COMPETITION AND TRANSPARENCY: THE PATHWAY FORWARD FOR A STRONGER HEALTH CARE MARKET

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH, EMPLOYMENT, LABOR, AND PENSIONS

OF THE

COMMITTEE ON EDUCATION AND THE WORKFORCE

U.S. HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTEENTH CONGRESS

FIRST SESSION

HEARING HELD IN WASHINGTON, DC, JUNE 21, 2023

Serial No. 118–15

Printed for the use of the Committee on Education and the Workforce

Available via: *edworkforce.house.gov* or *www.govinfo.gov*

U.S. GOVERNMENT PUBLISHING OFFICE

55–562 PDF WASHINGTON : 2024

COMMITTEE ON EDUCATION AND THE WORKFORCE

VIRGINIA FOXX, North Carolina, *Chairwoman*

JOE WILSON, South Carolina
GLENN THOMPSON, Pennsylvania
TIM WALBERG, Michigan
GLENN GROTHMAN, Wisconsin
ELISE M. STEFANIK, New York
RICK W. ALLEN, Georgia
JIM BANKS, Indiana
JAMES COMER, Kentucky
LLOYD SMUCKER, Pennsylvania
BURGESS OWENS, Utah
BOB GOOD, Virginia
LISA MCCLAIN, Michigan
MARY MILLER, Illinois
MICHELLE STEEL, California
RON ESTES, Kansas
JULIA LETLOW, Louisiana
KEVIN KILEY, California
AARON BEAN, Florida
ERIC BURLISON, Missouri
NATHANIEL MORAN, Texas
JOHN JAMES, Michigan
LORI CHAVEZ-DEREMER, Oregon
BRANDON WILLIAMS, New York
ERIN HOUCHIN, Indiana

ROBERT C. "BOBBY" SCOTT, Virginia,
Ranking Member
RAÚL M. GRIJALVA, Arizona
JOE COURTNEY, Connecticut
GREGORIO KILILI CAMACHO SABLAN,
Northern Mariana Islands
FREDERICA S. WILSON, Florida
SUZANNE BONAMICI, Oregon
MARK TAKANO, California
ALMA S. ADAMS, North Carolina
MARK DESAULNIER, California
DONALD NORCROSS, New Jersey
PRAMILA JAYAPAL, Washington
SUSAN WILD, Pennsylvania
LUCY MCBATH, Georgia
JAHANA HAYES, Connecticut
ILHAN OMAR, Minnesota
HALEY M. STEVENS, Michigan
TERESA LEGER FERNANDEZ, New Mexico
KATHY MANNING, North Carolina
FRANK J. MRVAN, Indiana
JAMAAL BOWMAN, New York

Cyrus Artz, *Staff Director*
Véronique Pluviose, *Minority Staff Director*

SUBCOMMITTEE ON HEALTH, EMPLOYMENT, LABOR, AND PENSIONS

BOB GOOD, Virginia, *Chairman*

JOE WILSON, South Carolina
TIM WALBERG, Michigan
RICK ALLEN, Georgia
JIM BANKS, Indiana
JAMES COMER, Kentucky
LLOYD SMUCKER, Pennsylvania
MICHELLE STEEL, California
AARON BEAN, Florida
ERIC BURLISON, Missouri
LORI CHAVEZ-DEREMER, Oregon
ERIN HOUCHIN, Indiana

MARK DESAULNIER, California
Ranking Member
JOE COURTNEY, Connecticut
DONALD NORCROSS, New Jersey
SUSAN WILD, Pennsylvania
FRANK J. MRVAN, Indiana
PRAMILA, JAYAPAL, Washington
LUCY MCBATH, Georgia
JAHANA HAYES, Connecticut
ILHAN OMAR, Minnesota
KATHY MANNING, North Carolina

C O N T E N T S

COMPETITION AND TRANSPARENCY: THE PATHWAY FORWARD FOR A STRONGER HEALTH CARE MARKET

Wednesday, June 21, 2023

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH, EMPLOYMENT, LABOR, AND PENSIONS,
COMMITTEE ON EDUCATION AND THE WORKFORCE,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:19 a.m., Rayburn House Office Building, Room 2175, Hon. Bob Good [Chairman of the Subcommittee] presiding.

Present: Representatives Good, Walberg, Allen, Comer, Burlison, Chavez-DeRemer, Houchin, Foxx, DeSaulnier, Wild, Jayapal, Hayes, Manning, and Scott.

Staff present: Cyrus Artz, Staff Director; Nick Barley Deputy Communications Director; Mindy Barry, General Counsel; Michael Davis, Legislative Assistant; Cate Dillon, Director of Operations; Isabel Foster, Press Assistant; Daniel Fuenzalida, Staff Assistant; Sheila Havenner, Director of Information Technology; Meghan Heckelman, Intern; Taylor Hittle, Professional Staff Member; Claire Houchin, Intern; Alex Knorr, Legislative Assistant; CJ Mahler, Professional Staff Member; John Martin, Deputy Director of Workforce Policy/Counsel; Hannah Matesic, Director of Member Services and Coalitions; Rebecca Powell, Staff Assistant; Seth Waugh, Director of Workforce Policy; Brittany Alston, Minority Operations Assistant; Nekea Brown, Minority Director of Operations; Ilana Brunner, Minority General Counsel; Daniel Foster, Minority Senior Health and Labor Counsel; Carrie Hughes, Minority Director of Health & Human Services Policy; Stephanie Lalle, Minority Communications Director; Raiyana Malone, Minority Press Secretary; Kota Mizutani, Minority Deputy Communications Director; Veronique Pluviose, Minority Staff Director; Jessica Schieder, Minority Economic Policy Advisor; Banyon Vassar, Minority IT Administrator.

Chairman GOOD. The Subcommittee on Health, Employment, Labor, and Pensions will come to order. I note that a quorum is present, so without objection, the Chair is authorized to call a recess at any time. I would like to make an opening statement.

While everyone seems to recognize that healthcare costs in the United States are continuing to rise at alarming rates, it seems that no one wants to take responsibility. The hospitals blame the insurance companies. The health insurance companies blame the

drug manufacturers, the drug manufacturers blame employers, the employers blame the pharmacy benefit managers or PBMs, and on it goes.

The American people do not want finger pointing. They want quality healthcare that they can afford. Today, this Subcommittee will dig deep into two broad policy ideas that have the potential to drive down costs, expand choice, and empower consumers.

All sectors of our healthcare system are plagued by market consolidation, and a lack of transparency. Until these issues are addressed patients will remain victims of a broken, exploitive healthcare system. Hospitals are a prime example. Market consolidation is a proven healthcare cost driver, and hospitals are consolidating at a rapid rate. From 1998 to 2021, 1,887, 1,887 hospitals merged.

Twenty years ago, we had around 8,000 hospitals in this country, and now we have about 6,000. Not only do hospitals buy each other, but they also buy the physicians' offices nearby. Physicians' offices were traditionally independent practices reserved for check-ups and screenings, but they are slowly being replaced by outpatient facilities.

Hospitals already have an advantage over other industries. Emergency medical care is a unique service when a patient needs care, they do not have the time or ability to shop around for options. Hospitals have a monopoly, and as a result there is no accountability regarding billing practices once a hospital takes control.

This is a major reason why employer sponsored insurance pays two to three times what Medicare pays for hospital services. One solution is to bring transparency and require hospitals to disclose where and what they charge. Hospitals should not be rewarded with high reimbursement rates for using incorrect billing addresses.

They should not charge hospital fees for services occurring in doctor's offices miles away. In some places, patients are getting x-rays from their family doctor, and being slapped with higher hospital facility fees just because the hospital is now the owner of the family doctor's practice.

Location should not increase the price for the same service. For too long, medical prices have been shrouded in mystery, and patients have lived in fear of how much their medical bills will end up costing them. The Trump administration issued a rule to require hospitals to give employers and consumers accurate pricing data.

Hospitals were required to file this information, but only 25 percent of hospitals fully complied. The Trump administration issued the Transparency and Coverage Rule to ensure that patients received the pricing information they need from their plans. This rule has been very successful, but there are improvements that can be made.

First, Congress should ensure the data that insurers are submitting is highly accurate, and useable. Many of the files currently submitted are too large and cannot be used by employers and academics. We must push for standardized data and make it useable so employers can effectively meet their fiduciary obligations.

Second, Congress must codify the Transparency and Coverage Rule to ensure the administration enforces requirements that plans submit drug pricing data. Without this critical information, employers and patients will be left in the dark when it comes to navigating the complexities and costs of the drug supply chain.

Consolidation and coverups are not only a factor for hospital services, but they are a problem for pharmaceuticals too. Drug makers have a large role in determining drug prices, but the role of PBMs must also be addressed due to their significant influence over what patients pay at the pharmacy counter. Three PBMs own a massive 80 percent of the market. Additionally, the big three are all subsidiaries of Fortune 500 healthcare companies that also own insurers, pharmacies, and most recently physicians, giving them even more influence over prescription benefits.

PBMs are also operating in a black box. Nobody knows the details of the rebate deals they negotiate with drug manufacturers creating perverse incentives for PBMs to choose more expensive drugs with larger rebates. If they truly pass rebate savings to consumers, like PBMs say they do, this would be a non-issue.

Without transparency, the PBM business model is ripe for abuse. Giving consumers choice works. The Trump Transparency and Coverage Rule has already helped some large employers save millions by rooting out waste in their health plan. Patients would benefit from more transparency from PBMs too. Corruption thrives in darkness, and as a conservative I believe that for good governance we ought to strive for more transparency.

At a minimum, you should be able to expect transparency from your elected representatives, and we in turn, need to demand it from our Nation's healthcare industry. These types of reforms have had widespread, bipartisan support, and I look forward to today's discussion and charting a path forward on robust healthcare reform to bring costs down for all Americans.

With that, I yield to the Ranking Member for his opening statement.

[The statement of Chairman Good follows:]

COMMITTEE ON EDUCATION & THE WORKFORCE

COMMITTEE STATEMENT

Opening Statement of Rep. Bob Good (R-VA), Chairman
Subcommittee on Health, Employment, Labor, and Pensions Hearing:
"Competition and Transparency: The Pathway Forward for a Stronger Health Care Market"
June 21, 2023

(As prepared for delivery)

While everyone seems to recognize that health care costs in the United States are continuing to rise at alarming rates, it seems that no one wants to take responsibility.

The hospitals blame the health insurance companies. The health insurance companies blame the drug manufacturers. The drug manufacturers blame employers. The employers blame the Pharmacy Benefit Managers (PBMs). And on it goes.

But, the American people don't want finger-pointing. They want quality health care that they can afford.

Today, this subcommittee will dig deep into two broad policy ideas that have the potential to drive down costs, expand choice, and empower consumers.

All sectors of our health care system are plagued by market consolidation and a lack of transparency. Until these issues are addressed, patients will remain victims of a broken, exploitative health care system.

Hospitals are a prime example.

Market consolidation is a proven health care cost driver, and hospitals are consolidating at a rapid rate. From 1998 to 2021, 1,887 hospitals merged. Twenty years ago, we had around 8,000 hospitals in this country. Now, we have about 6,000.

Not only do hospitals buy each other, but they also buy the physicians' offices nearby. Physician's offices were traditionally independent practices, reserved for check-ups and screenings, but they are slowly being replaced by outpatient facilities.

Hospitals already have an advantage over other industries. Emergency medical care is a unique service. When a patient needs care, they don't have the time or ability to shop around for options.

Hospitals have a monopoly and, as a result, there is no accountability regarding billing practices once a hospital takes control. This is a major reason why employer-sponsored insurance pays two to three times what Medicare pays for hospital services.

One solution is to bring transparency and require hospitals to disclose where and what they charge. Hospitals shouldn't be rewarded with high reimbursement rates for using incorrect billing addresses. They shouldn't charge hospital fees for services occurring in doctors' offices miles away.

In some places, patients are getting x-rays from their family doctor and being slapped with higher hospital facility fees, just because the hospital is now the owner of the family doctor's practice. Location shouldn't increase the price for the same service.

For too long, medical prices have been shrouded in mystery, and patients have lived in fear of how much their medical bills will end up costing them. The Trump administration issued a rule to require hospitals to give employers and consumers accurate pricing data. Hospitals were required to file this information, but only 25 percent of hospitals fully comply.

The Trump administration issued the transparency-in-coverage rule to ensure that patients receive the pricing information they need from their plans. This rule has been very successful, but there are improvements that can be made.

First, Congress should ensure the data that insurers are submitting is highly accurate and usable. Many of the files currently submitted are too large and cannot be used

by employers and academics. We must push for standardized data, and make it usable so employers can effectively meet their fiduciary obligations.

Second, Congress must codify the transparency-in-coverage rule to ensure the administration enforces requirements that plans submit drug pricing data. Without this critical information, employers and patients will be left in the dark when it comes to navigating the complexities and costs of the drug supply chain.

Consolidation and cover-ups are not only a factor for hospital services. They are a problem for pharmaceuticals too.

Drug makers have a large role in determining drug prices, but the role of PBMs must also be addressed, due to their significant influence over what patients pay at the pharmacy counter.

Three PBMs own a massive 80 percent of the market. Additionally, the "Big Three" are all subsidiaries of Fortune 500 health care companies that also own insurers, pharmacies, and—most recently—physicians; giving them even more influence over prescription benefits.

PBMs also operate in a black box. Nobody knows the details of the rebate deals they negotiate with drug manufacturers, creating perverse incentives for PBMs to choose more expensive drugs with larger rebates. If they truly passed rebate savings to consumers—like PBMs say they do—this would be a non-issue. Without transparency, the PBM business model is ripe for abuse.

Giving consumers choice works. The Trump transparency-in-coverage rule has already helped some large employers save millions by rooting out waste in their health plan. Patients would benefit from more transparency from PBMs too.

Corruption thrives in darkness, and as a conservative, I believe that for good governance, we ought to strive for more transparency. At a minimum, you should be able to expect transparency from your elected representatives, and we in turn need to demand it from our nation's health care industry.

These types of reforms have had wide bipartisan support, and I look forward to today's discussion and charting a path forward on robust health care reforms to bring costs down for all Americans.

Mr. DESAULNIER. Thank you, Mr. Chairman. I am delighted to hear your comments in our conversations about this subject matter. I am grateful to be here today. We are having the first of hopefully many bipartisan hearings on how we can lower healthcare costs for workers, families, and businesses by promoting transparency and competition.

I will say as a progressive, I agree with you. I believe in transparency. As we work to lower costs for all Americans, particularly consumers, it is important that we raise the quality of healthcare as well. These issues go hand in hand—value. Regrettably, the United States is an outlier when it comes to healthcare spending and quality outcomes.

As a share of gross domestic product, the U.S. spent nearly twice as much as the next closest developed country, Germany, in 2021. Over the past 5 years, average premiums for families have risen 22 percent in the United States. Unfortunately, it is clear we are not getting what we are paying for as Americans.

While our spending is No. 1 in the world, our health outcomes, unfortunately, are not. Americans do not get what they pay for when it comes to healthcare. One fundamental problem as the Chairman has said, is transparency. This limits our ability as policymakers to improve our healthcare system. It makes it harder for patients to find affordable, high-quality, healthcare providers.

It prevents employers from meeting their obligation to ensure that their workers' premium dollars are spent prudently. Transparency is also essential for fostering meaningful competition as the Chair has said, which keeps healthcare costs in check for both consumers and employers.

Over the past few years, Democrats and Republicans have made bipartisan progress to address these issues. In 2020, we came together to pass the No Surprises Act and the Consolidated Appropriations Act of 2021 in the CAA. These bipartisan achievements show that Democrats and Republicans can work together to lower healthcare cost for American workers and families.

However, there is still an urgent need for further action. Evidence on the ground suggests that some requirements of the CAA may not be working as intended. For example, despite the CAA's new disclosure requirements for group health plan service providers, entities such as pharmacy benefit managers or PBMs, and third-party administrators, often fail to disclose their compensation to plan fiduciaries.

Similarly, despite the prohibition on gag clauses under the CAA, third-party administrators and other service providers throw up roadblocks that prevent plan fiduciaries from using the information to lower costs and improve quality.

I also hope to explore ideas for changing the incentives of PBMs to make sure they act in the best interest of clients. As a minimum, we should all agree that employes and consumers deserve to know how the rebates PBMs receive from drug manufacturers impact their decisions that raise costs for workers and families.

Finally, Mr. Chairman, I look forward to learning more about improvements that can be made to the transparency in coverage regulations of the Affordable Care Act, and how to improve hospital billing policies. Without transparency and meaningful competition, healthcare costs will be driven by who has the most market power, not who provides the highest quality services.

As a result, the price we pay will continue to rise while the quality of what we receive in healthcare will decline. Last, I want to note something that you mentioned, that promoting transparency and competition alone will not solve the problem of high costs of healthcare.

As the issue of surprise medical billing shows, we cannot fully address market failure without a more direct action to ensure our constituents have access to affordable, high-quality care. It is my hope that this is only the first of many conversations about how we can make our healthcare system work for American patients and their families.

I want to thank you again, I want to thank our witnesses, and I look forward to a robust and constructive conversation. I yield back.

[The statement of Ranking Member DeSaulnier follows:]

ED & WORKFORCE DEMOCRATS

OPENING STATEMENT

House Committee on Education and the Workforce
Ranking Member Robert C. "Bobby" Scott

Opening Statement of Ranking Member Mark DeSaulnier (CA-10)
Subcommittee on Health, Employment, Labor, and Pensions Hearing
"Competition and Transparency: The Pathway Forward for a Stronger Health Care Market"
2175 Rayburn House Office Building
Wednesday, June 21, 2023 | 10:15 a.m.

Thank you, Mr. Chairman.

I'm delighted to hear your comments and our conversations about this subject matter.

I am grateful to be here today. We are having the first of hopefully many bipartisan hearings on how we can lower health care costs for workers, families, and businesses by promoting transparency and competition. I'll say, as a progressive, I agree with you. I believe in transparency. As we work to lower costs for all Americans particularly consumers, it is also important that we raise the *quality* of health care as well. These issues go hand in hand—value.

Regrettably, the United States is an outlier when it comes to health care spending and quality outcomes.

As a share of gross domestic product, the U.S. spent nearly twice as much as the next closest developed country, Germany, in 2021. Over the past five years, average premiums for families have risen 22 percent in the United States.

Unfortunately, it is clear we are not getting what we are paying for. While our spending is number one in the world, our health outcomes, unfortunately are not. Americans don't get what they pay for when it comes to health care.

One fundamental problem, as the Chairman has said, is transparency. This limits our ability as policymakers to improve our health care system. It makes it harder for patients to find affordable, high-quality health care providers. And it prevents employers from meeting their obligation to ensure that their workers' premium dollars are spent prudently.

Transparency is also essential for fostering meaningful competition, as the Chair has said, which keeps health care costs in check for both consumers and employers.

Over the last few years, Democrats and Republicans have made bipartisan progress to address these issues. In 2020, we came together to pass the *No Surprises Act* and the *Consolidated Appropriations Act of 2021*, or the CAA.

These bipartisan achievements show that Democrats and Republicans *can* work together to lower health care costs for workers and families. However, there is still an urgent need for further action.

Evidence on the ground suggests that some requirements of the CAA may not be working as intended.

For example, despite the CAA's new disclosure requirements for group health plan service providers, entities—such as pharmacy benefit managers, or PBMs, and third-party administrators—often fail to disclose their compensation to plan fiduciaries. Similarly, despite the prohibition on gag clauses under the CAA, third-party administrators and other service providers throw up roadblocks that prevent plan fiduciaries from using the information to lower costs and improve quality.

I also hope to explore ideas for changing the incentives of PBMs to make sure they act in the best interests of clients. At a minimum, we should all agree that employers and consumers deserve to know how the rebates PBMs receive from drug manufacturers impact their decisions that raise costs for workers and families.

Finally, Mr. Chairman I look forward to learning more about improvements that can be made to the Transparency in Coverage regulations of the *Affordable Care Act* and how to improve hospital billing policies.

