disaster assistance, bringing relief and lifesaving assistance amidst complex crises in desperate and dangerous parts of the globe. Much like in other demanding environments, humanitarian aid requires rapid adaptation to change. Particularly after 9/11, humanitarian workers are required to wear body armor, to use military escorts and to comply with increased documentation requirements.

The result is often hypervigilance among staff and increased distance between workers and the local community. Humanitarian workers frequently report that these conditions diminish the joy they feel in their work lives.

Greenleaf was given access to interview and survey leaders and workers in USAID's dispersed worksites across the world. The information gathered suggests that while people's greatest fears for violence happened infrequently *(Figure 1)*, workers were in constant anticipation of dangers related to their personal security, suffering frequent acute stress as well as cumulative stress. Workers were in a relentless hypervigilant state. Their sleep was often disturbed, they held negative expectations for the future and they had low levels of trust for their leaders.

FIGURE 1

THREAT-RELATED STRESSORS SUSTAINED

	Felt there was a risk	Occurred to someone known to me	Personally experienced
Caught in armed conflict (or active combat operations)	60%	46%	35%
Captivity (e.g. being kidnapped, abducted, held hostage, prisoner of war)	78%	35%	3%
Sexual assault (e.g. rape, attempted rape, made to perform any type of sexual act through force or threat of harm)	72%	37%	4%
Sudden, intentional/violent death (i.e. homicide, suicide)	54%	53%	13%
Serious injury, harm, or death you caused to someone else (e.g. accidental, combat-related)	68%	36%	9%

Threat-Related Stressors Sustained by USAID Workers. Used with permission from USAID.

LEADERSHIP AND MANAGEMENT ISSUES CONTRIBUTE TO STRESS

A large percentage of staff indicated that preventable stressors within their work context magnified their threat-related stressors, including poor communication, low focus of control in decision-making, dysfunctional policies and procedures, lack of appreciation of worker's efforts and judgmental attitudes toward self-care. The following quotes taken from interviews with USAID personnel or comments from surveys describe management-related stressors (Briggs, Shah, et al., 2015):

"Lack of gratitude and appreciation among senior managers and irritable managers with aggressive expectations."

"Management is quick to recommend external stress relievers but does not want to recognize its own contributions to stress."

"If they want people to stick around, USAID needs to be more professional, and needs to develop personnel management capabilities in their technical workforce."

"Leadership matters. It is the single biggest variable that relates to stress."

DUAL RESPONSIBILITY NEEDED

Following the gap analysis, Greenleaf developed recommendations for systemic organizational policy and practice changes, professional and leader development and stress mitigation and staff care programs in partnership with USAID leaders. Consultative work helped to reinforce a dual responsibility – workers need neuroscience-based and culture-specific skills that build greater resiliency, and organizations must commit to a diligent approach to maintain a resilient culture with appropriate policies, communications and behaviors.

So what changes are needed at an organization if the threat of violence is real? A more methodical approach is a bare minimum requirement. Resiliency – developed and applied – is the difference between the theoretically safe and the actually safe workplace.

We recommend an approach we call Greenleaf's Awareness-Regulation-Leadership Resilience Competencies™ (ARL).

3-STEP APPROACH

AWARENESS
REGULATION
LEADERSHIP

If any one of these ARL Competencies is weak, then what you have is fragility or brittleness, which makes an organization vulnerable to violence's more tragic and insidious outcomes.

The table at right illustrates the individual and organizational layers of these three competencies.

Without support and resources, many individuals and organizations default to the fragile/brittle state.

3-STEP APPROACH

AWARENESS-REGULATION-LEADERSHIP RESILIENCE COMPETENCIES

	INDIVIDUAL		ORGANIZATIONAL	
	COMPETENCY	**FAILURE**	**COMPETENCY**	**FAILURE**
AWARENESS	Skillful, mindful situational awareness. Calm, alert vigilance. Anticipation of predictable pressure points.	Missing signals of impending violence – or paranoia and anxiety.	Facilitating a non-stigmatizing culture of awareness regarding occupational stresses.	Allowing blame, shame and guilt to dominate when people are feeling over-taxed or fearful.
REGULATION	Toolkit to regulate stress responses in diverse circumstances (e.g. understanding of the neuroscience behind the stress and response, self-calming and emotion-regulation skills, cognitive methods, use of personal strengths).	Rapid dysregulation of physiological, mental and social functioning.	Providing opportunities and budgeting resources to promote well-being given that violence is a factor. Providing proportionate response to the layers of the organization that are affected when violence occurs.	Doing the bare minimum in preparation and response to violence. Leaving people unsupported and feeling as though they are alone.
LEADERSHIP	Enhancing connectedness and communication clarity. Building ethical, respectful and proactive cultures and climates. Acknowledging effects of stress and trauma (e.g., cultivating compassion for self; operating out of compassion for others; modeling and mentoring resilience skills).	Checking out, disengagement, stepping away from others.	Pre-, peri-, and post-event policies to address the emotional aspects of violence. Risk communication that gives factual assessment of violence probability and the commitment to prevent/respond to violence with great diligence and care for every individual. Emphasis on behaviors that align with organizational values.	Policies that only address the legal aspects such that a workforce perceives that the organization only wants to protect itself reputationally and financially. Lack of trust.

IMPORTANCE OF BUILDING RESILIENCE COMPETENCIES

Media attention to the high and continually increasing rates of burnout among physicians and nurses, as well as recent announcements of the rise in suicides in the U.S. *(see Figure 2)*, make resilience training all the more critical for workplaces. Workers who learn and are encouraged to practice strategies for reducing the effects of cumulative stress will not only be less likely to make errors, they will be more likely to remain calm and focused during critical incidents, to recover more quickly afterward and to model such skills to others.

PERCENTAGE EXPERIENCING HIGH RATES OF BURNOUT:

>50% PHYSICIANS

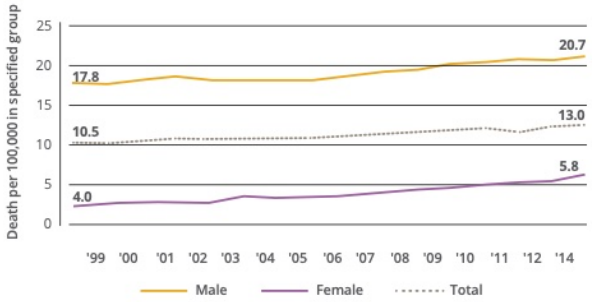
43% NURSES

28% OTHER WORKERS

Source:
As reported in Dyrbye, L. N., Shanafelt, T. D., Sinsky, C. A., Cipriano, P. F., Bhatt, J., Ommaya, A., ... & Meyers, D. (2017). Burnout among health care professionals: A call to explore and address this underrecognized threat to safe, high-quality care. NAM (National Academy of Medicine) Perspective.; Shanafelt, T. D., Hasan, O., Dyrbye, L. N., Sinsky, C., Satele, D., Sloan, J., & West, C. P. (2015, December). Changes in burnout and satisfaction with work-life balance in physicians and the general US working population between 2011 and 2014. In Mayo Clinic Proceedings (Vol. 90, No. 12, pp. 1600-1613). Elsevier.)

FIGURE 2

RATES OF SUICIDE CONTINUE TO RISE IN THE U.S.



Retrieved from https://www.cdc.gov/nchs/images/databriefs/201-250/db241_fig1.png

In our experience, people who serve in demanding environments often bring a sense of mission to their work, and they frequently develop a high level of competency in a variety of technical and professional skills. Over time, however, and with exposure to cumulative stressors and unexpected organizational strains, workers are prone to experiencing negative physiological and emotional effects, and their attendance, engagement and work performance often decline. Training such workers to hone resilience competencies of awareness, regulation and leadership is critical for helping to mitigate the hypervigilance and fears of violence that are common in demanding environments. When these resilience competencies become second nature and constantly operate in the background, they keep workers and community members safe and make workplaces more effective.

We appreciate our partnership with USAID as well as its willingness to share our study's findings. The full report is available at www.greenleafintegrative.com/?s=usaid+assessment.