Without transparency and meaningful competition, health care costs will be driven by who has the most market power, not who provides the highest quality services. And, as a result, the price we pay will continue to rise, while the quality of what we receive in health care will decline.

Lastly, I want to note something that you mentioned, that promoting transparency and competition, alone, will not solve the problem of the high cost of health care. As the issue of surprise medical billing shows, we cannot fully address market failure without more direct action to ensure our constituents have access to affordable, high-quality care.

It is my hope that this is only the first of many conversations about how we can make our health care system work for American patients and their families.

I want to thank you, again, I want to thank our witnesses I look forward to a robust and constructive conversation.

I yield back.

Chairman GOOD. Thank you, Mr. DeSaulnier. It sounds like competition and transparency are the themes of the day, and I look forward to this time together as well. Pursuant to Committee Rule 8(c) all members who wish to insert written statements into the record may do so by submitting them to the Committee Clerk electronically in Microsoft Word format by five o'clock, 14 days after the date of this hearing, which is July 5, 2023.

Without objection, the hearing will remain open for 14 days. The hearing record will remain open for 14 days to allow such statements and other extraneous material referenced during the hearing

to be submitted for the official hearing record. We will now turn to the introduction of our distinguished witnesses.

Our first witness is Dr. Gloria Sachdev, who is the President and CEO of Employers Forum of Indiana. Our second witness is Ms. Christine Monahan, who is an Assistant Research Professor at Georgetown University Center on Health Insurance Reforms.

Our third witness is Ms. Sophia Tripoli, who is the Director of Healthcare Innovation at Families USA. Our fourth witness is Mr. JC Scott, who is the President and CEO of the Pharmaceutical Care Management Association, and finally, we have Mr. Greg Baker, who is the CEO of AffirmedRX, located in Louisville, Kentucky.

I thank all of you for being here today, and we look forward to your testimony. Pursuant to Committee rules, I would ask that each of you limit your oral presentation to a 5-minute summary of your written statement, and I would also like to remind the witnesses to be aware of their responsibility to provide accurate information to the Subcommittee. We will first recognize Dr. Sachdev for 5 minutes.

THE STATEMENT OF DR. GLORIA SACHDEV, PRESIDENT AND CEO, EMPLOYERS' FORUM OF INDIANA

Ms. SACHDEV. Thank you, Chairman Good and Ranking Member DeSaulnier. I really appreciate the opportunity to be up here before this Committee today. My name is Gloria Sachdev, and I serve as President and CEO of the Employers' Forum of Indiana. My testimony today and my comments represent my own views, not those of forum members or organizations.

Indiana employers, large and small, are deeply invested in the well-being of their employees and their ability to receive the highest quality for the best price. Employers provide health insurance coverage to retain and recruit employees. They understand a healthy workforce is a productive workforce, and I appreciate this Committee's interest in helping working families and employers.

Just a few stats, as I expect my co-panelists will have some to share as well. Nationally, employer-sponsored health insurance covers 179 million people, representing 55 percent of the U.S. population. While Medicare spending on healthcare is a hot topic in Congress, working families and their employers are paying on average 2.5 times what Medicare is paying for the same services at the same hospitals.

If a particular hospital is charging a Medicare patient $1,000.00 for an MRI, the private sector for employers and employees is $2,500.00 for the same MRI at the same hospital. Some employers are paying $8,000.00 for that MRI at a different hospital. These high hospital prices harm workers and employers as it takes money away from other aspects of their lives and businesses.

Thankfully, some hospitals have lower prices and high quality, and that is where we all want to go. We all want to go to the best quality at the best price. We need more easily accessible price and quality data, which can be achieved by codifying the Transparency and Coverage Act, excuse me, and adding a few additional pieces to make the data more robust and usable.

Sadly, high healthcare prices have resulted in one in 8 adults in the U.S. being in collections for medical debt. One in 8 adults are in collections for medical debt. In Indiana, one in 6 adults are in collections due to medical debt. This is tragic. Being in collections ruins one credit score, which then makes it difficult to get a car loan, or a home loan, and thus can cause generational harm.

I would like to share a bit about some recent successes in Indiana and thoughts on how you can help. Per the RAND 2022 price transparency study, employers in Indiana were paying the fourth highest hospital facility prices in the country. Over three times what Medicare was paying for the same services.

As such, the Indiana House Speaker and Senate President Pro Tempore wholeheartedly committed to addressing hospital prices in 2023. With bipartisan support House-enrolled Act 1004 passed and includes many of the things that were just mentioned during these opening comments, including prohibiting hospitals from billing additional hospital facility fees for off-campus services.

Just because a hospital buys a physician clinic in a strip mall does not mean they should be allowed to add on hospital facility fees when nothing about the service, doctor, or location has changed. Tacking on hospital facility fees can easily double the price for no reason. We should pay the same amount for the same service regardless of who owns it.

I was honored to support our leadership by providing them with hospital price, quality, and cost data. This data allowed them to stand strong and do what is in the best interest of people despite fierce, and I mean fierce, opposition. Prohibiting unwarranted facility fees was not just passed in Indiana, but also in Colorado in 2023.

Texas had a bill too, but unfortunately it died. Connecticut, Maine, Massachusetts, and North Carolina have bills currently in progress, or they did at least as of last week. There is bipartisan Federal interest, too. There is the House PATIENT Act and the Senate SITE Act, among others.

While hospital prices are high, I would be remiss not to mention that drug price transparency is desperately needed in the entire drug supply chain, particularly in the PBM space. I am a pharmacist by background and training, managed patients for 12 years in physician office clinics, and really have seen firsthand the detriment that these high hospital prices and drug prices are causing to patients.

In closing, as we explore the pathway forward for a more functional healthcare market, let us not forget the human aspect of our decisions. Every American deserves access to affordable, high-quality healthcare that meets your unique needs.

By embracing competition and transparency, we can lay the foundation upon which evidence-based policy and purchasing can occur to create a healthcare system that ensures a healthier, more prosperous future for our Nation.

Thank you, Chairman Good and Committee members, for your attention.

[The Statement of Dr. Sachdev follows:]

June 21, 2023 Testimony
Gloria Sachdev. B.S. Pharm, Pharm.D.

Testimony for House Committee on Education and the Workforce; Subcommittee on Health, Employment, Labor and Pensions
"Competition and Transparency: The Pathway Forward for a Stronger Health Care Market"

Chairman Good, Ranking Member DeSaulnier, distinguished members of the House Committee on Education and the Workforce, ladies and gentlemen;

Thank you for the opportunity to appear before this esteemed committee today. My name is Dr. Gloria Sachdev, and I serve as the President and CEO of the Employers' Forum of Indiana. My testimony and comments represent my own views, not that of Forum members or organizations. Indiana employers, large and small, are deeply invested in the wellbeing of their employees and their ability to receive the highest quality health care for the best price. Employers provide health insurance coverage to retain and recruit talented employees, and they understand that a healthy workforce is a productive workforce. I appreciate this committee's purview and interest in helping working families and their employers. Employer-sponsored health insurance covers 179 million people representing 55% of the U.S population.

Health insurance premium contributions for employees and employers have been increasing every year over the past 2 decades. Per the Kaiser Family Foundation (KFF) 2022 Annual Employee Benefits Survey, the average family health insurance premium was an astonishing $22,463 (whereas 20 years ago it was $8,003), and the average single person premium in 2022 was $7,911 (whereas 20 years ago, it was $3,083). During open enrollment, employees select the insurance coverage from options provided by their employer. At this time, employees see how much money will be withheld from each paycheck representing their share of the insurance premium. For family insurance, in 2022, the average worker contributed over $500 per month just to have health insurance. Thus, workers paid an average of $6,106 annually. Employers paid the balance, thus $16,357 annually per employee who selects family insurance coverage (see Appendix A). When we look at where healthcare dollars are being spent, the majority of it is on hospitals services, followed by physician services. Numerous price transparency studies, including those conducted by RAND Corp, have found that employers are paying about 2.5 times what Medicare pays for the exact same service at the same hospital. While drug costs not the largest slice of the employer cost pie, it is the fastest growing slice, and thus also deserves our attention.

The Impact of High Healthcare Prices is Harmful to Workers

In addition to workers paying a portion of their insurance premium from their paycheck, most also pay other out-of-pocket healthcare expenses such as deductibles and coinsurance required by their healthcare insurance plan. The result of high healthcare costs to workers is they have less money to spend on other aspects of their lives such as housing, food, and transportation. The Urban Institute has a free online web tool which can be found by searching "Urban Institute medical debt" and it allows you to see what percent of adults in each state, and by every county, are in collections for medical debt using February 2022 data. Shockingly, the national average is 13%, meaning 13% of U.S. adults are in collections for medical debt. In Indiana the average is 16%, representing 1 in 6 adults. Medical debt and putting people in collections causes generational harm. An analysis of 528 hospitals in 2022 found that 2/3 of hospitals sued patients or took other legal action against them, such as garnishing wages or placing liens on property. A similar share of hospitals report patients with outstanding bills to credit rating agencies, putting patients' credit scores and their ability to rent an apartment, buy a car, or get a job at risk. Sadly, about 1 in 5 deny nonemergency care to people with outstanding debt. Thankfully, states such as New York and New Mexico have begun to protect Americans from these abhorrent practices.

When we compare the rate at which health insurance premiums have increased compared to inflation, and salary growth, the problem becomes crystal clear. From 1999 to 2022, family premiums increased 296% and worker contributions increased 288%, but overall workers' earnings only increased 103%. Inflation does not explain the increase in health insurance premiums as inflation increased by 73% over the same time period (see Appendix B). I appreciate the committee working to lower healthcare costs for working families.

The Impact of High Healthcare Prices is Harmful to Employers

After paying employee salaries, healthcare expenses are typically the second largest line item expense for employers. Employers pay the majority of health insurance premiums for their workers. Per KFF, on average, employers pay 74% of a workers' family insurance premium and 83% of a single person's insurance coverage. Thus, high health insurance premiums are also harmful to employers resulting in them having less money to offer raises to employees, less money to hire the best talent, and less money to expand their business footprint. With less resources, it is challenging to stay competitive in local and global markets. To manage their healthcare spending, many employers have established onsite/near-site provider clinics and offer a menu of preventative services, among other strategies. Most employers share the growing healthcare cost burden with employees because they cannot afford to cover it all. They do this by way of offering high deductible health plans (HDHPs), and limiting coverage of health services and medications. And through this all, healthcare costs have continued to increase rapidly.

Healthcare affordability is a non-partisan issue that impacts all of us. The root cause of our healthcare system being sick is a lack of competition and transparency. PBMs and insurance companies sit in the middle between employers/workers who pay for healthcare, and workers who receive healthcare. Employers contract with PBMs and insurers to help operationalize high value care. However, overtime, consolidation among these middlemen has resulted in less competition. The result has been implementation of detrimental practices by these middlemen such as refusing to provide employers with requested price and quality data about their own employees so they can make evidence based decisions. With transparency, purchasers can begin to shop for more affordable care. With transparency, policy makers will have additional data to inform development of evidence-based policy.

SUGGESTED OPPORTUNITIES FOR POLICY IMPROVEMENT

Healthcare price transparency is foundational to lowering healthcare prices. The information has to be available in a useable, understandable, and accessible format to allow employers, policy makers and the public to make evidence-based purchasing and policy decisions.

1. Policy: Establish Honest Billing – amend Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185 et seq.), ERISA

Typically, hospital systems that purchase independent physician clinics tack on a hospital facility fee even though nothing has changed about the location, physician, staff, or service provided. The only difference is now the hospital owns this clinic. Adding a hospital facility fee in addition to a doctor professional fee results in a much higher total price for the exact same service. The Healthcare Cost Institute has a wonderful new tool that illustrates the average price difference by state for an office visit and an ultrasound at hospital-owned clinic vs an independent clinic. In Indiana, the price difference is 79% higher for an office visit and 219% higher for an ultrasound. This means that because the hospital now owns the clinic, Hoosiers are paying more than double for the same ultrasound. Prohibiting hospitals from adding unwarranted facility fees is also helpful in creating competition because it removes a key incentive for hospitals wanting to buy independent clinics. We know from numerous studies that increased market consolidation leads to higher prices. Requiring hospital outpatient clinics that are far away from a hospital (off-campus) to bill as an independent clinic will result in an

immediate lowering of healthcare costs paid by workers and employers. The bottom line is that the healthcare service is the same so the price should be the same. There is strong bipartisan support for this policy. Indiana and Colorado recently passed laws prohibiting unwarranted hospital facility fees. Connecticut, Maine, Massachusetts, and North Carolina have bills currently in progress. Texas' had a bill, but it died. Recently, H.R. 3561, the PATIENT Act, passed the U.S. House Energy and Commerce Committee (summary), and a bipartisan SITE ACT authored by U.S. Senators Braun, Hassan, and Kennedy was introduced.

Policy ideas for consideration:

a. Correct Billing Form: All hospital services, medications, and products provided at a hospital off-campus site, defined by CMS as greater than 250 yards from a hospital, shall bill on a professional form (namely CMS-1500 form, HCFA-1500 form, or HIPAA X12 837P electronic claims transaction form for professional services or their successor forms). Hospitals shall not bill for any off-campus services, medications, or products on a hospital institutional form (namely, CMS-1450 form, the UB-04 form, or HIPAA X12 837I institutional electronic claims transaction form or their successor forms).
b. Correct Billing Address: Establish that the correct address of where a service, medication, or product was actually provided be noted on the billing claim.
    - This is important as some hospitals currently note the main hospital billing address instead of the address of where the service was provided on the bill claim field. Thus, if a service was provided at a physician clinic off-campus, but the address on the claim is the hospital's billing address, payers would assume that this service was provided within a hospital and mistakenly pay a higher amount.
    - CMS issued a clarification document, MLN Matters SE #19007 which was not about a new rule, but rather to clarify the intent of existing rule regarding proper billing. It noted that hospitals are to note the actual address of where an individual received the service on the billing claim field titled "service facility address" beginning April 1, 2020. Due to COVID-19, in March 2020, hospitals asked CMS for this implementation to be placed on hold. The hold on was granted as noted in MLN Matters SE #19007-Revised, but now the hold should be lifted for CMS and also be applied to all payers, including group and individual provider claims.
c. Correct Building Identification: Require that hospital systems establish and bill using a unique National Provider Identifier (NPI) number for each and every off-campus outpatient department. Direct HHS to treat outpatient departments as subparts of the parent organization and to issue these subparts unique NPIs.
    - This, too, is important as currently some hospital systems have multiple hospitals and/or off-campus physician office clinics billing for services all under a single NPI. This is a problem as it does not permit payers to discern hospital services provided on-campus or off-campus, and it makes it very difficult to separate price and quality transparency data. Importantly, having separate NPIs permits regulators to monitor for appropriate billing.
d. Office Visits: Consideration may wish to be given to require all on-campus hospital outpatient office visits designated by CPT billing codes 99201-99205 (new patient office visits) and 99211-99215 (follow-up patient office visits), as well as telehealth visits, to be billed on an individual provider bill form, namely the CMS-1500 form, HCFA-1500 form, or HIPAA X12 837P electronic claims transaction form for professional services or their successor forms.
    - In person office clinic visits and telehealth visits on-campus of a hospital do not use additional hospital resources beyond the services provided at off-campus provider office visits, thus they should not be permitted to tack on a hospital facility fee.
    - If hospitals are prohibited from adding hospital facility fees for off-campus office visits, a concern is that they may bring off-campus services on-campus. By paying office visits at the same rate whether they are on-campus or off-campus, the incentive for moving off-campus clinic services (which are more convenient to access) to on-campus will dissipate.

- If payment parity for on-campus and off-campus existed, hospitals may decide that it is in their financial best interest not to employ as many physicians who staff their outpatient clinics. This unwinding of hospital consolidation of physician services would be great as it would result in opportunities for physicians to be employed elsewhere or stand up an independent practice. The latter option would create more competition in local markets.

e. Accountability: Add a penalty for noncompliance and note claims do not need to be paid.

f. Background: America's working population should have the same benefit afforded to Medicare patients by not having to pay more for hospital-owned off campus services. CMS' current regulations:
   - Medicare began paying new off-campus hospitals-owned physician clinics lower hospital facility fee payments to equal independent physician office services per a Medicare program with site-neutral payment reform Bipartisan Budget Act of 2015, however they excepted, e.g. grandfathered, established off-campus clinics and on-campus clinics. In 2019, by administrative policy, CMS removed the grandfathering exception. The American Hospital Association sued CMS and eventually the case landed at the U.S. Supreme Court. In 2021, the Supreme Court decided not to hear this case, thus the immediate lower court's decision became final.
   - CMS Outpatient Clinic Visit Services at Excepted Off-Campus Provider-Based Departments: Payment Update, Sept 9, 2019 notes, "By November 1, 2021, CMS will begin reprocessing claims for outpatient clinic visit services provided at excepted *[grandfathered]* off-campus Provider-Based Departments (PBDs) so they're paid at the same rate as non-excepted *[not grandfathered]* off-campus PBDs for those services under the Physician Fee Schedule (PFS)."
   - Thus, CMS now pays the same amount to all off-campus clinics for all services the same amount whether the hospital owns the off-campus clinic or if it is an independent clinic.
   - In 2023, CMS noted one off-campus exception in 2023 CMS new outpatient prospective payment system (OPPS) Rule: "We're exempting rural sole community hospitals from the site-specific Medicare Physician Fee Schedule-equivalent payment for the clinic visit service when an off-campus provider-based department provides the service."
   - 2022 MedPAC report to Congress recommends expansion of CMS site neutral payments.

2. **Require PBM Transparency -** by amending it into Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185 et seq.), ERISA

   Drug price transparency is desperately needed in the entire drug supply chain. The large PBMs sit in the middle and operate in secrecy, negotiating prices from drug manufacturers on behalf of employers and insurers, yet not telling their clients what the actual discounts they negotiated were per drug. Typically, PBMs provide aggregate drug rebate data, but this is not helpful in determining how best an employer should design their drug benefit plan for workers. Drug prices are soaring and, in an effort to bring relief, in Indiana we passed SEA 8 in 2023 requiring at least 85% of each drug rebate, which is broadly defined to include fees and other remuneration, to go to certain patients at the point of sale at the pharmacy counter, or to ERISA-exempt employers get 100% of the rebates. Without additional transparency policies, we have no way of knowing if PBMs are providing the appropriate 85%-100% rebates amount. In general, we must have full transparency in order to follow the money in the drug supply chain. Policy ideas for consideration include:

   a. Prohibit gag clauses
      - Gag clauses between PBMs and all entities they have business and agreements with result in employers not having the information to develop the drug benefit plan design that is in the best interest of their employees. PBMs have partnerships with drug manufacturers, wholesalers, distributors, pharmacies, hospitals, physician groups, and importantly, Group Purchasing

Organizations (GPOs). It is important to include GPOs and all other partnerships PBMs in any policy.

b. Full Drug Price Transparency on all drugs dispensed and administered
   - Full price transparency is needed to understand drug prices PBMs have negotiated with drug manufactures at the drug level, wholesale acquisition (WAC) price; net price; all discounts delineated by way of rebates, fees, or other remuneration per drug; data on co-pay assistance, out-of-pocket spending, and other pricing metrics. It is important to note that while most drugs are dispensed to patients at the pharmacy counter, employers often have injections and other drugs that are "administered" that flow through their PBM, so administrated medications should also be included.

c. Prohibit Spread Pricing
   - A terrible practice conducted by some PBMs is when they pay the pharmacy a lower price for an employee's drug claim but bill the employer a higher price for that exact drug , keep the spread. This practice should be prohibited. To ensure that this practice is not occurring, employers need the data to monitor what pharmacies and workers received and paid, respectively.

d. Require Insurers and PBMs to Report Companies that they have Full and Partial Ownership in and Contracts With.
   - Mergers and acquisitions are rampant (see Appendix C).
   - Insurers, PBMs, pharmacies, physician groups, home health agencies, and more are now often owned by a single parent company but have different business names, so ownership is not transparent. For example, a single physician group may be partially owned by numerous companies including a physician, a hospital, and an insurance company.

e. Prohibit Self-Dealing
   - Some insurers and PBMs mandate self-dealing, meaning they mandate their employers use the PBM and pharmacy owned or contracted by the insurer/PBM, and because all insurer payments are 100% passed through to the employers/workers, these entities could easily provide higher payment to their own company affiliates and pass this prices to employers/workers. This behavior leads to decreased competition and consolidation. It is important for all to know where potential conflicts of interest exist and monitor payment flow.

f. Prohibit Insurers and PBMs from requiring employers to choose or to pay fees for services not rendered.
   - Unbelievably, some insurers charge self-funded employers a huge penalty fee if they opt out from using their PBM or pharmacy, wishing to use an alternate PBM or pharmacy instead of ones they own/partner with. This anti-competitive behavior results in even greater consolidation, making it challenging or innovators to break into a market. Due to existing insurer/PBM consolidation, many employers, especially small employers, have no choice but to sign a contract using the insurers' entire suite of businesses.
   - Prohibit insurers/PBMs from limiting or charging fees to employers who wish to carve out any aspect of the plan offerings as employer have fiduciary responsibility, not the insurer/PBM.

g. Monitoring Competition Adequacy - Require Insurers/PBMs to report Merger and Acquisition information within a designated time period of them occurring and/or before they occur.
   - To better understand who is contributing to consolidation, where it is geographically occurring, and to be able to analyze the impact of mergers and acquisitions on prices and quality, merger and acquisition information should be made publicly available, allowing researchers, purchasers, and policy makers to have the facts.
   - This will allow regulators to be more effective at monitoring for increased consolidation, reduced market competition, and intervene more quickly.

h. Provide data in a Timely Manner

3. Codify the Transparency in Coverage (TiC) Rule - by amending it into Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185 et seq.), ERISA

The TiC rule enacted by HHS in 2020 requires group health plans and health insurance issuers in the individual and group markets to disclose cost-sharing information upon request to a participant, beneficiary, or enrollee beginning January 1, 2021 and to make publicly available on their own business websites their negotiated prices per procedure per insurance plan, and other price measures in a machine readable file (MRF). The intent is terrific: all people and purchasers have price transparency allowing them to shop for more affordable care. The following are policy considerations to help attain this admirable goal.

Policy: **Codify the TiC rule to protect its endurance and add the following:**

a. Standardize Insurer MRF - Develop a standardized method and uniform format.
   - Researchers from Georgetown University published a report titled, Transparency in Coverage: Recommendations for Improving Access to and Usability of Health Plan Price Data which note numerous recommendations identified by a group of national data experts.

b. Ensure monitoring and compliance – To increase transparency compliance, require that a copy of each insurer's MRF be uploaded to a secure federal website.
   - Having all MRFs will make monitoring substantially easier for regulators and increase compliance.

c. Codify the TiC rule to include prescription drug price transparency.
   - Codifying this rule would allow employers to have the transparency they need to shop for which insurer and PBM have the best negotiated prices.
   - This level of transparency will eventually create drug price competition in the market if purchasers use this information to make purchasing and benefit design decisions.

d. Require Provider Quality Transparency - add new language for CMS to display on their existing CMS Compare website, provider quality data by procedure, or at least by clinical categories.
   - Currently, CMS Compare includes quality data resources including Hospital Compare, Physician Compare and 6 other useful quality resources/datasets. However, people and employers do not shop for quality in the manner in which quality information is presented, i.e., hospital readmission rates, mortality rate, etc. People and employers seek healthcare services by either individual procedure or by clinical category, i.e., X-ray of wrist or imaging, colonoscopy or GI procedures, heart failure or cardiac procedures.
   - Using existing CMS clinical categories is an easy first step is to bring forward Shoppable Hospital and Physician Quality Transparency. This is important as we all want to go to the best quality at the best price….not necessarily the to the place with the cheapest price.

e. Increase Access to Transparency Data – require insurers to not only post it on their own websites, but also send a copy to HHS. HHS shall in turn place all of this data into one federal database freely accessible to the public, researchers, and policy makers. This database may be managed by a contractor.
   - It is very challenging to find all MRF on each insurer's website. Also, most of these MRF are so large that they are unable to be downloaded by the average person/organization.
   - An organization such as the Employers' Forum of Indiana has no choice but to pay third party data contractors, who have big data storage capabilities and data expertise, to download and merge the MRFs from hospital and insurer websites. My data contractors provide me with a cleaned up Excel document that I use to upload into Sage Transparency, a free, online, hospital price and quality transparency tool. While I am grateful to have these restricted use data sets, I am not able to make available to the public all that I want, even though the raw data in the MRF have what I wish to display and is available in a publicly. Requiring summary reports could be useful as the resulting data file will be smaller, thus in a format that I can use to incorporate this important data.

- If the federal government maintained a single data warehouse, policy makers, employers, consultants, and innovators would have access to single dataset and subsets to make evidence-based decisions.
- Importantly, this database would easily allow regulators to easily monitor insurers and other healthcare organizations for transparency compliance.

f. Creation of a federal All-Payer-Claims-Database (APCD) – Create a national APCD.
- This user-friendly, customizable, interactive online service would be transformational as all people and employers could easily shop for services, and policy makers could see the impact of their policies.
- The USE of transparency data by purchasers and policy makers is key to competition increasing.
- Insurer MRFs have much of the data included to create a robust federal APCD, and to this CMS Medicaid and Medicare price and quality data files could be added. Thus, this single, easy-to-use database would not only have comparable pricing data, but also include comparable quality data across all payers in public tool that would allow Americans to shop for services by state, insurance plan (or cash paying), procedure, and radius from zip code. Innovators could develop phone apps to make this data even more usable.
- Numerous State APCDs exist and much can be learned from them.
- A CBO report published in 2022 notes a favorable assessment for a federal APCD.
- It creates competition within the insurer and provider industries as people will see and go to offerings that have the best quality at the best price.
- This data would also be useful to states who have or are building APCDs such as Indiana. States could secure a data extract for their state and build upon it to other state-level data they collect.

4. Consolidated Appropriations Act (CAA) of 2022

ERISA establishes that employers have fiduciary duty if they manage and control their health plan. This includes self-funded employers who must follow minimum ERISA standards for managing health benefit plans. CAA Section II requires that the plan fiduciary attest in writing that all facets of the CAA have been applied to the applicable plans, that the guidelines have been adhered to, and that the plan has made a good faith effort to expend plan assets in a PRUDENT manner on behalf of the plan participants and their beneficiaries. At present, the CAA attestation format for self-funded employers remains unclear. As self-funded employers are plan fiduciaries, in order for them to meet this CAA requirement and use plan funds in a prudent manner, employers must have timely access to price, quality, and utilization data, as well as the full cooperation of all of their contracted healthcare partners. Otherwise, how can they make evidence-based decisions that are in the best interest of their employees? A concern is that employees will sue employers over not managing their benefit plan in their best interest. We need government support, so employers have unfettered, timely, and accurate access to their data. The alternate is that employers, in an effort to minimize their legal risk, consider alternatives to being the benefit plan administrator. Most employers still want to be the plan administrator in an effort to have a healthy, thriving workforce. To strengthen transparency, the following policies are offered for consideration:

Policy:

a. Gag Clauses noted in CAA Title II - Section 201
- The problem for self-funded employers, who are all the plan administrator, is that many of their insurer and PBM partners do not provide price and quality data requested which makes it impossible for employers to comply with their fiduciary responsibility. Some insurers and PBMs may provide the data requested but it takes repeated requests and months to finally get it.
- The current law prohibits plans and issuers from entering into an agreement with a provider, network or association of providers, third-party administrator, or other service provider offering

access to a network of providers that would directly or indirectly restrict the plan or issuer from: (1) providing provider-specific cost or quality of care information or data to referring providers, the plan sponsor, participants, beneficiaries, or enrollees, or individuals eligible to become participants, beneficiaries, or enrollees of the plan or coverage; (2) electronically accessing de-identified claims and encounter data for each participant, beneficiary, or enrollee; and (3) sharing such information, consistent with applicable privacy regulations. In addition, plans and issuers must annually submit to the Departments an attestation of compliance with these requirements. These provisions are effective December 27, 2020 (the date of enactment of the CAA).

b. Claims data ownership – establish that employers own their covered lives claims data, not their insurer partner, PBM partner, or other organization.
   - Ownership of the data must be made clear that it belongs to the employer, and they can do with it what they want. This includes their insurer/PBM partner sending it to a third party of the employers choosing for analysis.

c. Unfettered Employer Auditing privileges
   - Some insurers and PBMs note auditing restrictions in their employer contracts. These may include who the independent auditor is, approval required of the independent auditor the employer selects, what data can be audited, frequency of audits, depth of audits, etc. With significant insurer and PBM consolidation in Indiana and across the country, most employers have little choice but to sign these contracts.

d. Reasonable Fees to Supplying Data for Audits
   - To obstruct employer access to their own claims data, insurers and PBMs may charge employers high fees, thus a maximum fee should be established for their efforts to send the employer claims data file to an auditor or any designee of the employers' choice.

e. Responsiveness for Requests: Add a specified timeline by which all requested data is provided.
   - In Indiana in HEA1004, we added a 15 business day turnaround time for insurers to provide employers with their claims data upon request.
   - It is important that data that is "requested" is provided and not just a "response" is provided as the response could have nothing to do with actually providing the requested data.

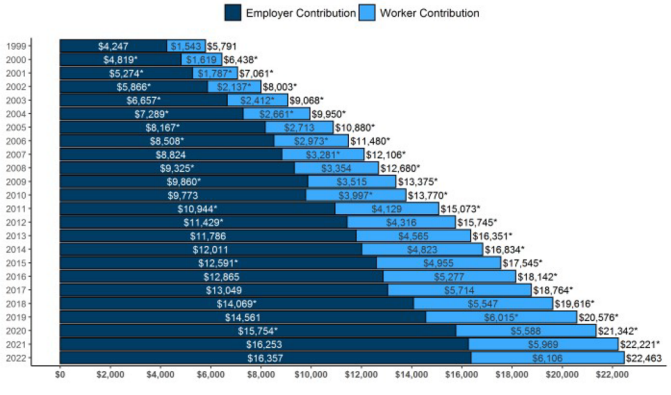
f. Prohibit anti-steering/anti-tiering, all-or-none language, and most favored nation clauses.
   - Gag clauses were prohibited because they are anti-competitive. Additional anticompetitive clauses were initially in the CAA, but they did not make the final cut.

As we explore the pathway forward for a stronger healthcare market, let us not forget the human impact of our decisions. Every American deserves access to affordable, high-quality healthcare that meets their unique needs. By embracing competition and transparency as guiding principles, we can create a healthcare system that fulfills this promise and ensures a healthier, more prosperous future for our nation.

Thank you Chairman Good and members of the committee for your attention and commitment to this vital issue. I look forward to engaging in a productive dialogue on these policy matters and more.

APPENDIX A

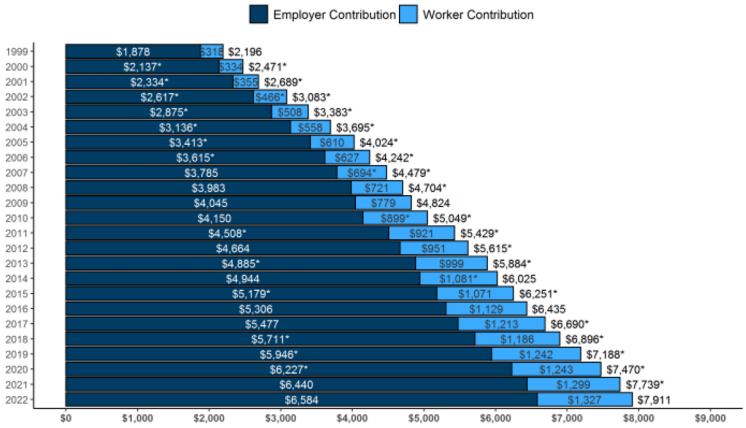
Average Annual Worker and Employer Contributions to Premiums and Total Premiums for Family Coverage, 1999-2022



* Estimate is statistically different from estimate for the previous year shown (p < .05).
SOURCE: KFF Employer Health Benefits Survey, 2018-2022; Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 1999-2017

KFF

Average Annual Worker and Employer Contributions to Premiums and Total Premiums for Single Coverage, 1999-2022

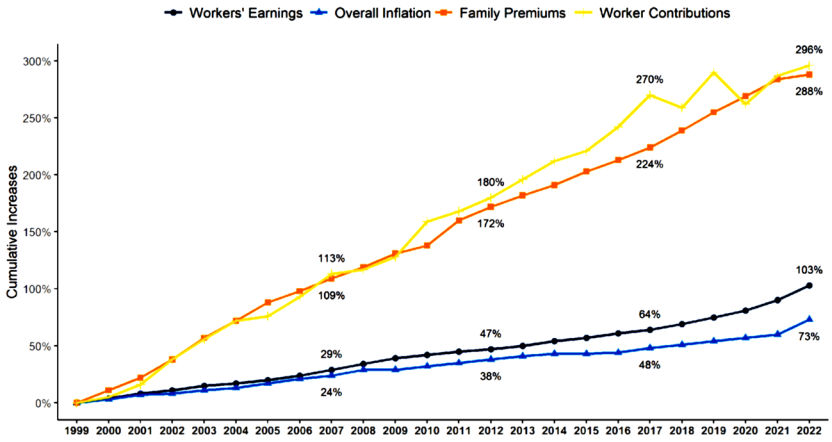


* Estimate is statistically different from estimate for the previous year shown (p < .05).
SOURCE: KFF Employer Health Benefits Survey, 2018-2022; Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 1999-2017

Reference: Section 6: Worker and Employer Contributions for Premiums – 10020 | KFF

APPENDIX B

Cumulative Increases in Family Premiums, Worker Contributions to Family Premiums, Inflation, and Workers' Earnings, 1999-2022



SOURCE: KFF Employer Health Benefits Survey, 2018-2022; Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 1999-2017. Bureau of Labor Statistics, Consumer Price Index, U.S. City Average of Annual Inflation, 1999-2022; Bureau of Labor Statistics, Seasonally Adjusted Data from the Current Employment Statistics Survey, 1999-2022.

Reference: https://www.kff.org/slideshow/2022-employer-health-benefits-chart-pack/

APPENDIX C

Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies, and Providers, 2023

Reference: https://www.drugchannels.net/2023/05/mapping-vertical-integration-of.html

Chairman GOOD. Thank you, Dr. Sachdev. Now we will hear from Ms. Monahan.

STATEMENT OF MS. CHRISTINE MONAHAN, ASSISTANT RESEARCH PROFESSOR, GEORGETOWN UNIVERSITY CENTER ON HEALTH INSURANCE REFORMS

Ms. MONAHAN. Good morning, Chairman Good, Ranking Member DeSaulnier, and members of the Subcommittee on Health, Employment, Labor, and Pensions. My name is Christine H. Monahan, and I am an Assistant Research Professor at the Center on Health Insurance Reforms within Georgetown University's McCourt School of Public Policy.

I am honored to testify today regarding competition and transparency in our healthcare markets. Consolidation in the U.S. healthcare system is growing—to the detriment of everyone who uses and pays for healthcare. In both the provider and insurer markets, we have seen significant horizontal and vertical consolidation over the past decade, contributing to rising prices for healthcare.

The expansion of large health systems with multiple hospitals, outpatient departments, and physician practices under the same roof has been significantly increasing what commercial insurers, and ultimately consumers and employers, pay for care. One egregious example of this is the addition of outpatient facility fee charges for healthcare services that can be safely and effectively provided outside of a hospital.

These charges often come as a surprise to patients who go in for a routine doctor's visit, and they can lead to significantly higher out-of-pocket costs than consumers have traditionally paid for such care. Some states, from Connecticut to Maine, to Indiana, have started to tackle this issue by prohibiting these charges in certain circumstances.

A handful of private insurers and at least one State employee health plan have also taken steps to limit these charges and protect consumers from these bills. One challenge to targeting and implementing these reforms, however, is a lack of transparency in the claims providers submit to insurers which can obscure where care was actually provided.

For example, a State or insurer may want to end hospital facility fee charges for care provided in off-campus departments or physician offices, since this care inherently does not need to be provided in a hospital setting. All of the claims from a hospital system may look like they are coming from the main campus of a hospital.

There are simple reforms the Federal Government can take to address this issue and set the stage for additional action to limit what commercial insurers pay for care in these circumstances, and ultimately move toward site neutral payments, as we are seeing in Medicare. These reforms include requiring that each separate facility or office where care is provided, like a hospital off-campus department, acquire a unique national provider identifier, or NPI, and that both the hospital and all healthcare practitioners include this NPI on their claims for any care they provide there.

This would give insurers, as well as regulators and policymakers relying on claims data, a much better sense of who is charging out-

patient facility fees, and when they are charging them, and take appropriate action.

More broadly, it would also allow insurers to better tailor other reimbursement decisions based on the location of care, considering factors like quality and cost. Let us not be naive about how far relying solely on private insurers to contain costs will get us.

They too have consolidated horizontally and vertically, and it is often in their interest to not push back strongly against provider prices. This may be because the providers charging the highest rates are considered must-have providers for their networks, or these providers have demanded that their insurer include anti-competitive clauses in their contracts.

The major insurers also have little incentive to use what negotiating power that they do have. This is a particular problem in the employer-sponsored insurance market, the majority of which is insured through self-funded health plans with the major insurers serving as third-party administrators, or TPAs.

In this role, the insurers have little incentive to negotiate competitive provider reimbursement rates due to the relative market power and information monopoly vis-&-vis employers. What is more, employer contracts with TPAs and pharmacy benefit managers or PBMs are often rife with hidden fees and overpayments, while the consultants and brokers employers hire to help arrange the contracts are taking in massive commissions.

This is all happening despite the fact that employers, as plan sponsors, have a legal duty under ERISA to act solely in the interest of plan members, and to ensure that they are paying reasonable compensation to service providers and no more.

Thankfully, the employer community is starting to awaken to these problems due in large part to recent efforts by Congress and the executive branch to bring more transparency to our healthcare system. More still needs to be done to give employers the information they need to become more prudent purchasers in this system.

This includes codifying and strengthening Federal price transparency rules, revisiting the Consolidated Appropriations Act's ban on gag clauses, and clarifying and expanding service provider disclosure requirements.

Given their critical role and power in the system, it is also worth exploring whether entities like TPAs and PBMs themselves should be treated as plan fiduciaries when performing functions where it is more important that they act in the best interest of plan members than their own business interests. Thank you for your time. I welcome your questions.

[The Statement of Ms. Monahan follows:]

GEORGETOWN UNIVERSITY
McCourt School of Public Policy

CENTER ON HEALTH INSURANCE REFORMS

STATEMENT OF CHRISTINE H. MONAHAN, J.D.
ASSISTANT RESEARCH PROFESSOR
CENTER ON HEALTH INSURANCE REFORMS
MCCOURT SCHOOL OF PUBLIC POLICY
GEORGETOWN UNIVERSITY

BEFORE THE U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON EDUCATION AND THE WORKFORCE SUBCOMMITTEE ON HEALTH, EMPLOYMENT, LABOR, AND PENSIONS

HEARING ON

"COMPETITION AND TRANSPARENCY: THE PATHWAY FORWARD FOR A STRONGER HEALTH CARE MARKET"

WEDNESDAY, JUNE 21, 2023

Good morning Chairman Good, Ranking Member DeSaulnier, and members of the Subcommittee on Health, Employment, Labor, and Pensions.

My name is Christine H. Monahan and I am an Assistant Research Professor at the Center on Health Insurance Reforms within Georgetown University's McCourt School of Public Policy. At the Center, we study private health insurance and health care markets.

I am honored to be invited to testify today regarding competition and transparency in our health care markets. In my testimony, I will briefly address the growth of consolidation across our provider and insurance markets, and the effects this is having on consumers and employers, the users of and ultimate payors for health care in the commercial market. I will then turn to opportunities for Congress to address consolidation and its harms, with a particular focus on measures that shed more light on different aspects of our health care system.