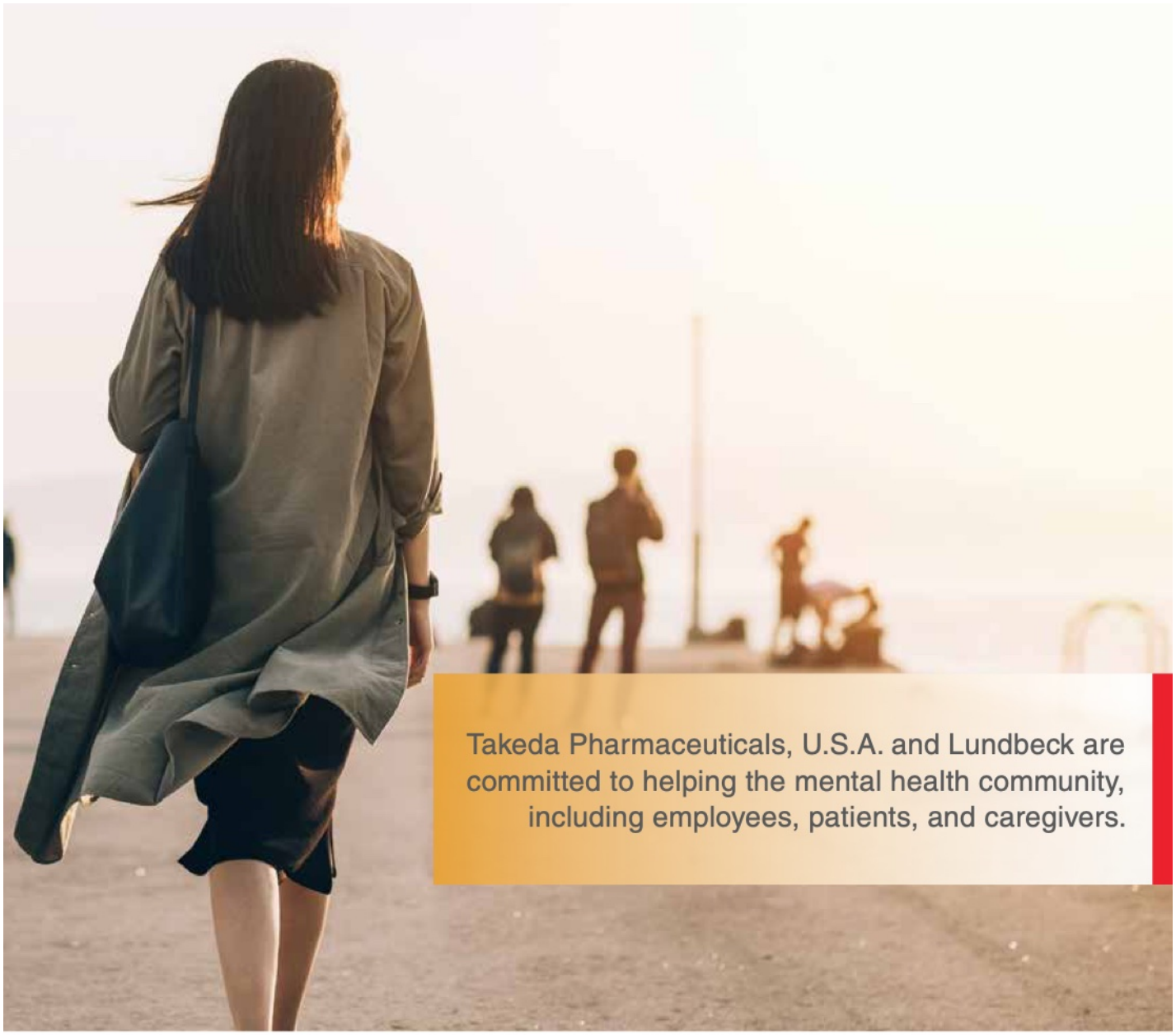
References:
Briggs, L.R., Shah, S.A., et al. (2015). Stress and resilience issues affecting USAID personnel in high operational stress environments. Greenleaf Integrative study commissioned by USAID.

Centers for Disease Control and Prevention (2018). Occupational Violence. Retrieved from https://www.cdc.gov/niosh/topics/violence/fastfacts.html.

Dyrbye, L. N., Shanafelt, T. D., Sinsky, C. A., Cipriano, P. F., Bhatt, J., Ommaya, A., ... & Meyers, D. (2017). Burnout among health care professionals: A call to explore and address this underrecognized threat to safe, high-quality care. NAM (National Academy of Medicine) Perspective.

Letvak, S. A., Ruhm, C. J., & Gupta, S. N. (2012). Nurses' presenteeism and its effects on self-reported quality of care and costs. AJN The American Journal of Nursing, 112(2), 30-38.