Please note that these views are my own. They do not necessarily reflect the views of the Center on Health Insurance Reforms, the McCourt School of Public Policy, or Georgetown University.

Consolidation in health care markets is growing, to the detriment of everyone who uses and pays for health care

Both horizontal and vertical consolidation are increasing across our health care system, and have been for years now. In health care provider markets, health systems have been allowed to merge with each other and further expand their reach by acquiring physician practices and other ambulatory care settings. Today, the majority of physicians, including those that help diagnose and treat everyday conditions like family doctors, are employed by hospitals and other corporate entities.[1]

These changes to ownership in our health care provider markets are driving up costs for consumers and employers. One cause behind this increase is that hospitals charge and insurers typically pay more for the same care when it is provided in a hospital setting, like a hospital outpatient department, than an independent practice. While this may be appropriate when the care being provided is more complex and the patient may need additional services only a hospital can safely provide, these higher payments currently extend even to the most routine, everyday services that can be safely and effectively provided outside of a hospital. As hospital acquisitions expand the scope and volume of services that are delivered in hospital-owned or -affiliated

[1] R. Shawn Martin, Exec. Vice President & Chief Exec. Off., Am. Acad. of Family Physicians, Statement to the U.S. Sen. Comm. on Finance 4 (June 8, 2023), https://www.finance.senate.gov/download/06082023-shawn; *COVID-19's Impact on Acquisitions of Physician Practices and Physician Employment 2019-2020* at 11, PHYSICIANS ADVOC. INST. (June 2021), https://www.physiciansadvocacyinstitute.org/Portals/0/assets/docs/Revised-6-8-21_PAI-Physician-Employment-Study-2021-FINAL.pdf?ver=K6dyoekRSC_c59U8QD1V-A%3D%3D.

settings, we end up paying much more than we previously were paying or need to be paying for ambulatory care.[2]

Another reason consolidation among health care providers increases costs is that large, conglomerate systems gain significant leverage in negotiations with commercial insurers. They become must-have-providers to any insurers seeking to build a provider network, and can extract greater reimbursement rates because of that status.[3] They can also impose anticompetitive contracting clauses on insurers, for example requiring insurers to contract with all the providers in their system under the same terms, regardless of factors like the cost or quality of care they may provide.[4]

Compounding these issues, we have a commercial insurance market dominated by just a handful of major insurers.[5] Often, insurance markets pit only two or three major insurers against each other, and these insurers frequently are following the same business models under which constraining health care prices and spending is not necessarily a priority.[6] As experts writing for the Urban Institute have summarized: "even dominant insurers do not need to achieve low prices, only the lowest rates among their competitors to establish favorable market conditions and prevent entry of would-be competitors."[7] Indeed, a dominant insurer may even engage in anti-competitive arrangements with the dominant health system to keep rates high.[8]

Some also point out that the Affordable Care Act's (ACA's) medical loss ratio requirements discourage insurers from containing costs because the amount of profits they can take home is

---

[2] *See, e.g.*, Frederick Isasi et al., *Gaming the System: How Hospitals Are Driving up Health Care Costs by Abusing Site of Service* 5–7, FAMILIES USA (June 7, 2023), https://familiesusa.org/wp-content/uploads/2023/06/Gaming-the-System-How-Hospitals-Are-Driving-Up-Health-Care-Costs-by-Abusing-Site-of-Service.pdf; *Facility Fees and How They Affect Health Care Prices: Policy Explainer*, HEALTH CARE COST INST. (June 6, 2023), https://healthcostinstitute.org/all-hcci-reports/facility-fee-explainer; *Moving to Site Neutrality in Commercial Insurance Payments* 2–4, COMM. FOR A RESP. FED. BUDGET (Feb. 2023), https://www.crfb.org/sites/default/files/media/documents/Moving_to_Site_Neutrality_in_Commercial_Insurance_Payments_4.pdf; Aditi P. Sen et al., *Site-Based Payment Differentials for Ambulatory Services Among Individuals with Commercial Insurance*, Health Servs. Res. (Jan. 18, 2022), https://doi.org/10.1111/1475-6773.13935.

[3] *See, e.g.*, Katherine L. Gudiksen et al., *Mitigating the Price Impacts of Health Care Provider Consolidation* 3, MILBANK MEM'L FUND (Sept. 2021), https://www.milbank.org/wp-content/uploads/2021/09/Mitigating-the-Price-Impacts-of-Health-Care-Provider-Consolidation_2.pdf; Katherine L. Gudiksen et al., *Preventing Anticompetitive Contracting Practices in Healthcare Markets* at 22–23, 40–41, THE SOURCE (Sept. 2020), https://sourceonhealth.wpenginepowered.com/wp-content/uploads/2020/09/Preventing-Anticompetitive-Contracting-Practices-in-Healthcare-Markets-FINAL.pdf; Robert Berenson et al., *Addressing Health Care Market Consolidation and High Prices* 3, URBAN INST. (Jan. 2020), https://www.urban.org/research/publication/addressing-health-care-market-consolidation-and-high-prices.

[4] *See, e.g.*, Gudiksen et al., MILBANK MEM'L FUND, *supra* note 3 at 3, 5–7; Gudiksen et al., THE SOURCE, *supra* note 3 at 22–23, 39–41.

[5] U.S. GOV'T ACCOUNTABILITY OFF., GAO-23-105672, PRIVATE HEALTH INSURANCE: MARKETS REMAINED CONCENTRATED THROUGH 2020, WITH INCREASES IN THE INDIVIDUAL AND SMALL GROUP MARKETS (Nov. 2022) https://www.gao.gov/assets/gao-23-105672.pdf.

[6] Marshall Allen, *Why Your Health Insurer Doesn't Care About Your Big Bills*, PROPUBLICA (May 25, 2018), https://www.propublica.org/article/why-your-health-insurer-does-not-care-about-your-big-bills.

[7] Berenson et al., *supra* note 3, at 2.

[8] Gudiksen et al., THE SOURCE, *supra* note 3, at 11–13.

capped to a percentage of spending.[9] However, the ACA's subsidy structure can incentivize cost containment when multiple insurers compete to be one of the two lowest cost plans in the individual marketplace, as these plans tend to get large percentages of enrollment.[10] On the other hand, the bulk of major insurers' commercial business comes from administrative-services-only (ASO) contracts with employers,[11] for which they may have little incentive to negotiate competitive rates due to their relative market power and information monopoly vis-à-vis most employers.[12] These perverse incentives are only worsening as the major insurers engage in vertical consolidation themselves, including ownership of all the major pharmacy benefit management (PBM) companies,[13] and growing acquisitions of health care provider practices and other suppliers of health care.[14]

The effects of all of this consolidation is the continued rise in the prices that consumers and employers pay for health care. This, in turn, translates to increased premiums and out-of-pocket costs for employees and individual market consumers, which many are ill-prepared to take on. A recent study by the Commonwealth Fund found that 29% of individuals with employer-sponsored insurance and 44% of those with individual market insurance were underinsured—meaning they have insurance, but that coverage does not adequately protect them from unaffordable out-of-pocket costs.[15]

---

[9] *See, e.g.*, Robert Book, *How the Medical Loss Ratio Requirement Could Increase Health Insurance Premiums and Insurer Profits at Taxpayer Expense*, Am. Action Forum (Apr. 2013), https://www.americanactionforum.org/wp-content/uploads/files/research/MLR_Paper_Final.pdf.

[10] *See* Jane M. Zhu et al., *Association Between Number of Insurers and Premium Rates in the Affordable Care Act Marketplace*, 177 JAMA INTERNAL MED. 1684, 1686 (Nov. 2017); John Holahan et al., *Marketplace Competition and Premiums, 2019–2022* at 9, URBAN INST. (Apr. 12, 2022), http://kff.org/health-reform/issue-brief/analysis-of-2015-premium-changes-in-the-affordable-care-acts-health-insurance-marketplaces.

[11] *Inside Big Health Insurers' Side Hustle*, TRADEOFFS (Sept. 23, 2021), https://tradeoffs.org/2021/09/23/inside-big-health-insurers-side-hustle/; Cathy Schoen & Sara R. Collins, *The Big Five Health Insurers' Membership and Revenue Trends: Implications for Public Policy*, 36 HEALTH AFFS. 2185, 2188 (Dec. 2017).

[12] CONG. BUDGET OFF., POLICY APPROACHES TO REDUCE WHAT COMMERCIAL INSURERS PAY FOR HOSPITALS' AND PHYSICIANS' SERVICES 11 (2022), https://www.cbo.gov/system/files/2022-09/58222-medical-prices.pdf; TRADEOFFS, *supra* note 11; Bob Herman, *Seven Health Insurance CEOs Raked in a Record $283 Million Last Year*, STAT NEWS (May 12, 2022), https://www.statnews.com/2022/05/12/health-insurance-ceos-raked-in-record-pay-during-covid/; Sarah Kliff & Josh Katz, *Hospitals and Insurers Didn't Want You to See These Prices. Here's Why.*, N.Y. TIMES (Aug. 22, 2021), https://www.nytimes.com/interactive/2021/08/22/upshot/hospital-prices.html.

[13] Adam J. Fein, *Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?*, DRUG CHANNELS (Dec. 12, 2019), https://www.drugchannels.net/2019/12/insurers-pbms-specialty-pharmacies.html.

[14] *See, e.g.*, Jakob Emerson, *Meet America's Largest Employer of Physicians: UnitedHealth Group*, BECKER'S HEALTHCARE (Feb. 16, 2023), https://www.beckerspayer.com/payer/meet-americas-largest-employer-of-physicians-unitedhealth-group.html; Bob Herman, *Profits Swell When Insurers Are Also Your Doctors*, AXIOS (July 16, 2021), https://www.axios.com/2021/07/16/unitedhealth-optum-providers-intercompany-eliminations; Jack O'Brien, *Why Health Insurers Want to Merge with Retail Giants*, HEALTH LEADERS MEDIA (Apr. 16, 2018), https://www.healthleadersmedia.com/finance/why-health-insurers-want-merge-retail-giants.

[15] Sara Collins et al, *The State of U.S. Health Insurance in 2022*, COMMONWEALTH FUND (Sept. 29, 2022), https://www.commonwealthfund.org/publications/issue-briefs/2022/sep/state-us-health-insurance-2022-biennial-survey.

Reducing the harms of consolidation through greater transparency and further interventions

The American public recognizes that health care provider pricing for people with commercial insurance is too high, too variable, and makes little sense. For example, a recent poll shows that a majority of voters, across political affiliation, believe that hospital prices are unreasonable (80%) and that it is important for the current Congress to act to reduce hospital prices (89%).[16] Similarly, large proportions of voters support specific policy reforms currently on the table, including "[r]equiring hospitals to publicly disclose their prices (87%)" and "[l]imiting outpatient fees to the same price charged by doctors in the community (85%)."[17] And, by far, more voters fear that Congress won't do enough (74%) than that it will go too far (26%).[18]

Action by Congress to shed more light about the financial incentives driving the growth in health spending is an important component to making our health care markets work better and addressing the harms that derive from consolidation. It can empower employers and employer coalitions to negotiate better deals from their vendors and health care providers. It can also inform regulators, including state and federal insurance and antitrust agencies that are charged with overseeing our health care markets and enforcing existing protections. Critically, it can also help policymakers at the state and federal levels develop and monitor the effects of new reforms, and ensure that the steps we are taking are moving us towards a health care system that provides affordable, high quality care to all. To that end, I'd like to address two broad areas for action: (1) shedding more light on and rationalizing commercial payment practices, and (2) exposing and eliminating wasteful and inappropriate spending in employer-sponsored coverage.

(1) Moving towards more transparent and rational payment practices in commercial insurance

Health care claims are a valuable source of information for payers, regulators, and policymakers, in addition to the broader research community. But consolidation in provider markets has obscured information about who provides care where. This lack of clarity undermines the ability of payers to make informed payment decisions and hinders our collective ability to understand the extent and effects of consolidation and target appropriate policy and legal interventions.

When health care is provided in a hospital-based setting, both the physician or other health care practitioners providing care and the hospital or health system typically will submit claims to the patient's insurer. These claims are submitted on separate forms. Currently, neither the physician form nor the hospital form needs specify the actual location where care was provided. Although the forms include address lines, providers typically will list the address for where payment

[16] *New Poll: Majority of Voters Support Aggressive Congressional Action to Lower Hospital Prices*, ARNOLD VENTURES (Mar. 23, 2023), https://www.arnoldventures.org/stories/new-poll-majority-of-voters-support-aggressive-congressional-action-to-lower-hospital-prices.
[17] *Id.*
[18] *Id.*

should be sent—which may be a billing office in a different state—rather than the care setting. Providers will also include a national provider identifier (NPI), a ten-digit, federally assigned identification number that providers use for administrative and financial transactions. But hospital claims often include the NPI for the hospital main campus or whatever entity in the system is assigned to collect payment, while the physician claim will include the individual physician's NPI (or that of whoever is responsible for billing in a group practice), even though they may practice out of several different locations. To those on the receiving end of these claims or who rely on public and private claims databases, the actual physical location of care is often a mystery. What's more, because of these and other discrepancies between the claim forms submitted by hospitals and physicians, it is challenging to reliably associate separate claims and know the total cost of care for a given outpatient service.

From dozens of interviews I and my team conducted this winter and spring, the absence of this information is an immense frustration to those in private and public spaces trying to understand and respond to hospital outpatient facility fee charges and other outcomes of vertical integration. For example, a growing number of states are seeking to prohibit hospital-controlled facilities from charging facility fees in certain types of settings, like off-campus facilities or physician offices. Outpatient facility fees can significantly and unexpectedly increase the amount patients pay in out-of-pocket costs for routine medical care, while also contributing to overall premium growth. But states may have difficulty enforcing facility fee prohibitions if insurers and regulators alike cannot tell the actual location care was provided. [19] I also worry that insurers not having this information will undermine the benefits of ongoing efforts at the state and federal level to prohibit anti-competitive clauses in contracts between providers and insurers. An insurer may, for example, want to pay lower prices to or simply not contract with certain practice locations owned by a health system that have poor quality ratings. But if they cannot tell what care was provided at which location, they may be unable to effectively implement such changes.

Fortunately, there are very simple, minimally burdensome reforms that Congress can take to improve billing transparency. Specifically, as states like Colorado[20] and Nebraska[21] have done, Congress can require that each separate physical location where care is provided obtain a unique NPI, and that providers, including hospitals and individual physicians and other professionals, list this unique NPI on all claims for care provided at that location. This would mean, for example, that every off-campus hospital outpatient department would have a unique NPI and claims would clearly convey when services are provided there.

This reform comes with another potential benefit: The NPI application form currently includes fields asking an applicant to provide the Legal Business Name (LBN) and Taxpayer Identification Name (TIN) of its parent organization on the application form. To ensure this information is consistently captured, Congress could specify that any application that does not

[19] *See* Christine H. Monahan et al., *Protecting Patients from Unexpected Outpatient Facility Fees: States on the Precipice of Broader Reform*, CTR. ON HEALTH INS. REFORMS (forthcoming summer 2023) (on file with witness).
[20] Colo. Rev. Stat. §§ 25-3-118(1); 25.5-4-420.
[21] Neb. L.B. 296 § 12 (2023).

include this information must be rejected. This information can, in turn, help the federal government, as well as private insurers, better track who owns each of these locations and monitor consolidation across the health care provider market.

From here, it will also be important to take additional steps to limit hospitals' and health systems' ability to charge outpatient facility fees and ultimately move towards site neutral payments for care that can be safely and effectively provided in independent practice settings. As I previously discussed, major insurers often lack the financial incentives and market leverage to take these actions on their own. Several states, from Indiana, to Maine, to Connecticut, are showing us ways to tackle these issues in the commercial sector. Their reforms provide important protections to consumers who can face substantial out-of-pocket exposure to outpatient facility fee charges and bring us closer to a more rationale payment system that hopefully will ultimately help drive down costs at the system level.[22]

(2) Exposing and eliminating inappropriate spending in the employer-sponsored insurance market through increased transparency

The employer-sponsored insurance market is rife with excessive and wasteful spending, from wildly disparate reimbursement rates, many of which are far above levels that would enable hospitals to "break even,"[23] to hidden fees and overpayments to third-party administrators (TPAs) and PBMs,[24] to massive commissions for employer benefit consultants and brokers recommending and arranging contracts on behalf of employers.[25] This occurs despite the fact that employers, as plan sponsors, have a legal duty under ERISA to act "solely in the interest of the participants and beneficiaries of the plan" when administering their employee benefit plans,[26] and ensure the compensation they pay service providers (including health care providers) is "reasonable."[27]

---

[22] *See* Monahan et al., *supra* note 19.
[23] *See* Christopher Whaley, *Prices Paid to Hospitals By Private Health Plans: Findings from Round 4 of an Employer-Led Transparency Initiative*, RAND (2022), https://www.rand.org/content/dam/rand/pubs/research_reports/RRA1100/RRA1144-1/RAND_RRA1144-1.pdf; *Understanding NASHP's Hospital Cost Tool: Commercial Breakeven*, NAT'L ACAD. FOR STATE HEALTH POL'Y (Mar. 28, 2022), https://nashp.org/commercial-breakeven/
[24] Bob Herman, *Fed up with Exorbitant Health Costs, Employers and Workers Are Taking Insurers to Court*, STAT NEWS (June 12, 2023), https://www.statnews.com/2023/06/12/employers-sue-health-insurers; Christine Monahan, *Questionable Conduct: Allegations Against Insurers Acting as Third-Party Administrators*, CHIRBLOG (Mar. 24, 2023), https://chirblog.org/questionable-conduct-allegations-insurers-acting-third-party-administrators/; *Pharmacy Benefit Tactics Drive up Drug Prices, Limit Access, Contribute to Health Risks*, PURCHASER BUS. GRP. ON HEALTH (Dec. 2022), https://www.pbgh.org/wp-content/uploads/2022/12/Pharmacy-Benefit-Tactics-Drive-Up-Drug-Prices-Limit-Access-Contribute-to-Health-Risks.pdf; Erin E. Trish et al., *PBMs Are Inflating the Cost of Generic Drugs. They Must Be Reined in.*, STAT NEWS (June 30, 2022), https://www.statnews.com/2022/06/30/pbms-inflating-cost-generic-drugs/.
[25] *EP379: How Much Money, Really, Are Employee Benefit Consultants and/or Brokers Making from Plan Sponsors? With AJ Loiacono*, RELENTLESS HEALTH VALUE (Sept. 15, 2022), https://relentlesshealthvalue.com/episode/ep379.
[26] 29 U.S.C. § 1104(a)(1).
[27] Information Letter 02-19-1998, U.S. Dep't of Labor, https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/information-letters/02-19-1998.

The incongruity between the expectations on employers as plan fiduciaries and the reality of spending under employer plans today is driven by several factors discussed above, including the market dominance of hospitals, health systems, and major insurers vis-à-vis individual employers. A lack of transparency into the health care system also significantly undermines employers' ability to investigate and meaningfully engage in negotiations over plan spending and the terms of their contracts. This factor, however, has begun to become less of a barrier than it once was, thanks to efforts by Congress and the Executive Branch to bring more transparency into our health care system. Since Congress passed the Consolidated Appropriations Act of 2021 (CAA) and the administrative federal price transparency rules went into effect, there has been an awakening by many in the employer community to the need to begin acting on the new information becoming available. At the same time, continued improvements to these efforts can still be made to better equip employers and others to make sure health care dollars are well spent.

(a) Codifying and strengthening federal price transparency rules

The first reforms to go into effect were the federal price transparency rules requiring various disclosures by hospitals and insurers and health plans. Implementation of these rules has been challenging, from court battles, to administrative delays, to outright noncompliance and obstruction by hospitals. And although insurers and health plans released their data more readily than many hospitals, the format and volume of their files were largely inaccessible to anyone without a supercomputer.[28] Work by private organizations—like the Employers Forum of Indiana's creation of the Sage Transparency tool—has helped harness some of available the price transparency data and combine it with other information to help employers make better decisions. Nonetheless more must be done to ensure all of the data covered by these rules is widely accessible and meaningful to the public.