Shanafelt, T. D., Hasan, O., Dyrbye, L. N., Sinsky, C., Satele, D., Sloan, J., & West, C. P. (2015, December). Changes in burnout and satisfaction with work-life balance in physicians and the general US working population between 2011 and 2014. In Mayo Clinic Proceedings (Vol. 90, No. 12, pp. 1600-1613). Elsevier.)



Takeda

Lundbeck

To learn more, visit **www.takeda.com** or **www.lundbeck.com**

We spoke with Darcy Gruttadaro, Director of the Center for Workplace Mental Health. In addition to Right Direction, the center provides valuable tools, resources and support for employers across the U.S.

Collaboration Spotlight

Darcy Gruttadaro

DIRECTOR OF THE CENTER FOR WORKPLACE MENTAL HEALTH

In 2012, Employers Health joined forces with the American Psychiatric Association Foundation's (APAF) Center for Workplace Mental Health to develop an employer-facing initiative to address depression in the workplace. It was a significant undertaking and unclear how it would be received, but the relationship between the APAF and Employers Health has proven beyond successful.

What is your background and how did it lead to your work in mental health and the employer space?

I began my professional career as a lawyer, working at a law firm with a large health care practice that included hospitals. One hospital client had a psychiatric unit and I represented the hospital for civil commitment and medication over objection hearings. This increased my interest in mental health policy and practice issues.

I left the law firm, moved to Washington, D.C. and began working with the American Managed Behavioral Healthcare Association, now the Association for Behavioral Health and Wellness. I then moved to the National Alliance on Mental Illness (NAMI), to focus on mental health policy and advocacy. After 17 years at NAMI, I accepted the opportunity to lead the Center for Workplace Mental Health at the American Psychiatric Association Foundation. I embraced the opportunity to work with employers given the influence and leverage they have to positively impact the delivery of mental health care in our nation.

You have been at the APAF for almost a year at this point. What has been most enlightening? Or has there been an "aha" moment?

I have been quite impressed with the high level of employer interest in improving the mental health and well-being of employees. The employers we work with have a significant commitment to raising mental health awareness, creating a culture of caring that helps people feel safe when coming forward for help and improving access to mental health and substance use care.

There have been many "aha" moments, including seeing employers highly value the health and well-being of employees and recognizing its contribution to the bottom line. Also, although large employers are often better resourced to do more in this area, small employers are also quite creative in improving the mental health and wellness of their employees.

The center has been working on these issues for more than 12 years and is pleased to see the growing level of commitment to workplace mental health across diverse industries and organizations. This holds tremendous promise in bringing positive change to the mental health and well-being of millions of Americans.

What is the mission of the Center for Workplace Mental Health?

Our mission is to provide employers with the tools, resources and programs needed to promote the mental health of employees and their families.

While mental health treatment works and is cost effective, many people who need help are not getting it, despite the availability of services and supports through employee assistance programs and mental health benefit coverage. Employers increasingly recognize that untreated mental health conditions, like depression and anxiety, lead to costly challenges, including:

- Absenteeism and presenteeism resulting in reduced productivity
- Increased health care costs with comorbidity of mental health and other health conditions
- Increased disability and retention costs

Our team works with employers, business groups on health, health-focused coalitions and other strategic partners to solve challenges and highlight innovative approaches to improving workplace mental health and making it a higher organizational priority.

We engage employers and other partners in eliminating stigma, reducing barriers to care, raising broader mental health awareness, improving and implementing mental health programs and designing benefits that improve employee mental health. This work is done through turn-key programs, toolkits, employer case studies, topical resources, publications and more.

Better workplace mental health policies and practices improve employee productivity, engagement and quality of life for all those affected by mental health issues.

What have employers taught you?

Employers have taught us a tremendous amount, and we continue to learn from them about the challenges and opportunities in workplace mental health. Here are five lessons that come to mind:

1. Employers are busy with competing priorities and appreciate the availability of practical and actionable workplace mental health guidance and resources.

2. Employers appreciate the opportunity to customize and tailor resources and initiatives to meet the unique climate and culture of their organization.

3. Data and measuring outcomes are key. It helps justify sustainability and growth of workplace mental health initiatives.

4. Leadership matters. If the corner office and organizational leaders are involved and committed to workplace mental health, it stands a great chance of success.

5. It is important to make the business case for creating, sustaining and expanding workplace mental health initiatives with facts and stats on organizational cost and impact.

With so many competing priorities, why should employers care about mental health?

Employers see that not paying close attention to workplace mental health is costly. Mental health conditions are common, impacting 1 in 5 employees. When you add employees who serve as caregivers of loved ones with mental health conditions, the numbers go higher. Depression, a common condition in the workplace, costs employers about $210 billion annually, with approximately half of that representing lost productivity and a little less than half representing direct health care costs. The health care costs for employees experiencing co-morbid mental health and other serious health conditions are 2-to-3 times higher than for employees without co-morbid conditions.

Mental health is also moving out of the shadows in the media, with high profile celebrities and athletes coming forward. This will likely lead to more employees talking about lived experience, especially younger employees, with the expectation that mental health will be a topic discussed in the workplace along with other health and wellness issues. Mental health as a topic is slowly moving the way of cancer, formerly referenced as the "C" word but now openly discussed everywhere.

What challenges do you see for employers that are addressing mental health in the workplace?

Stigma and climate. As much as we are making progress, stigma remains a barrier to employees seeking help when needed. Employees may not be comfortable coming forward out of fear that doing so may negatively impact promotional opportunities, retention and result in harsh judgment. Unfortunately, perception remains nine-tenths of the law, so it helps to create a culture and climate in which employees feel safe seeking care when it's needed, just as they would for any other health concern.

Access to care. A major challenge for employers is ensuring access to care for employees that come forward for help. Employers are aware that employees face challenges in navigating overly complex systems of care. Many communities have a shortage of psychiatrists and people may face challenges with psychiatrists who are not accepting insurance coverage, making care financially out of reach. Employees also may not know how to initiate care, whether to start in primary care or go directly to specialty mental health care.

The center recognizes the importance of improving access to care and recently engaged in a major project with the American Psychiatric Association, business coalitions and employers to improve access to mental health and substance use care.

What are some ways that employers can take on the topic of mental health?

There are multiple ways for employers to take on mental health. Based on more than 70 case studies that the center has completed and our work with employers, here are several key areas of focus:

- Engaging employees with lived experience who would like to advise the organization in addressing mental health and wellness, along with other interested employees.
  - Consider forming a committee of interested employees to generate ideas on how to best address mental health given the organization's unique climate and culture
  - Survey employees on what is needed to effectively address workplace mental health

- Offering programs in raising awareness, education and training.
  - Right Direction – a turnkey program on depression awareness
  - ICU – a turnkey program on broader emotional and mental health issues
  - Manager training on how mental health conditions impact performance
  - Speakers with lived experience sharing stories of help and hope

Since the formal launch in May 2013, Right Direction has been utilized by hundreds of employers across the country, with countless quantitative and qualitative outcomes. From savings in direct health care costs related to depression, positive impacts on presenteeism and absenteeism, to increased EAP utilization, the first-of-its-kind initiative provides a platform to address a sensitive topic.

- Creating a culture of caring and a safe climate for discussion and seeking care.
  - Leadership support – the more the "corner office" and leadership are talking and sharing about mental health, the more it opens the door for others to do the same
  - Raising the visibility of mental health issues in employee surveys, in all discussions about health, well-being and related issues
  - Placing information about mental health conditions on the organization's website, newsletters and wherever health information is shared

- Improving access to mental health and substance use care.
  - Employers leveraging their purchasing power to ensure health plans maintain adequate provider networks
  - Employers working to ensure effective and quality mental health and substance use care is delivered and outcomes are reported
  - Employers partnering with EAP vendors in providing employees with tools that assist in navigating access to care, including explanations on how to initiate care and provide ongoing support

- Measuring results of workplace mental health initiatives
  - Examining productivity, disability rates and performance
  - Evaluating health care utilization in pharmacy, health claims and more
  - Reviewing EAP use and surveying employees on engagement and related issues

Employers are encouraged to explore the case studies on the Center for Workplace Mental Health website with detailed descriptions of the workplace mental health activity employers are engaged in and the results many are seeing.

"Employers increasingly recognize that effectively addressing mental health is important to recruit and retain the highest quality candidates."

To learn more visit: www.workplacementalhealth.org.

The Real Deal About Real-Time Benefits

In today's era of rising drug prices, consumers are shouldering a greater portion of their health care costs, which includes their prescription drugs. CVS Health launched real-time benefits to help make it easier for plan members to afford the medications they need to stay on the path to better health.