Congress can take steps to fortify existing efforts, including codifying the price transparency rules and requiring greater standardization to enable plan-to-plan and provider-to-provider comparisons. Congress also needs to strengthen federal enforcement, such as by increasing the penalties for noncompliance and requiring the random auditing of data disclosures. Other changes that can make the information more useable would be to require insurers to make their data available in smaller files and provide an index or directory to help users navigate the information better, and to require that pricing and reimbursement data be posted as a percentage of Medicare rates in addition to flat dollar rates. Finally, Congress could require federal agencies to create a publicly available central repository for hospital and insurer price data combined with quality information, and report annually on this information so legislators and other stakeholders

[28] *See generally* Maanasa Kona & Sabrina Corlette, *Hospital and Insurer Price Transparency Rules Now in Effect but Compliance is Still Far Away*, HEALTH AFFS. (Sept. 12, 2022), https://www.healthaffairs.org/content/forefront/hospital-and-insurer-price-transparency-rules-now-effect-but-compliance-still-far-away; Julie Appleby, *Health Insurance Price Data: It's Out There, but It's Not for the Faint of Heart*, KAISER HEALTH NEWS (July 27, 2022), https://kffhealthnews.org/news/article/health-insurance-price-data-access/.

are kept informed regarding health care costs. For additional ideas for improving the Transparency in Coverage rules in particular, I would refer you to a set of recommendations to which some of my colleagues at CHIR contributed.[29]

(b) Revisiting the ban on gag clauses

Congress sought to shed further light on health care prices with the CAA's prohibition on gag clauses. This provision specifically prohibits employer health plans from entering into agreements with service providers that contain gag clauses restricting the plan's access to cost and quality information, including deidentified claims data.[30] Unfortunately, reports from the field suggest insurers acting as TPAs have continued to put up barriers to plan sponsors accessing this information.[31] One problem appears to be that the responsibility for compliance ultimately falls on plan sponsors, while control of the data remains with TPAs. Indeed, in recent litigation in which plan sponsors are seeking access to their claims data, their TPA, a major insurer, has argued that the plan sponsors can seek to renegotiate their contracts to meet "***their*** obligations" if they so desire, but the gag clause prohibition does not impose any duties on the TPA.[32] Additionally, as this guidance has been implemented by federal agencies, employers can rely on TPAs to attest that their contracts comply. But it is in the TPA's interest to assert compliance even if they may still retain arguably problematic contract terms. The fox, in effect, is guarding the henhouse.

Congress should explore ways to ensure that its intent in prohibiting gag clauses and giving plan sponsors access to their claims data, subject to appropriate privacy protections for plan members, is manifested. This will better enable employers to monitor their TPAs and the provider reimbursement rates the TPAs negotiate.

(c) Clarifying and expanding service provider disclosure requirements

In the CAA, Congress further empowered employers to better monitor their service providers and health plan expenditures by requiring service providers to describe in writing all direct and indirect compensation they expect to receive in connection with their services.[33] In speaking with employers and experts working in this area, they expect many employers will be shocked to learn of the amounts their consultants are making in commissions and other forms of compensation. As one example, many stakeholders highlight a Florida school district that alleged in 2021 that a

---

[29] *Transparency in Coverage: Recommendations* for Improving Access to and Usability of Health Plan Price Data, and Usability of Health Plan Price Data*, https://georgetown.app.box.com/s/1ezsggz1c7smsaexkr8rght15sokgusl.
[30] 29 U.S.C. § 1185m.
[31] Sabah Bhatnagar et al., *Improving and Strengthening Employer-Sponsored Insurance* 22–23, BIPARTISAN POL'Y CTR. (Oct. 2022), https://bipartisanpolicy.org/wp-content/uploads/2022/10/BPC-Improving-and-Strengthening-Employer-Sponsored-Insurance-Oct-2022.pdf.
[32] Memorandum of Law in Support of Defendants' Motion to Dismiss Plaintiffs' Complaint at 25, Trs. of Int'l Union of Bricklayers & Allied Craftworkers Local 1 Conn. Health Fund v. Elevance, No. 3:22-cv-01541-VLB (D. Conn. Mar. 10, 2023) (emphasis in original).
[33] 29 U.S.C. § 1108(b)(2)(B).

consultant it hired to help them select a TPA for their employee health plan secretly received more than $2 million in extra insurer commissions over eight years.[34]

As this Committee already is familiar, however, some service providers—including PBMs and TPAs—maintain that this requirement does not apply to them. In December 2022, Committee leadership sent a letter to the Department of Labor regarding this issue and encouraging the agency to issue guidance clarifying that the compensation disclosure requirements fully apply to PBMs and TPAs. Because the agency has yet to act on this recommendation, further clarification from Congress may be necessary and appropriate to ensure that the CAA is implemented to its fullest effect and intent.

Beyond this, it is worth exploring what additional information TPAs, PBMs, and other service providers should disclose to current and potential plan sponsors to ensure plan sponsors have adequate information to fulfill their fiduciary duties. In doing so, it is important to balance several considerations. Information must be sufficiently specific to be actionable. One concern is that many disclosures are in the form of formulas, percentages, and other metrics that do not necessarily convey the extent of compensation (and, thus, potential conflicts of interest). PBM and TPA contracts are immensely complex, and identifying the specific metrics that matter most may be challenging. What's more, PBMs and TPAs may adapt to any new disclosure requirements, shifting where and how they maximize revenue and profits to areas that remain secret. A flexible approach that focuses on articulating the goal of disclosures, such as better informing plan sponsors of how their plan assets are being spent and potential conflicts of interest among their service providers, may be more effective in the long term than an overly detailed law that focuses only on the problems we already know exist.

Alternatively, Congress and DOL may want to explore avenues to ensure TPAs and PBMs are fiduciaries when performing key functions for employer health plans. In identifying these functions, I again encourage you to think about the goals you are seeking to achieve. Where, for example, is it important that TPAs or PBMs act in the best interest of the members of the plans they are administering rather than their own business interests, and what would that look like? There are likely to be some answers that are obvious, like not charging hidden fees or retaining recovered overpayments, and others that may be desirable but prove trickier, such as negotiating reimbursement rates that would apply across multiple plans.

[34] Amended Complaint ¶ 36, Sch. Bd. of Osceola Cnty., Fla. v. Gallagher Benefit Servs., No. 6:21-cv-01979-ACC-LRH (M.D. Fla. Dec. 30, 2021).

Chairman GOOD. Thank you, Ms. Monahan, and now we will hear from Ms. Tripoli for her testimony.

STATEMENT OF MS. SOPHIA TRIPOLI, SENIOR DIRECTOR OF HEALTH POLICY

Ms. TRIPOLI. Chairs Good and Foxx, Ranking Member DeSaulnier and Scott, members of the Committee, thank you for the opportunity to testify today. It is an honor to be with you. On behalf of Families USA, a leading national non-partisan voice for healthcare consumers, working to ensure the best health and healthcare are equally accessible and affordable to all, I want to thank you for this critical discussion on healthcare affordability, transparency, and competition.

Today's hearing is urgently needed. Our healthcare system is in crisis, evidenced by a lack of affordability and poor quality. It will take all of us working together across political parties from rural and urban communities alike to fix it.

Every person in the United States should have high-quality healthcare that prevents illness, allows them to see a doctor when needed, and keeps their families healthy at a price they can afford.

Almost half of all Americans are foregoing medical care due to the cost. A third say that the cost of care affects their ability to secure basic needs, like food and housing, and over 40 percent of American adults, 100 million people, face medical debt. Every American knows we pay too much for the healthcare that we get.

Healthcare accounts for one-fifth of our Nation's economy, yet our health is not better. Our moms and babies die at high rates, and a quarter of a million people a year are killed by the healthcare system, from medical errors, infections, and the like.

Over the last 40 years, workers' wages have remained virtually stagnant, while employer health insurance premiums have risen dramatically, crippling the ability of working people to earn a living wage. 90 percent of large employers now say healthcare costs threaten the ability to provide healthcare benefits to employees.

This crisis is driven by misalignment between the business interests of the healthcare sector, and the health and financial security of our Nation's families. The healthcare sector siphons money out of workers' paychecks and into building C-suites of big healthcare corporations to increase healthcare prices, rewarding building local monopolies and price gouging, instead of promoting the health and well-being of our Nation's families.

The economic freedom of American families is eroding right before our eyes. We cannot afford to retire when we want, live in the homes of our choice, send our kids to college, or even meet basic needs like paying for rent or heat. Healthcare industry consolidation has eliminated competition and allowed monopolistic prices to push our Nation's families to the brink of financial ruin.

Nowhere is this clearer than looking at the prices of drugs and hospital care. For more than a decade, drug prices increased 20 percent per year, far exceeding inflation. Just since 2015, hospital prices increased 31 percent nationally, accounting for one-third of U.S. healthcare spending, and growing more than four times faster than workers' paychecks.

These higher prices are passed on to families as annual increases in insurance premiums and cost sharing become profit margins for large healthcare corporations. Particularly concerning is that healthcare is one of the only sectors in the U.S. economy where consumers are blinded to prices until after they have received a service and a subsequent bill.

This lack of transparency is a major barrier to the healthcare sector competing based on fair prices and high-quality care. It does not have to be this way. We know what is driving the crisis and how to fix it. Solutions can be deployed right away to end these pricing abuses, restore competition, and make healthcare more affordable.

We urge the Committee to consider well-vetted, bipartisan solutions to increase price transparency, address hospital billing practices, and payment differentials that drive consolidation and increase costs, and limit anti-competitive behavior in provider and health plan contracts.

Ultimately, the sector's economics must change to align with the health and financial security of the American people. Congress has overwhelming support to do this. 93 percent of Americans agree that we pay too much for the quality of healthcare we get. I would like to finish my remarks with the story of Brittany Tesso and her son, Roman, from Aurora, Colorado to illustrate the impact of these abusive pricing practices on people.

Roman's pediatrician referred him to a hospital to receive an evaluation for speech therapy. Because of the COVID–19 pandemic, the Tessos met with a panel of specialists via videoconference. The specialists, who appeared to be calling from their homes, observed Roman speaking, playing, and eating.

Later, Mrs. Tesso received a $700.00 bill for the 1-hour video appointment. Then she received another bill for nearly $1,000.00. Thinking it was a mistake, Mrs. Tesso called the hospital. Despite the fact that the Tessos never stepped foot inside the hospital, he was told the bill was a facility fee, designed to cover the costs of being seen in a hospital-based setting.

This is a national scandal. This Committee has the power and responsibility to stand up for our Nation's families and stop pricing abuses driven by big healthcare corporations. I thank the Committee for your time, and I look forward to answering any questions.

[The Statement of Ms. Tripoli follows:]

Testimony of Sophia Tripoli, MPH
Senior Director of Health Policy and Director of the Center for Affordable Whole-Person Care,
Families USA

Before the House Committee on Education and the Workforce
Subcommittee on Health, Employment, Labor, and Pensions

Competition and Transparency: The Pathway Forward for a Stronger Health Care Market

June 21, 2023

Families USA
1225 New York Avenue, NW
Suite 800
Washington, DC 20005

Chairs Good and Foxx, Ranking Members DeSaulnier and Scott, members of the Subcommittee, thank you for the opportunity to testify today at this critical hearing focused on health care affordability, transparency, and competition. It is an honor to be with you this afternoon. My name is Sophia Tripoli, and I am the Senior Director of Health Policy at Families USA and the Director of our Center on Affordable Whole Person Care. For more than 40 years, Families USA has been a leading national, non-partisan voice for health care consumers working to achieve our vision of a nation where the best health and health care are equally accessible and affordable to all. In October 2022, we launched the Center for Affordable Whole Person Care in affirmation of our commitment to revolutionize America's health care system to hold the health care industry accountable for delivering affordable, equitable, high-quality health care.

The U.S. Health System in Crisis

Today's hearing is urgently needed. Our health care system is in crisis, evidenced by a lack of affordability and poor quality.[1] And it is going to take all of us working together, across political party and health policy philosophy, from rural and urban communities alike, to fix it.

At its core, our nation's affordability crisis is driven by a fundamental misalignment between the business interests of the health care sector and the health and financial security of our nation's families – a business model that allows industry to set prices that have little to do with the quality of the care they offer. These high and irrational prices are largely due to trends in health care industry consolidation that have eliminated competition and allowed monopolistic pricing to push our nation's families to the brink of financial ruin.[2]

The good news is that you and your colleagues in Congress have the support of the American people in making needed changes. Ninety-three percent of Americans agree that our country is paying too much for the quality of health care we receive, and more than half of adults in that same poll said that their most recent health care experience was not worth the cost.[3] Brand new polling shows that almost 90% of voters say it is important for this Congress to take action to reduce hospital prices, including 95% of Biden voters and 85% of Trump voters.[4]

It is not surprising that Americans are united around the urgent need to address these issues. Almost half of all Americans have reported having to forgo medical care due to the cost, and almost a third have indicated that the high cost of medical care is interfering with their ability to secure basic needs like food and housing,[5] and over 40 percent of American adults – 100 million people – face medical debt.[6] High and rising health care costs are a critical problem for national and state governments, and affect the economic vitality of middle-class and working families – crippling the ability of working people to earn a living wage. Today's real wages – wages after accounting for inflation – are roughly the same as four decades ago, while employer health insurance premiums have risen dramatically.[7] At the same time, nearly 90% of large employers say that rising health care costs will threaten their ability to provide health care benefits to employees over the next five to 10 years if costs are not lowered.[8]

Notably, the excessive cost of health care does not generally buy Americans higher-quality care or even higher volumes of care. In fact, the opposite is true. Despite spending two to three times

more on health care than other industrialized countries, the United States has some of the worst health outcomes, including some of the lowest life expectancy and highest infant mortality rates.[9,10,11] These health outcomes are even worse for people of color who experience higher rates of illness and death across a range of health conditions compared with their white counterparts.[12]

These abysmal health outcomes and extraordinarily high prices are the product of broken financial incentives within the U.S. health care system. Our current system rewards building local monopolies and price gouging instead of rewarding success in promoting the health, well-being and financial security of the community.[13] And hospital prices in particular have become highly problematic as the role of hospitals in our economy has shifted over the last 60 years from charitable institutions to corporate entities, resulting in a fundamental misalignment between the business interests of the hospital sector and the interests of the patients they serve.[14] These higher prices result in $240 billion annually coming out of workers' paychecks and instead becoming profits for large health care corporations.[15,16,17]

Health Industry Consolidation Driving High Prices

America's health care affordability crisis stems from high, rising, and variable prices across a wide range of health care goods and services, including prescription drugs and diagnostic tools such as MRIs and CT scans. For example, the price of Humira — a drug used to treat arthritis — is more than four times as expensive in our country as in the United Kingdom and almost twice as expensive as in Germany.[18] The average price of a hospital-based MRI in the United States is $1,475.[19] That same scan costs $503 in Switzerland and $215 in Australia.[20] These higher prices for an identical service are the main driver of the dramatic increase in per capita health care spending in our country, where health care accounted for nearly 20% of the nation's GDP in 2020, far exceeding health care spending by any other industrialized country.[21]

These irrational and unjustifiable prices are largely due to trends in health care industry consolidation that have eliminated competition and allowed monopolistic pricing to flourish.[22] This consolidation has taken place without meaningful regulatory oversight or intervention, and is becoming more acute.[23] In fact, there are few truly competitive health care markets left, with 95% of metropolitan statistical areas (MSAs) having highly concentrated hospital markets, nearly 80% of MSAs having highly concentrated specialist physician markets, and 58% of MSAs having highly concentrated insurer markets.[24]

- **Hospital consolidation:** Hospital mergers are occurring more frequently both within and across health care markets, leading to higher prices in both cases. According to the American Hospital Association, there were 1,577 hospital mergers from 1998 to 2017.[25,26] An estimated 40% of those mergers took place from 2010 to 2015.[27]

- **Insurance consolidation:** Insurance markets are not as highly concentrated as providers, but there is evidence of markets with little competition between insurers. Between 2006 and 2014, the four-firm concentration ratio — the extent of market control held by the four largest firms, Aetna, Blue Cross Blue Shield, United and Anthem — for the sale of private insurance increased from 74% to 83%.[28]

- **Vertical Integration:** The number of hospital-acquired physician practices grew from 35,700 in 2012 to more than 80,000 in 2018.[29] Over this same time period, the percentage of physicians employed by a hospital or health system nearly doubled, from 25% to 44%.[30] Recent research found that over 55% of physicians are now employed in hospital-owned practices.[31] This trend was accelerated by the COVID-19 pandemic, which exacerbated the financial vulnerabilities of independent and smaller physician practices and threatened the near collapse of entire sectors of the health care system — particularly primary care.[32] Nearly 23,000 physicians left independent practice to work for a hospital or other corporate entity after the onset of the COVID-19 pandemic, while hospitals and other corporate entities acquired nearly 21,000 additional physician practices from 2019 to 2020, representing a 25% increase in corporate-owned practices.[33]

- **Mergers and Vertical Integration of Pharmacy Benefit Managers (PBMs), Insurers, and Pharmacies:** Though big drug companies bear the lion's share of the responsibility for our high and rising drug costs, other industry players also contribute.[34] Just as consolidation in hospitals and large health care corporations causes price increases, similar trends in consolidation among PBMs, insurers, and pharmacies can lead to increased costs for patients who are trying to access and afford their medications.[35] The top three PBMs, all of which are affiliated with major insurers and/or pharmacies, control 80% of the market: CVS, including Caremark and Aetna; Express Scripts owned by Cigna; and Optum owned by UnitedHealth Group.[36] As PBMs buy up more and more of the market, they have increased negotiating power with drug manufacturers, which results in pricing structures that serve PBM financial interests at the expense of the financial security of our nation's families. For example, a Delaware state auditor report found Express Scripts overcharged the state employee prescription drug plan by $24.5 million.[37] Or, take the Ohio Department of Health which found that CVS Caremark and Optum Rx pocketed the nearly 9% difference between what they billed managed care plans and what they paid pharmacies instead of passing those savings on to families.[38] Consolidation in the PBM market also allows PBMs to prioritize the pharmacies they own, which reduces patient choice and access to some drugs by "steering" patients to specific pharmacies.[39] As of 2017, PBM-owned pharmacies represented 46% of the industry's revenue growth.[40] This is a major threat to the ability of independent pharmacies to operate and threatens access to pharmaceuticals for millions of families living in rural and underserved communities.

Hospital Pricing Abuses

Nowhere is the negative impact of consolidation more evident than the rising cost of hospital stays and services, which have increased dramatically in the last decade and make up a large portion of increasing health care costs overall.[41,42,43] These cost increases have occurred despite lower hospital utilization and are largely due to escalating prices, which are the result of hospitals buying other hospitals and community doctors to eliminate competition and form big health care corporations and medical monopolies.[44,45]

Americans in many communities have watched as their local hospitals became health systems, and those health systems were bought by large health care corporations. What most in the public and

policymaking community have not realized is how much this has destroyed any real competition in our health care sector, allowing hospitals to dramatically increase their prices every year.[46,47] Between 1990 and 2023, hospital prices have increased 600% – and just since 2015, hospital prices have increased as much as 31% nationally, now accounting for nearly one-third of U.S. health care spending, and growing more than four times faster than workers' paychecks.[48,49,50,51]

These high prices, combined with intentionally opaque billing practices, often hit consumers at their most vulnerable moments. Consider the story of Nicki Pogue:

> *In August 2018, Pogue ran a high-altitude trail race with a chest cold. After returning home she started having difficulty breathing, rapid pulse, tingling in her extremities, dizziness, and had difficulty walking. Her neighbor rushed her to the closest hospital where they ran multiple tests – an EKG, chest X-rays, and blood tests – but they could not pinpoint what was wrong with her. Luckily after four hours she stabilized and was sent home. A month later, a $13,000 bill arrived. When she reviewed her bill, she noticed that the biggest charge was a mysterious line item for "ER EX/TX RM LEVEL V," which came with a fee of more than $11,000. She had no idea what this charge was and did not get any transparency or explanation from the hospital. She spent the next five months working to decipher the bill on her own, only to discover the hospital had miscoded her Emergency Severity Index and severely over-charged her.*[52]

High and Irrational Prices Fueled by a Lack of Transparency

Importantly, hospital prices are not only high, but have become essentially irrational:

- In 2020, across all hospital inpatient and outpatient services, employers and private insurers paid on average 224% of what Medicare pays for the same services.[53]
- Prices at hospitals in concentrated markets are 12% higher than those in markets with four or more rivals without any demonstrated improvement in the quality or access to care.[54,55,56] All the while, the workforce in these concentrated markets suffers – wages for nurses and other health care workers decrease significantly after mergers and acquisitions.[57]
- Prices for the exact same service vary widely, sometimes even within a single hospital system:
    - A colonoscopy at a single medical center in Mississippi can range from $782 to $2,144 depending on insurance.[58]
    - At one health system in Wisconsin, an MRI costs between $1,093 and $4,029 depending on level of insurance.[59]
    - Across the country, the average price for a knee replacement ranges from $21,976 in Tucson, Arizona to $60,000 in Sacramento California.[60]
    - The price of an MRI at Mass General Hospital in Boston Massachusetts ranged from $830 to $4,200 depending on the insurance carrier.[61]

What's more, consumers and employers, who are the ultimate purchasers of health care, have limited insight into what the prices of health care services are until after they've received a bill. For the majority of Americans – 66% – who receive health care through private insurance,[62] health

care prices are established in closed-door negotiations between large hospital corporations and health plans based on who has more market power.[63] These health care prices, often referred to as the negotiated rate, are buried in proprietary contracts without allowing for insight into or oversight over the price of health care services by the public and policymakers.[64] Health care is one of the only markets in the U.S. economy in which consumers are blinded to the price of a service until they receive a bill after the services is delivered.[65] It is the epitome of a broken market that threatens the financial security of American families and fails to serve their needs.

Congress has the Power to Fix our Broken System

It does not have to be this way. We know what the major drivers of high and irrational health prices are, and we know how to fix them. As federal lawmakers, you have an obligation to carefully steward our national health care resources and taxpayer dollars. We urge the Committee to consider well-vetted, bipartisan, and commonsense legislation that would remedy some of the most obvious health system failings, and to take on rising health industry consolidation among hospitals, insurers, and other health care organizations that enables anticompetitive behaviors, prevents healthy competition in markets and results in monopolies that set outrageous and unjustifiable prices. Policymakers should also ensure there is a great deal more transparency around both the cost of care and health care outcomes, including for vulnerable populations living in rural America, people of color and people living with disabilities.

Price Transparency

One crucial way this Committee can address provider consolidation and encourage competition in the health care system is through price transparency. Unveiling prices is a critical step towards achieving truly affordable health care, improved health, and more competitive health care markets across the U.S. health care system. Price transparency pulls back the curtain on prices so that policymakers, researchers, employers, and consumers can see how irrational health care prices have become and take action to rein in pricing abuses.[66] Further, unveiling prices can specifically inform where the highest and most irrational prices are occurring in the health care system, so policymakers can implement more targeted policy solutions to bring down the cost of health care.[67]

Consumer advocates have long sought transparency in health care prices. Following years of consumer advocacy, the Center for Medicare and Medicaid Services (CMS) finalized the Hospital Price Transparency Rule and Transparency in Coverage Rule, which require hospitals and insurers respectively to disclose health pricing information, including their negotiated rates and to provide consumer-friendly online tools to allow consumers to compare prices and estimate out-of-pocket costs.[68]

Taken together, these two regulations mark a critical step forward in driving towards higher value health care across the US health care system. While this rulemaking represents progress, more work is needed to achieve meaningful transparency of health care price and quality data. To achieve this goal, Transparency in Coverage regulations should be strengthened and codified to improve the quality and usability of the data files to ensure the data is actionable. This can be

achieved by enacting at least one of several policy options including establishing a national data format and file standard, reducing the redundancy of the data files, and regularly assessing the data quality to address poor data quality and make needed corrective actions.[69]

And while not the primary focus of this Committee, compliance with and usability of data from the Hospital Price Transparency Rule remains poor[70] and we encourage you to work with the other committees of jurisdiction to push back on industry gaming to skirt the rule's conditions by sharpening data requirements and establishing standard formats, eliminating loopholes, and further increasing penalties to encourage greater compliance by hospitals. Ultimately, policymakers must pass legislation that creates a national database such as a national All-Payer Claims Database (APCD) to house health care cost and quality data, claims data and clinical data that would allow policymakers, researchers, employers and consumers to analyze health care costs and quality data in order to drive higher value care into the health care system and lower costs for America's families. Because the Employee Retirement Income Security Act of 1974 (ERISA) preempts states from enforcing regulations on self-funded employer-sponsored health plans, which accounts for 65% of the data in the employer-sponsored insurance market, these self-insured plans are exempt from any state laws that attempt to collect health care cost and quality information. As a result, Congressional action is needed to access this data. This committee is the only committee that has the jurisdiction to make ERISA data available so that researchers and policymakers can analyze data across all payers in the health care system to drive towards higher value care for all consumers who rely on private insurance. Ultimately, the data collected through the Transparency in Coverage and Hospital Price Transparency should be collected into a national database such as an APCD.

Site of Service Payment Differentials and Dishonest Billing

We also encourage the Committee to crack down on industry practices that take advantage of market inefficiencies that come from site-specific payment rates. This broken financial incentive that pays hospitals higher reimbursement rates for outpatient services than for the exact same services provided at independent physician offices are a significant problem, a major driver of unaffordable care for America's families, and if addressed comprehensively could save American families and payers billions of dollars.[71]

These payment differentials across sites of service drive care delivery from physician offices to higher-cost hospital outpatient departments[72] and incentivize further consolidation – encouraging health systems to buy physician practices and rebrand them as outpatient facilities in order to generate higher reimbursement and charge consumers and payers higher prices. This type of consolidation – vertical integration between hospitals and physicians – leads to a growingly anticompetitive market where hospitals increase market power to demand even higher prices from commercial payers.[73] These higher commercial prices are then passed on to American families and come directly out of workers' paychecks, typically as monthly health insurance premiums.[74]

In some cases, hospitals intentionally reclassify a doctor's office they own as a hospital-based setting in order to charge consumers and insurers higher prices – this is "dishonest billing".

Currently, hospitals are able to purchase off-campus doctors' offices and use their hospital national provider number to charge Medicare and private insurance plans at hospital rates. An analysis by Northwestern University found the price of physician services increases 14 percent[75] after a hospital purchases a physician practice. Site of service payment differentials and dishonest billing result in higher premiums, higher copays, and higher deductibles for families and individuals. This broken incentive is ripe for this Committee's oversight and action.

These practices negatively impact real people every day, all across our country.

Kyunghee Lee, a then 72-year-old retiree who lives in Mentor, Ohio:

> *Kyunghee Lee has arthritis and once a year she would go to a rheumatologist for a steroid injection in her hand to relieve pain in her knuckles. For a few years, each round of injections cost her $30. In 2021, she arrived at her usual office and the rheumatologist she regularly saw had moved to a new floor of the building - just one floor up. She didn't think anything of it, as the rest of the appointment went as usual, until she received a bill for $1,394. The infusion clinic that Lee went to had been moved from an office-based practice to a hospital-based setting, and as a result the price of the same service she had been relying upon increased a staggering 4,546%. Lee's bill had a $1,262 facility fee attached, making up the majority of the increase in cost, even though she saw the same doctor and received the same treatment as the years prior. Lee and her family didn't know what they would do about the shot in the following year when the story was reported.*[76]

Brittany Tesso and her then 3-year-old son Roman from Aurora, Colorado:

> *In 2021, Roman's pediatrician referred him to Children's Hospital Colorado to receive an evaluation for speech therapy. With in-person visits on hold due to the Covid-19 pandemic, the Tessos met with a panel of specialists via videoconference. The specialists, who appeared to be calling from their homes, observed Roman speaking, playing, and eating. Later, Mrs. Tesso received a $700 bill for the one-hour video appointment. Then, she received another bill for nearly $1000. Thinking it was a mistake, Mrs. Tesso called to question the second bill. Despite the fact that the Tessos never set foot inside the hospital, she was told the bill was a "facility fee" designed to cover the costs of being seen in a hospital-based setting.*[77]

This is patently ridiculous, and this kind of abusive pricing should not be allowed to continue. In addition to cracking down on "dishonest billing" practices by requiring hospitals to accurately report their site of service, we urge the Committee to work with the other committees of jurisdiction to consider implementing comprehensive site-neutral payment policies as recommended by MedPAC in 2022,[78] and to eliminate site-dependent reimbursement distortions that indirectly incentivize acquisition of non-hospital patient access points.[79]

Anticompetitive Contracting Practices

We also urge the Committee to take a close look at anticompetitive practices and clauses in health care contracting agreements, which when occurring between providers and insurers give large

entities in highly consolidated markets the upper hand in contract negotiations to build networks and set prices. As a result, many of these contracts include terms that limit access to higher-quality, lower-cost care. Congress made important progress by banning gag clauses in executed contracts between insurance plan issuers and providers or provider networks as part of the Consolidated Appropriations Act of 2021. This policy has the potential to enable consumers and employers to be more informed purchasers of health care and to unveil fundamental information that policymakers, employers, researchers and other stakeholders need to identify health care markets with the highest prices and then build policy that encourage competition. With the first set of attestations due at the end of 2023, we encourage this committee to continue monitoring the implementation of the gag clause prohibition, and to work with the other committees of jurisdiction to go further by prohibiting additional anti-competitive contracting practices by providers including hospitals, health plans and issuers that are used to gain market power, raise prices and limit access to higher-quality, lower-cost care.

Drug Pricing and PBM Transparency

This Committee can also play a role in building on last year's historic reforms to address high drug costs. While the unscrupulous business models of big drug corporations are most squarely to blame for our drug costs crisis, PBMs also have played an important role in driving unaffordable drug prices.[80] As third party administrators designed to serve as intermediaries between health insurance providers and drug manufacturers, the key function of a PBM is to negotiate drug price concessions from pharmacies and drug manufacturers to lower prescription drug costs for health plans and employers.[81] To be clear, some drug costs are lower than they otherwise would be because of PBMs – and pharmaceutical corporations have taken particular aim at PBMs because of their role in negotiating a better price.

However, there is far too much opaqueness in the functioning of PBMs and certain business practices that are good for PBMs are bad for consumers. PBMs receive rebates and discounts from drug companies in exchange for formulary placement, or a place of the list of drugs a PBM has agreed to cover.[82] Importantly, although PBMs negotiate rebates, their revenue is based on a percentage of the drug's list price.[83] The result is that PBMs have a strong financial incentive to prioritize higher cost drugs. In many plan designs, PBMs pocket a percent of the rebate they get for consumers, making it advantageous for them to negotiate a higher rebate for a higher priced drug than a lower overall list price.[84] Pharmaceutical companies, then, raise both the list price and the rebate year after year making the overall cost of the drug higher.[85] A 2020 study showed that for every $1 increase in drug rebates there is a $1.17 correlating increase in the drug list price.[86] As result, PBMs are able to substantially increase their profits from rebates in addition to their normal revenue cycle, which relies on administrative fees, and in some cases they are not actually lowering the costs of drugs for consumers.[87]

We support the Committee's work to investigate the role of PBMs and urge you to continue to take action on abusive and anti-competitive business practices by increasing transparency into PBM negotiations and contracting including ensuring PBMs report on revenue, price and utilization data, and allowing plans and employers to receive data on negotiated rates, gross PBM profits, cost effectiveness of the PBM's drug list and spending patterns; increasing oversight and regulation of vertical and horizontal PBM consolidation; and ensuring 100% pass-through of

rebates and cost-sharing based on the actual price paid, and that 100% of rebates are passed on to consumers. Additionally, we urge you to work with your colleagues to continue to pursue reforms that take on the systemic abuses from big drug companies that are the main drivers of high drug prices.

Beyond these immediate steps, policymakers should focus on a broader redesign of the economic incentives of the health care sector to align with consumers and families. Ultimately, policy solutions should reorient health care payment and delivery to the goal that we all have — improved health for ourselves and our families that is affordable and economically sustainable.

Once again, the American people want action. Large majorities of voters support a range of policies to lower prices. Voters from both sides of the aisle broadly support:[88,89]

- Requiring all health care organizations to publicly disclose their prices (87%)
- Limiting outpatient fees to the same price charged by doctors in the community (85%)
- Preventing hospitals from engaging in business tactics that reduce competition (75%)
- Limiting mergers and acquisitions (74%)

Thank you again for holding this hearing today. Congress should seize this momentum to immediately implement commonsense policies that rein in abusive health care prices and make health care more affordable for everyone. The journey to fully transform our health care system is long, but Congress holds the power to take the next critical steps. Families USA stands ready to support you in this essential and urgently needed work.

---

[1] Emma Wager, Jared Ortaliza, and Cynthia Cox, *How Does Health Spending in the U.S. Compare to Other Countries?,* Peterson-KFF Health System Tracker, January 21, 2022, https://www.healthsystemtracker.org/. See also, Nisha Kurani, Emma Wager, *How does the quality of the U.S. health system compare to other countries?,* Peterson-KFF Health System Tracker, September 30, 2021. https://www.healthsystemtracker.org/.

[2] Robert A. Berenson et al., *Addressing Health Care Market Consolidation and High Prices*, The Urban Institute https://www.urban.org/sites/default/files/publication/101508/addressing_health_care_market_consolidation_and_high_prices_1.pdf. See also, Naomi N. Levey, "100 Million People in America are Saddled with Health Care Debt," Kaiser Health News, June 16, 2022, Health https://khn.org/news/article/diagnosis-debt-investigation-100-million-americans-hidden-medical-debt/

[3] West Health, *West Health-Gallup 2021 Healthcare in America Report*, West Health-Gallup 2021 Healthcare in America Report - westhealth.org.

[4] Arnold Ventures, Arnold Foundation Survey (Study #14460), February 2023. https://www.arnoldventures.org/stories/new-poll-majority-of-voters-support-aggressive-congressional-action-to-lower-hospital-prices?x-craft-preview=FZfdMAYpOB&token=WENwOldeHSblx2pRQ6y01tk_BGY5flyX

[5] NORC at the University of Chicago and West Health, *Americans' Views on Healthcare Costs, Coverage and Policy*, March 2018 https://www.norc.org/NewsEventsPublications/PressReleases/Pages/survey-finds-large-number-of-people-skipping-necessary-medical-care-because-cost.aspx

[6] Naomi N. Levey, *100 Million People in America are Saddled with Health Care Debt*, Kaiser Health News, June 16, 2022, https://khn.org/news/article/diagnosis-debt-investigation-100-million-americans-hidden-medical-debt/

[7] Drew DeSilver, "For Most U.S. Workers, Real Wages Have Barely Budged in Decades," Pew Research Center, August 7, 2018, https://www.pewresearch.org/fact-tank/2018/08/07/for-most-us-workers-real-wages-have-barely-budged-fordecade. See also, Gary Claxton et al., *Health Benefits in 2022: Premiums Remain Steady, Many Employers Report Limited Provider Networks for Behavioral Health*. Health Affairs, October 27, 2022. https://www.healthaffairs.org/stoken/tollfree/2022_11_CLAXTON/full

[8] *"Vast Majority of Large Employers Surveyed Say Broader Government Role Will Be Necessary to Control Health Costs and Provide Coverage, Survey Finds,"* Kaiser Family Foundation, April 29, 2021, Vast Majority of Large Employers Surveyed Say Broader Government Role Will Be Necessary to Control Health Costs and Provide Coverage, Survey Finds | KFF

[9] Munira Z. Gunja et al., U.S. Health Care from a Global Perspective, 2022: Accelerating Spending, Worsening Outcomes, Commonwealth Fund (Jan. 31, 2023), https://www.commonwealthfund.org/publications/issue-briefs/2023/jan/us-health-care-global-perspective-2022.

[10] OECD (2023), Life expectancy at birth (indicator). doi: 10.1787/27e0fc9d-en (Accessed on 27 January 2023); See *also*, Peterson-KFF Health System Tracker: Health Consumption Expenditures Per Capita. https://www.healthsystemtracker.org/chart-collection/health-spending-u-s-compare-countries-2/#Health%20consumption%20expenditures%20per%20capita,%20U.S.%20dollars,%20PPP%20adjusted,%202020%20or%20nearest%20year (accessed 27 January 2023).

[11] Rabah Kamal, Julie Hudman, and Daniel McDermott, "What Do We Know About Infant Mortality in the U.S. and Comparable Countries?" Peterson-KFF Health System Tracker, October 18, 2019, https://www.healthsystemtracker.org/

[12] "Racism and Health," Centers for Disease Control and Prevention, last reviewed November 24, 2021, https://www.cdc.gov/minorityhealth/racism-disparities/index.html

[13] Robert A. Berenson et al., *Addressing Health Care Market Consolidation and High Prices*, The Urban Institute https://www.urban.org/sites/default/files/publication/101508/addressing_health_care_market_consolidation_and_high_prices_1.pdf. See also, Assessing Current and Expected Growth of Alternative Payment Models: A Look at the Bold New Goals for Downside Risk," Leavitt Partners, November 18, 2019, https://leavittpartners.com/assessing-current-and-expected-growth-of-alternative-payment-models-a-look-at-the-bold-new-goals-for-downside-risk/. See also MedPAC, *Report to Congress: Medicare Payment Policy,* March 2023. https://www.medpac.gov/wp-content/uploads/2023/03/Mar23_MedPAC_Report_To_Congress_SEC.pdf

[14] From 1970 to 2019 the percentage of hospitals that were part of hospital systems rose substantially, from 10 percent to 67 percent, including a moderate increase from 58 percent to 67 percent between 2009 and 2019. For more information, see Fulton BD, Arnold DR, King JS, Montague AD, Greaney TL, Scheffler RM. The rise of cross-market hospital systems and their market power in the US. Health Aff (Millwood). 2022;41(11). https://doi.org/10.1377/hlthaff.2022.00337. See also, Bob Herman, *The corporatization of hospital systems,* Axios, June 21, 2019. https://www.axios.com/2019/06/21/the-corporatization-of-hospital-systems.

[15] William H. Shrank, Teresa L. Rogstad, and Natasha Parekh, "Waste in the US Health Care System: Estimated Costs and Potential for Savings," JAMA 322, no. 15 (2019): 1501–1509, https://jamanetwork.com/journals/jama/articleabstract/2752664

[16] Ioana Marinescu and Herbert J. Hovenkamp, "Anticompetitive Mergers in Labor Markets," Indiana Law Journal 94 (2019): 1031–1063, https://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=2967&context=faculty_scholarship

[17] David I. Auerbach and Arthur L. Kellermann, "A Decade of Health Care Cost Growth Has Wiped Out Real Income Gains for an Average US Family," Health Affairs 30, no. 9 (2011): 1620–1636, https://www.rand.org/pubs/external_publications/EP201100172.html

[18] Nisha Kurani, Dustin Cotliar, and Cynthia Cox, "How Do Prescription Drug Costs in the United States Compare to Other Countries?" Peterson-KFF Health System Tracker, February 8, 2022, https://www.healthsystemtracker.org/

[19] Michael Chernew et al., Are Health Care Services Shoppable? Evidence from the Consumption of Lower-Limb MRI Scans, Working Paper 24869 (Cambridge, MA: National Bureau of Economic Research, July 2018, revised January 2019), https://www.nber.org/system/files/working_papers/w24869/w24869.pdf

[20] Sarah Kliff, "The Problem Is the Prices: Opaque and Sky High Bills Are Breaking Americans — and Our Health Care System," Vox, October 16, 2017, https://www.vox.com/policy-and-politics/2017/10/16/16357790/health-care-pricesproblem.

[21] Emma Wager, Jared Ortaliza, and Cynthia Cox, "How Does Health Spending in the U.S. Compare to Other Countries?" Peterson-KFF Health System Tracker, January 21, 2022, https://www.healthsystemtracker.org/chart-collection/healthspending-u-s-compare-countries-2/#GDP%20per%20capita%20and%20health%20consumption%20spending%20per%20capita,%202020%20(U.S.%20dollars,%20PPP%20adjusted).