It's one of the most comprehensive solutions in the market today, which has proven to save members money.

Delivering Real Savings

- For prescriptions written by physicians using real-time benefits information, which are filled by the member, when a lower-cost preferred alternative is presented, physicians are switching to the lower-cost alternative 40 percent of the time. In these cases, the member cost was $130 lower per fill, on average, compared to the original non-preferred drug selected.
- Members using our Check Drug Cost tool are filling lower-cost alternatives 20 percent of the time and saving an average of $120 per fill.
- CVS pharmacists using Rx Savings Finder* help members save an average of $420 per year.

Reaching Multiple Care Points

Our real-time benefits solution connects with more stakeholders through numerous touchpoints.

- We seamlessly connect to physician offices through electronic health records. We expect to be connected to more than 250,000 physician's offices by the end of 2019.
- Nearly 30,000 CVS pharmacists can identify savings opportunities using Rx Savings Finder.
- All members have access to our Check Drug Cost tool, which today, averages 230,000 searches per month.

Member-Specific, Actionable Information

Our proprietary engine, Script Intelligence, powers our unique database of clinically mapped drugs. It provides:

- Up to five clinically appropriate brand or generic alternatives specific to the member's plan design.
- Drugs with equal or better formulary status on the member's specific plan.

By year's end, we anticipate our engine will be mapped to more than 90 percent of prescriptions written for our members.

Ease of Use for Prescribers

When physicians use real-time benefits they get:

- A response on alternative therapies within 1 second, on average.
- A decision on an electronic prior authorization request in as little as 6 seconds.
- Brand and generic alternatives, clinically mapped for 90% of drugs written for our members**

Physicians are switching to a covered drug 75 percent of the time when the original drug is not covered. This helps get more affordable medications to members faster.

For more information, visit payorsolutions.cvshealth.com or contact your CVS Health Account team.

*When members present their prescriptions.

**Projected as of end of 2018.

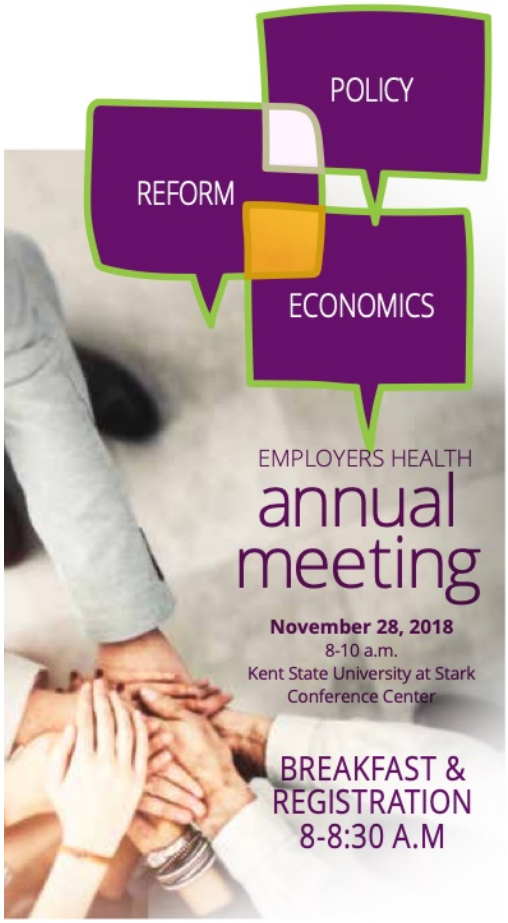
Source: CVS Health Enterprise Analytics, 2018.

CVS Health uses and shares data as allowed by applicable law, and by our agreements and our information firewall.

Savings will vary based upon a variety of factors including things such as plan design, demographics and programs implemented by the plan.

CVSHealth

EMPLOYERS HEALTH®
COALITION, INC.
4771 Fulton Drive NW, Canton, OH 44718



employershealthco.com

Northeast Ohio Office
4771 Fulton Drive NW
Canton, OH 44718
330.305.6565

Central Ohio Office
5775 Perimeter Drive, Suite 100
Dublin, OH 43017
614.336.2883

Southwest Ohio Office
9032 Union Centre Blvd, Suite 202
West Chester, OH 45069
513.889.3952