[22] Robert A. Berenson et al., *Addressing Health Care Market Consolidation and High Prices*, The Urban Institute https://www.urban.org/sites/default/files/publication/101508/addressing_health_care_market_consolidation_and_high_prices_1.pdf. See also, Congressional Budget Office, *Policy Approaches to Reduce What Commercial Insurers Pay for Hospitals' and Physicians' Services,* September 2022. https://www.cbo.gov/system/files/2022-09/58222-medical-prices.pdf

[23] Gerard Anderson, Peter Hussey, and Varduhi Petrosyan, "It's Still the Prices, Stupid: Why the US Spends So Much on Health Care, and a Tribute to Uwe Reinhardt," Health Affairs 38, no. 1 (2019), https://www.healthaffairs.org/doi/10.1377/ hlthaff.2018.05144.

[24] Jaime S. King et al., Preventing Anticompetitive Healthcare Consolidation: Lessons from Five States (Source on Healthcare Price and Competition and Nicholas C. Petris Center on Health Care Markets and Consumer Welfare of the University of California. Berkeley School of Public Health, June 2020), https://sourceonhealthcare.org/profile/preventing-anticompetitive-healthcare-consolidation-lessons-from-five-states/

[25] "Chart 2.9: Announced Hospital Mergers and Acquisitions, 1998–2015," TrendWatch Chartbook 2016: Trends Affecting Hospitals and Health Systems (Washington, DC: American Hospital Association, 2016)

[26] Chart 2.9: Announced Hospital Mergers and Acquisitions, 2005–2017," TrendWatch Chartbook 2018: Trends Affecting Hospitals and Health Systems (Washington, DC: American Hospital Association, 2018).

[27] Martin Gaynor, "Examining the Impact of Health Care Consolidation," statement before the U.S. House Committee on Energy and Commerce Oversight and Investigations Subcommittee, Washington, D.C., February 14, 2018.
[28] Leemore S. Dafny, "Evaluating the Impact of Health Insurance Industry Consolidation: Learning from Experience," The Commonwealth Fund, November 2015, https://www.commonwealthfund.org/publications/issue-briefs/2015/nov/evaluatingimpact-health-insurance-industry-consolidation.
[29] "Updated Physician Practice Acquisition Study: National and Regional Changes in Physician Employment, 2012-2018," Physicians Advocacy Institute (PAI), February 2019, http://www.physiciansadvocacyinstitute.org/Portals/0/assets/docs/021919- Avalere-PAI-Physician-Employment-Trends-Study-2018-Update.pdf?ver=2019-02-19-162735-117.
[30] PAI, "Physician Practice Acquisition Study."
[31] Venkatesh, Shruthi. 2019. "The Impact of Hospital Acquisition on Physician Referrals." Unpublished manuscript, Carnegie Mellon University, Pittsburgh, PA
[32] Avalere Health, "COVID-19's Impact on Acquisitions of Physician Practices and Physician Employment 2019-2020," Physicians Advocacy Institute, June 2021, http://www.physiciansadvocacyinstitute.org/Portals/0/assets/docs/Revised-6-8-21_PAI-PhysicianEmployment-Study-2021-FINAL.pdf?ver=K6dyoekRSC_c59U8QD1V-A%3D%3D.
[33] Ibid.
[34] Frederick Isasi Testimony, House Oversight Committee, "The Role of Pharmacy Benefit Managers in Prescription Drug Markets Part I: Self-Interest or Health Care?" May 23, 2023. Available at: https://oversight.house.gov/wp-content/uploads/2023/05/F.-Isasi-Written-Testimony-for-Oversight-5.23.23.pdf
[35] Cooper, Z., Craig, S., et al, *The Price Ain't Right? Hospital Prices and Health Spending on the Privately Insured,* The Quarterly Journal of Economics, Sept. 2018, https://academic.oup.com/qje/article-abstract/134/1/51/5090426?redirectedFrom=fulltext&login=false
[36] *The Top Pharmacy Benefit Managers of 2021: The Big Get Even Bigger,* Drug Channels, April 2022, https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html
[37] Bhatnagar, S., *High Drug Prices: Are PBMs the Right Target?,* Bipartisan Policy Center, Feb. 2023, https://bipartisanpolicy.org/blog/are-pbms-the-right-target/
[38] Bhatnagar, S., *High Drug Prices: Are PBMs the Right Target?,* Bipartisan Policy Center, Feb. 2023, https://bipartisanpolicy.org/blog/are-pbms-the-right-target/
[39] Freed, Z., *the Pharmacy Benefit Mafia: The Secret Health Care Monopolies Jacking Up Drug Prices and Abusing Patients and Pharmacists,* American Economic Liberties Project, http://www.economicliberties.us/wp-content/uploads/2022/06/2022-6-22-PBM-Quick-Take.pdf
[40] Carrier, M., *A Six-Step Solution to the PBM Problem,* Health Affairs, Aug. 2018, https://www.healthaffairs.org/content/forefront/six-step-solution-pbm-problem (Report Source: Fein, A., *The 2017 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers,* Drug Channels Institute, Feb. 2017, https://drugchannelsinstitute.com/files/2017-PharmacyPBM-DCI-Overview.pdf)
[41] Health Care Cost Institute, *2020 Health Care Cost and Utilization Report*, May 2022. https://healthcostinstitute.org/images//pdfs/HCCI_2020_Health_Care_Cost_and_Utilization_Report.pdf
[42] Emily Gee, *The High Price of Hospital Care*, June 26, 2019. Center for American Progress. https://www.americanprogress.org/article/high-price-hospital-care/
[43] Nisha Kurani and Cynthia Cox, "What drives health spending in the U.S. compared to other countries" Peterson-KFF Health System Tracker, September 25, 2020, https://www.healthsystemtracker.org/. See also, Zack Cooper, et al., *Hospital Prices Grew Substantially Faster Than Physician Prices for Hospital Based Care in 2007-14*. Health Affairs, February 2019. https://doi.org/10.1377/hlthaff.2018.05424
[44] Health Care Cost Institute, *2020 Health Care Cost and Utilization Report*, May 2022. https://healthcostinstitute.org/images//pdfs/HCCI_2020_Health_Care_Cost_and_Utilization_Report.pdf
[45] Robert A. Berenson et al., *Addressing Health Care Market Consolidation and High Prices*, The Urban Institute https://www.urban.org/sites/default/files/publication/101508/addressing_health_care_market_consolidation_and_high_prices_1.pdf.
[46] Martin Gaynor, What to Do About Health-Care Markets? Policies to Make Health-Care Markets Work (Washington, DC: The Hamilton Project, March 2020), https://www.brookings.edu/wp-content/uploads/2020/03/Gaynor_PP_FINAL.pdf.
[47] Robert A. Berenson et al., *Addressing Health Care Market Consolidation and High Prices*, The Urban Institute https://www.urban.org/sites/default/files/publication/101508/addressing_health_care_market_consolidation_and_high_prices_1.pdf.
[48] Nisha Kurani and Cynthia Cox, "What drives health spending in the U.S. compared to other countries" Peterson-KFF Health System Tracker, September 25, 2020, https://www.healthsystemtracker.org/.
[49] Drew DeSilver, "For Most U.S. Workers, Real Wages Have Barely Budged in Decades," Pew Research Center, August 7, 2018, https://www.pewresearch.org/fact-tank/2018/08/07/for-most-us-workers-real-wages-have-barely-budged-fordecade.

[50] Health Care Cost Institute, *2020 Health Care Cost and Utilization Report*, May 2022. https://healthcostinstitute.org/images//pdfs/HCCI_2020_Health_Care_Cost_and_Utilization_Report.pdf
[51] West Health, *The Healthcare Cost Crisis: An American Epidemic.* https://healthcostcrisis.org/, (ARC analysis of Healthcare Cost and Utilization Project, Agency for Healthcare Research and Quality).
[52] Families USA, "Center for Affordable Whole Person Care Launch," Facebook, https://www.facebook.com/watch/live/?ref=watch_permalink&v=502440418144915. Accessed March 26, 2023.
[53] Whaley, C. et al. Prices Paid to Hospitals by Private Health Plans. RAND. 2022. https://www.rand.org/pubs/research_reports/RRA1144-1.html
[54] Cooper, Z. et al. The Price Ain't Right? Hospital Prices and Health Spending on the Privately Insured. The Quarterly Journal of Economics. 2019. https://academic.oup.com/qje/article-abstract/134/1/51/5090426?redirectedFrom=fulltext&login=false
[55] Gaynor, M. Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets. Statement before the Committee on the Judiciary Subcommittee on Antitrust, Commercial, and Administration Law. U.S. House of Representatives. 2019. https://www.congress.gov/116/meeting/house/109024/witnesses/HHRG-116-JU05-Bio-GaynorM-20190307.pdf
[56] *The Impact of Hospital Consolidation on Medical Costs.* NCCI Insights. 2018. https://www.ncci.com/Articles/Pages/II_Insights_QEB_Impact-of-Hospital-Consolidation-on-Medical-Costs.aspx
[57] Prager, E. Schmitt, M. *Employer Consolidation and Wages: Evidence from Hospitals.* American Economic Association. 2021. https://www.aeaweb.org/articles?id=10.1257/aer.20190690
[58] Kliff, S. Katz, J. *Hospitals and Insurers Didn't Want You to See These Prices. Here's Why.* The Upshot. The New York Times. 2021. https://www.nytimes.com/interactive/2021/08/22/upshot/hospital-prices.html
[59] Ibid.
[60] *National Chartbook of Health Care Prices.* The Health Care Cost Institute. 2016. https://healthcostinstitute.org/national-chartbook-health-care-prices-2015
[61] Kliff, S. Katz, J. *Hospitals and Insurers Didn't Want You to See These Prices. Here's Why.* The Upshot. The New York Times. 2021. https://www.nytimes.com/interactive/2021/08/22/upshot/hospital-prices.html
[62] US Census, Health Insurance Coverage in the United States: 2020, https://www.census.gov/library/publications/2021/demo/p60-274.html.
[63] Kliff, S. Katz, J. *Hospitals and Insurers Didn't Want You to See These Prices. Here's Why.* The Upshot. The New York Times. 2021. https://www.nytimes.com/interactive/2021/08/22/upshot/hospital-prices.html.
[64] Jaime King, Testimony before the House Committee on Energy and Commerce and Subcommittee on Oversight and Investigations, (July 17, 2018), https://democrats-energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Testimony-King-OI-Hrg-on-Examining-State-Efforts-to-Improve-Transparency-of-Health-Care-Cost-2018-07-17.pdf.
[65] Danielle Scheurer, *Lack of Transparency Plagues U.S. Health Care System*, The Hospitalist, May 1, 2013. https://www.the-hospitalist.org/hospitalist/article/125866/health-policy/lack-transparency-plagues-us-health-care-system
[66] Robert A. Berenson et al., *Addressing Health Care Market Consolidation and High Prices*, The Urban Institute https://www.urban.org/sites/default/files/publication/101508/addressing_health_care_market_consolidation_and_high_prices_1.pdf. See also, Robert A. Berenson et al., *Addressing Health Care Market Consolidation and High Prices;* Jaime King, Testimony before the House Committee on Energy and Commerce and Subcommittee on Oversight and Investigations, (July 17, 2018), https://democrats-energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Testimony-King-OI-Hrg-on-Examining-State-Efforts-to-Improve-Transparency-of-Health-Care-Cost-2018-07-17.pdf.
[67] Phillip Longman and Harris Meyer, *Why Hospitals Keep Their Prices Secret*, July 6, 2020. Washington Monthly. https://washingtonmonthly.com/2020/07/06/why-hospitals-keep-their-prices-secret/
[68] "Transparency in Coverage Final Rule Fact Sheet (CMS-9915-F)," Centers for Medicare & Medicaid Services, October 29, 2020, https://www.cms.gov/newsroom/fact-sheets/transparency-coverage-final-rule-fact-sheet-cms-9915-f.
[69] Georgetown University, letter on policy problems and solutions for Transparency in Coverage Regulation with leading national experts, available at: https://georgetown.app.box.com/s/1ezsggz1c7smsaexkr8rght15sokgusl
[70] Patient Rights Advocate, *Fourth Semi-Annual Hospital Price Transparency Report*, February 2023, https://www.patientrightsadvocate.org/february-semi-annual-compliance-report-2023. See also, Emefah C. Loccoh, et al., *Hospital Adherence to the Federal Price Transparency Mandate: Results from a Nationally Representative Sample*, January 17, 2023. Journal of General Internal Medicine. See also, Morgan Henderson and Morgan Mouslim, *Assessing Compliance with Hospital Price Transparency over Time*, Journal of General Internal Medicine. https://link.springer.com/article/10.1007/s11606-023-08039-0.
[71] Committee for a Responsible Federal Budget, *Moving to Site Neutrality in Commercial Insurance Payments*, February 14, 2023. https://www.crfb.org/papers/moving-site-neutrality-commercial-insurance
[72] Ibid.
[73] Hannah T. Jerash et al. "Association of Financial Integration Between Physicians and Hospitals with Commercial Health Care Prices." *JAMA Internal Medicine* 2015;175(12):1932-1939.

[74] Ibid. See also, David I. Auerbach and Arthur L. Kellerman, "A Decade of Health Care Cost Growth Has Wiped Out Real Income Gains for an Average US Family," Health Affairs 30, no. 9 (September 2011), https://www.rand.org/pubs/external_publications/EP201100172.html

[75] https://www.ipr.northwestern.edu/our-work/working-papers/2015/ipr-wp-15-02.html

[76] Lauren Weber, *Her Doctor's Office Moved One Floor Up. Her Bill Was 10 Times Higher*, March 26, 2021, Kaiser Health News. https://khn.org/news/article/bill-of-the-month-hospital-facility-fee-outpatient-arthritis-injections/

[77] https://www.washingtonpost.com/business/2023/04/01/hospital-facilities-telehealth-fees/

[78] MedPAC, *Medicare and the Health Care Delivery System, Report to the Congress,* June 2022. https://www.medpac.gov/wp-content/uploads/2022/06/Jun22_MedPAC_Report_to_Congress_v2_SEC.pdf

[79] Committee for a Responsible Federal Budget, *Moving to Site Neutrality in Commercial Insurance Payments*, February 14, 2023. https://www.crfb.org/papers/moving-site-neutrality-commercial-insurance

[80] *Pharmacy Benefit Managers and Their Role in Drug Spending,* The Commonwealth Fund, April 2019, https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending

[81] *Pharmacy Benefit Managers,* The Center for Insurance and Policy Research, NAIC, April 2022, https://content.naic.org/cipr-topics/pharmacy-benefit-managers

[82] Bhatnagar, S., *High Drug Prices: Are PBMs the Right Target?,* Bipartisan Policy Center, Feb. 2023, https://bipartisanpolicy.org/blog/are-pbms-the-right-target/#:~:text=The%20role%20of%20PBMs&text=For%20certain%20prescriptions%2C%20some%20PBMs,and%20copays%20for%20plan%20enrollees.

[83] *Pharmacy Benefit Managers and Their Role in Drug Spending*, The Commonwealth Fund, April 2019, https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending

[84] Yeung, K., Dusetzina, S., Basu, A., *Association of Branded Prescription Drug Rebate Size and Patient Out-of-Pocket Costs in a Nationally Representative Sample, 2007-2018,* JAMA Network Open, June 2021, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780950

[85] Sood, N., Ribero, R., et al, *The Association Between Drug Rebates and List Prices,* USC Schaeffer, Feb. 2020, https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/

[86] Sood, N., Ribero, R., et al, *The Association Between Drug Rebates and List Prices*, USC Schaeffer, Feb. 2020, https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/

[87] *Pharmacy Benefit Managers*, The Center for Insurance and Policy Research, NAIC, April 2022, https://content.naic.org/cipr-topics/pharmacy-benefit-managers

[88] Arnold Ventures, Arnold Foundation Survey (Study #14460), February 2023. https://www.arnoldventures.org/stories/new-poll-majority-of-voters-support-aggressive-congressional-action-to-lower-hospital-prices?x-craft-preview=FZfdMAYpOB&token=WENwOldeHSblx2pRQ6y01tk_BGY5flyX

[89]https://static1.squarespace.com/static/60065b8fc8cd610112ab89a7/t/60162177264e0108022d68cc/1612063095367/May%2B2020%2BPolling%2BSlides.pdf

Chairman GOOD. Thank you, Ms. Tripoli, and now we will hear from Mr. Scott.

STATEMENT OF MR. JC SCOTT, PRESIDENT AND CEO, PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

Mr. JC SCOTT. Good morning, Chairman Good, Ranking Member DeSaulnier, and members of the Subcommittee. Thank you for the opportunity to testify. The questions the Subcommittee is raising today on transparency and competition in healthcare markets are important, and we agree that thoughtfully applying these tools to the prescription drug market is aligned with what should be our ultimate objective: securing greater affordability, which translates into greater access to medications and better health outcomes.

Too often, what we are trying to solve gets lost in all the rhetoric and misinformation around this issue, and we lose focus on how to do better for patients, employers, and other payers. I hope today's discussion can stay focused on positive solutions, and the legislative proposals avoid the unintended consequences of increased cost and limited choices for employers and patients.

Efforts to lower drug costs must start with an understanding that drug prices are set by drug companies and that in the prescription drug market, as in many markets, competition is vitally important. Lawmakers must ensure that the misuse of the patent protections originally put in place to balance rewarding innovation and ensuring affordable access for patients is not blocking competition and keeping prices high.

Pharmacy benefit companies both harness that drug company competition, and also compete with each other for employers and health plan sponsors to hire them. Our companies are hired to administer prescription drug plans for more than 275 million Americans who have health coverage through public and private employers, labor unions, retiree plans, and Federal programs.

Our company secures savings through negotiations with drug companies, serving as the only actor in the private market putting downward pressure on drug costs. Pharmacy benefit companies also partner with over 60,000 lower cost, higher quality pharmacies on behalf of employers.

In addition, pharmacy benefit companies promote a variety of clinical programs to improve medication adherence and healthcare outcomes. To be clear, no employer, union, or other plan sponsor is under any obligation to hire or use a pharmacy benefit company, but virtually all choose to do so because it brings them significant savings and enables them to better serve the patients in their plans.

The employers choose how to best use those savings, whether to lower premiums, lower cost at the pharmacy counter, or make benefits more robust. This is a key point. The pharmacy benefit company delivers the savings and the employer decides how to use them. Employers and other plan sponsors select a pharmacy benefit company through a transparent and highly competitive bidding process, with 73 full service pharmacy benefit companies operating today, and new entrants with competing models coming into the market regularly, employers can choose to contract with a company that best meets their unique needs.

In the last 2 years, we have seen close to 9 percent growth in the number of pharmacy benefit companies competing in the market. Employers and plan sponsors may choose a pharmacy benefit company based on scale and ability to negotiate deep discounts. Others prioritize innovative care management programs or different levels of service.

The various pharmacy benefit companies in the market compete fiercely based on the strengths of their individual business models and innovative offerings. As part of their bid requests, employers determine what information, transparency, and audit rights they need, and those are memorialized in their contracts.

Our companies provide a broad array of actionable information on price and quality, so employers can make informed decisions on how to design their benefits and how to deploy the value delivered by their pharmacy benefit company. Our companies offer additional data and information, including tools with real time information on cost and drug coverage, to patients and doctors to help informed prescribing decisions. In recent years, Congress has added more requirements for pharmacy benefit companies to report to Federal agencies, as well as public reporting.

These laws included guardrails to prevent enabling drug companies from raising costs, and we supported that approach. We also supported enacted legislation to provide Congress with access to claims data to inform oversight and policymaking.

As we work on our mission to lower costs, the principles of informed employer choice and flexibility in selecting a pharmacy benefit company, designing the benefit, and choosing how best to use the savings, are key to keeping the private market evolving and delivering more affordable drug coverage.

Given that, and to avoid increasing costs for employers and patients, we would caution against policies that have the government dictating and locking in terms of private business contracts, limiting choices for employers, or otherwise narrowing how we can achieve more affordability for patients.

PCMA and the companies we represent are proud of our record in constraining prescription drug cost growth, improving access to medications, and helping improve health outcomes, and we look forward to working with this Subcommittee, and constructively engaging to build on this record.

Thank you for inviting me to testify today, and I look forward to the conversation.

[The Statement of Mr. JC Scott follows:]

Testimony of

Juan Carlos "JC" Scott
President and Chief Executive Officer

Pharmaceutical Care Management Association
325 7th Street, NW
Suite 900
Washington, DC 20004

Submitted to the

United States House of Representatives
Committee on Education & the Workforce
Subcommittee on Health, Employment, Labor, and Pensions

"Competition and Transparency: The Pathway Forward for a Strong Health Care Market"

June 21, 2023

Introduction

Good morning, Chairman Good, Ranking Member DeSaulnier, and other members of the Subcommittee. My name is JC Scott, and I am the President and Chief Executive Officer of the Pharmaceutical Care Management Association (PCMA). PCMA appreciates the opportunity to testify at today's hearing on competition and transparency in health care. PCMA is the national association representing America's pharmacy benefit companies, which administer prescription drug plans and operate home delivery and specialty pharmacies for more than 275 million Americans with health coverage through public and private employers, labor unions, retiree plans, Medicare, Medicaid, the Federal Employees Health Benefits (FEHB) program, and the exchanges established by the Affordable Care Act (ACA). Our members work closely with health plans and health insurance issuers to secure lower costs for prescription drugs and achieve better health outcomes for patients.

Health plan sponsors, including employers, voluntarily hire PCMA's members primarily to secure savings and provide choice and specialized expertise on pharmacy benefit design, coverage, and delivery. PCMA's diverse membership works closely with health plans and health insurance issuers to secure lower costs for prescription drugs and achieve better health outcomes. These savings allow employers and labor unions to keep offering quality drug benefits to their employees and retirees across America – ensuring that premiums are affordable, and patients have choices and access to pharmacies where they can get the drugs they need at a price they can afford.

Pharmacy benefit companies lower prescription drug costs for patients and a wide range of health plan sponsors – specifically by:

- Negotiating rebates from brand drug companies and discounts from pharmacies to reduce costs for patients, their families, and health plans – saving plan sponsors and patients an average of $1,040 per patient per year across the private sector and government programs.[i]
- Encouraging the use of more affordable alternatives to brand drugs, such as generics and biosimilars.
- Offering services that benefit patients, such as home delivery, which saves patients time and money while increasing access and care coordination.
- Managing and helping patients access high-cost specialty medications.
- Reducing waste, preventing potentially harmful drug interactions, and improving adherence.
- Providing clinical support in the form of services to plan enrollees, internal clinical expertise to support business operations, and assembling clinical experts to evaluate drug therapies and make coverage recommendations to plan sponsors.

Pharmacy benefit companies support a competitive market for prescription drugs. Today I will review the policies PCMA members support to encourage a competitive market for prescription drugs, as competition is the most effective way to drive down high drug prices. I will also discuss ways pharmacy benefit companies work to generate value for the U.S. health care system.

As an industry, pharmacy benefit companies welcome any opportunity to discuss and advance ways to improve the prescription drug marketplace so Americans can better afford their prescription drugs, and we believe any attempt at understanding the factors driving drug costs must include an examination of the entire supply chain, including drug companies, large pharmacy collectives known as Pharmacy Services Administrative Organizations (PSAOs), wholesale

distributors, employer benefit consultants, pharmacies, and all others with impact on the cost of prescription drugs. For instance, there is irrefutable evidence of certain drug companies repeatedly abusing the patent system to keep more affordable alternatives from entering the marketplace, which allows those companies to increase prescription drug prices for far longer than Congress contemplated when it established patent and exclusivity periods. We encourage the committee to review all these entities and potential anticompetitive practices as it assesses how to improve the prescription drug market.

Pharmacy Benefit Companies Support Policies to Encourage Competition as the Best Way to Lower Prescription Drug Costs

Pharmacy benefit companies encourage use of the most affordable drugs for patients by providing prescribers with information about less expensive generic alternatives, setting performance standards for pharmacies to encourage generic fills and adherence, and ensuring patients are aware of lower-cost alternatives. Due in large part to these efforts by PBMs, 90 percent of prescriptions are filled with generics.[ii] Pharmacy benefit companies also support increased uptake of biosimilars by preferring both the brand and a biosimilar to ensure patients and providers have the incentive to choose lower-cost options and the choice to continue with a drug from which they may be reluctant to switch.

Pharmacy benefit companies offer programs to keep out-of-pocket costs low and work with those providing insurance to encourage patients, through formulary design and cost-sharing incentives, to use the most affordable drugs, which are usually generics. Generic dispensing has grown over the past decade as more generics have entered the market and patients have responded to health plan designs encouraging their use.[iii] PBMs also employ other tools designed to deliver high-quality drug benefits while bringing down costs.[iv] For many brand drugs, PBMs negotiate directly with drug manufacturers, who compete for formulary placement by offering a type of discount called rebates.[v] For drugs on a preferred tier of a plan's formulary (list of covered drugs), patients typically have lower cost sharing.[vi] As competing products enter the market, PBMs gain the flexibility to leverage competitor products to negotiate deeper drug discounts for patients and employers.[vii]

To enhance competition and enable pharmacy benefit companies to further drive down drug costs, PCMA encourages policymakers to do the following:

1. **Stop patent abuse.** Addressing drug companies' abuses of the patent system that allow them to block competition by extending monopoly pricing well beyond their products' original patent expirations would increase access to lower-cost generics and go a long way toward reducing drug costs for patients and families.
2. **Reserve market exclusivities for true innovation.** Addressing overlong exclusivity periods for biologics and orphan indications will create more competition and lead to lower overall drug costs for patients.
3. **Ensure drugs can compete fairly.** Preventing practices like "shadow pricing" and abuses of the U.S. Food and Drug Administration's citizen petition process will improve the competitive market.
4. **Promote generic and biosimilar competition.** The most effective way to reduce prescription drug costs is to increase competition in the marketplace.

Pharmacy Benefit Companies Reduce Costs for Employers

Employers need choice and flexibility when designing prescription drug benefits that meet the health and affordability needs of unique employee populations. Employers vary dramatically in size, resources, and function, serving diverse populations. No plan sponsor, public or private employer, union, retiree health plan, pension fund, or other health plan is required to hire or use a pharmacy benefit company, but virtually all do. Each of those plan sponsors knows more about their financial resources and plan participants than any other entity, and they need the ability to design plans tailored to the unique needs of their participants. As health plan sponsors strive to create accessible, affordable benefits that meet the needs of the populations they cover, policymakers should avoid mandates that could increase costs and decrease quality.

PBMs have an established record of negotiating price concessions from drug manufacturers (through formularies and other tools) and pharmacies (via networks) to reduce drug costs. Pharmacy benefit companies will save employers and patients a collective $124 billion over the next ten years.[viii] Health plan sponsors choose PBMs through a transparent and highly competitive bidding process. With 73 full-service PBMs in the market, including regular new entrants, health plan sponsors have diverse options, allowing them to select the PBM that best meets their unique needs.[ix]

Recent findings from the PricewaterhouseCoopers (PwC) 2021 "Health and Well-being Touchstone Survey" of 368 companies explains why employers, including small and mid-sized businesses, voluntarily hire pharmacy benefit companies to help them provide affordable, quality prescription drug coverage for their health plan enrollees.[x] PBMs offer their expertise in pharmacy benefits by recommending formulary design options, and employers decide how their plan will function. The survey states, "To help manage overall drug cost trends, over 80% of employers told us that they continue to look to their pharmacy benefits manager (PBM) for solutions, supported by traditional management strategies," demonstrating the value employers derive from the advice of their PBM. However, highlighting the importance of employer choice, another survey of employers from the Pharmaceutical Strategies Group shows just 15 percent of survey respondents said their PBM had the most influence on their drug benefit design.[xi]

For health plan sponsors, it is important to maintain a competitive market that provides choice among PBMs and the ability to decide how to set up drug benefits to best serve their unique populations. Some may choose a PBM based on its scale and its ability to negotiate deep discounts or manage the risk of price changes. Others choose to hire PBMs based on their innovative care management programs or different levels of service. For small employers, many of whom may struggle to provide health insurance to employees, PBMs both lower drug costs and provide cost predictability, enabling them to stretch their benefit dollars even further.

Plan sponsors should have the option of determining how they would like to pay the pharmacy benefit company they select for their services. Employers can choose "pass-through" contracting, in which the plan sponsor pays whatever the pharmacy charges, or "spread pricing." Today, 34% of employers choose "spread pricing," [xii] which is a risk-based contracting model in which employers choose to let the pharmacy benefit company hold the risk that plan participants may use more expensive pharmacies to fill their prescriptions. In exchange, the pharmacy benefit company keeps the savings when a patient uses a less expensive pharmacy, and takes a loss when they use costlier pharmacies. While larger employers may select pass-through contracts, as they have the scale to deal with the variability of pharmacy charges, smaller employers may choose spread contracts because of the pricing predictability and savings they derive.

As a result, PBMs have a pro-competitive influence on the prescription drug marketplace, and PBM services provide a significant and measurable benefit for businesses and others providing health insurance.[xiii] Without PBMs in the marketplace, those organizations would be left to negotiate drug costs on their own or pay the full costs of these drugs.[xiv] One economist estimates that without PBMs, employers and other plan sponsors would pay 40 percent more to undertake themselves the services currently provided by pharmacy benefit companies.[xv]

The PBM Market is Diverse and Competitive

Savings from pharmacy benefit companies benefit health plans, employers, retirees, and patients directly. Pharmacy benefit companies save health plans and their enrollees an average of $1,040 per person per year.[xvi] The PBM market is dynamic, diverse, and growing. In 2019, there were 66 full-service pharmacy benefit companies active in the market.[xvii] As of March 2023, there are 73 full-service pharmacy benefit companies in the U.S., with six new PBMs entering the market since 2021.[xviii] In addition to these full-service companies, there are many companies that provide narrower PBM services to customers, with some catering to specific sectors, such as workers' compensation.

Prior to the shift in focus of the Federal Trade Commission (FTC), which has recently moved away from consumer protection, the commission evaluated the PBM industry numerous times and found it to be appropriately competitive. In 2005, the commission issued a report showing that PBM ownership of pharmacies does not result in higher costs for consumers. The chair at the time noted, "Health insurers manage their drug costs by choosing among a variety of PBM services and service providers," and "Data in the report demonstrate that PBMs' use of owned mail-order pharmacies generally is cost-effective for plan sponsors."[xix]

Additionally, in 2012, the FTC completed an investigation evaluating the potential impact of a proposed merger between two PBMs, Express Scripts and Medco. As a result, the commission observed that the "market for the provision of full-service PBM services to health care benefit plan sponsors is moderately concentrated and consists of at least ten significant competitors," and further found that "competition for accounts is intense."[xx] Over the 11 years since that investigation, the market for full-service PBMs has grown, with 73 full-service pharmacy benefit companies of varying sizes operating across the nation in a variety of markets in 2023.

Preserving the competitiveness of the PBM market is as important as ensuring competitiveness in all other aspects of the prescription drug supply and payment chain.

Pharmacy Benefit Companies Support a Robust and Competitive Market for Pharmacies

The structure of a health plan's provider and participating pharmacy network is among the most important elements of health benefit design. Working with their PBMs, plans exercise careful judgment to construct pharmacy networks that meet beneficiary needs, balancing breadth of coverage, access, quality, and cost-efficiency, often on a multi-jurisdictional basis.

There are many types of pharmacies – retail, specialty, hospital, clinic, home care, mail-order, compounding, and assisted living or long-term care. These pharmacies offer different levels of expertise and services to ensure patients are getting what they need to secure the best health outcomes. In fact, there are more than 60,000 retail pharmacies in the United States, including 23,000 independent community pharmacies. Health plans with a variety of sites of care in their pharmacy networks promote access, affordability, and value. For example, the right mix of brick-

and-mortar retail, mail, and specialty pharmacies improves adherence to therapy and patient safety.

Pharmacists are skilled health care practitioners who are often more convenient to access than doctors in a hospital, private practice, or other clinical setting. To better contain drug costs and improve access to quality patient care, pharmacy benefit companies support laws and regulations that allow pharmacists to "practice at the top of their license," based on their specific expertise. Pharmacy benefit companies continue to call on policymakers to enact legislation enabling pharmacists, where appropriate, to perform diagnostic testing, prescribe indicated medication, and administer vaccines to expand access to care.

Pharmacies large and small are important partners in delivering care to patients, and where a patient acquires a drug can impact its cost significantly. Pharmacy benefit companies negotiate with pharmacies to establish networks that support consumer choice while offering high quality care at competitive prices. Most pharmacy networks provide patients with a variety of options allowing them to get the drugs they need where they need them. Policies that restrict pharmacy benefit companies' ability to develop such networks drive costs up, while well-managed networks offer savings to both plan sponsors and enrollees. For instance, some states have passed laws constraining pharmacy networks, to the detriment of employers and union plan sponsors. Such regulation sometimes even seeks to intrude into ERISA despite federal pre-emption, which should prohibit states from acting on exclusive areas of federal regulation. These pharmacy network restrictions could lead to a patchwork of inconsistent state laws, creating administrative burdens for plan sponsors offering benefits across state lines and boosting costs for employers, which can result in higher patient cost-sharing and premiums.

Understanding the Role of Wholesalers and PSAOs is Critical

As the committee considers the factors impacting the competitiveness of the drug supply chain, it is important to understand the role of PSAOs. PSAOs negotiate pharmacy network contracts with PBMs and perform fundamental back-office operations for the pharmacies they contract with, and the relationships between large wholesaler-owned PSAOs and independent pharmacies are complex and worthy of scrutiny.

The largest PSAOs are subsidiaries of the three largest wholesalers, which also typically operate the equivalent of networks of pharmacy franchises, providing branding, organizational support, and back-office support. The significant role large wholesalers play in the prescription drug supply chain and the often-symbiotic relationship wholesalers have with independent pharmacies is just beginning to be explored. Shining a light on this relationship is exposing potential areas of concern, underscoring the need for Congress to examine all players in the supply chain that have a direct impact on the price of prescription drugs. For example, the PSAO marketplace is dominated by the "Big Three" wholesalers, AmerisourceBergen, Cardinal Health, and McKesson. Unlike pharmacy benefit companies, PSAOs operate with no state or federal regulation or oversight, and according to PBM reporting data, negotiate higher rates than PBMs typically pay non-independent retail and chain pharmacies. Approximately 83 percent of independent pharmacies use PSAOs to negotiate favorable contracts with pharmacy benefit companies.[xxi]

While some claim otherwise, the independent pharmacy market is stable and profitable. Data shows that over the last ten years, the number of independent retail pharmacies nationwide increased by 1,638 stores or 7.5 percent.[xxii] Over the last five years, the number of independent pharmacies has increased 0.5 percent, indicating a stable marketplace. In fact, independent

pharmacies' financials have also been stable. From 2016 to 2020, the average per prescription gross profit margin for independent pharmacies ranged from 20.8 percent to 21.1 percent, showing little fluctuation.[xxiii]

Data from the lobby group for independent pharmacy, the National Community Pharmacists Association (NCPA), agrees that the independent pharmacy market is stable, growing 0.4 percent over the last year,[xxiv] and it is the only sector of retail pharmacy that has experienced growth over the last 10 years. The same report finds that between 2020 and 2021, the average independent pharmacy location dispensed ten percent more prescriptions, gross profit margins increased to 23.3 percent, and average sales per location were up more than $570,000 – in excess of $4 million. As noted, by leveraging the power of large pharmacy collectives to negotiate with pharmacy benefit companies on their behalf, independent pharmacies can secure favorable contract terms, and on average, higher reimbursements than chain drugstores.[xxv] PSAOs and PBMs also provide pharmacies with software, such as Pharmacy Quality Solutions' Electronic Quality Improvement Platform for Plans and Pharmacies (EQuIPP), which allows pharmacies to access their contracted pharmacy measures, track their own performance against those measures, and compare benchmark measures of their contracts across plans and against other pharmacies.

PBMs Support Meaningful, Actionable Transparency to Enhance Market Competition

Pharmacy benefit companies provide health plans, employer plan sponsors, and consumers with a broad array of accurate, actionable information on price and quality to make efficient purchasing decisions. As part of their requests for proposals when putting their pharmacy benefits out to bid, PBMs' customers lay out the terms of the transparency and information they want to receive, as well as their audit rights, and those terms are formalized in their contracts.

Transparency that helps patients and payers is necessary across the entire prescription drug chain. Pharmacy benefit companies support and practice actionable transparency that empowers patients, their physicians, those sponsoring health coverage, and policymakers, so that each of these actors can make informed decisions that can lead to lower prescription drug costs. Actionable transparency encourages consumers to shop for coverage that best fits their health needs and budgets, and once covered, use the most cost-effective, highest-value health care goods and services. It enables prescribers and patients to avoid pharmacy-counter surprises and helps ensure that physicians can prescribe drugs that are affordable for patients.

To that end, pharmacy benefit companies provide patients and prescribers with real-time benefits tools, RTBTs, which provide real-time information on exactly where the patient is with respect to progressing through a deductible or another benefit phase, what drugs are on the patient's formulary, and exactly what cost sharing a patient should expect for a given drug at the pharmacy. PBMs also provide patients with information on in-network pharmacies, premiums, general cost-sharing, and benefits for their prescription drug coverage.

Pharmacy benefit companies also provide employers and plan sponsors with a broad array of accurate, actionable information on price and quality to make efficient purchasing decisions. Beyond this extensive information sharing, PBMs' customers have the ability to set their own terms for the transparency and information they want to receive, as well as their audit rights, as part of their contracts.

In recent years, Congress has added more requirements for PBMs to report to federal agencies, as well as public reporting in more aggregated form. In both cases, these laws included appropriate protections for confidential data to avoid encouraging tacit collusion, and PCMA supported that approach. We have also supported legislation that is now law, which provides congressional support agencies, including the Congressional Budget Office (CBO), Government Accountability Office (GAO), Medicare Payment Advisory Commission (MedPAC), and Medicaid and CHIP Payment and Access Commission (MACPAC), with access to Medicare and Medicaid claims-level data to ensure that Congress is able to perform appropriate oversight.

PBMs support and practice transparency that empowers patients, their physicians and pharmacists, those sponsoring health coverage, and policymakers to make informed decisions that can lead to lower prescription drug costs. That is why the PBM industry supported legislation enacted in 2018 to empower pharmacists to share information with patients about lower out-of-pocket cost alternatives. As the committee considers how best to preserve the competitiveness of the PBM market, we encourage consideration of the administrative burdens extensive, unharmonized, duplicative reporting requirements create for smaller PBMs. While larger PBMs may be able to adapt, smaller PBMs may find these new regulations overly burdensome or wholly unworkable, forcing them to either close their doors or consolidate; effectively reducing the competitive market for PBMs. It is also important to note that these added reporting burdens on top of the existing requirements could lead to higher costs for people taking prescription drugs.

Exposing Proprietary Pricing Information Can Raise Drug Prices

More recently, in February of this year, the U.S. Department of Justice Antitrust Division withdrew three outdated antitrust policy statements related to enforcement in health care markets. As Principal Deputy Assistant Attorney General Doha Mekki remarked:

> *Courts have long recognized that the exchange of competitively sensitive information can subvert the competitive process and harm competition. …The Second Circuit explained in Todd that "[p]rice exchanges that identify particular parties, transactions, and prices are seen as potentially anticompetitive because they may be used to police a secret or tacit conspiracy to stabilize prices." …Where competitors adopt the same pricing algorithms, our concern is only heightened. Several studies have shown that these algorithms can lead to tacit or express collusion in the marketplace, potentially resulting in higher prices, or at a minimum, a softening of competition."*[xxvi]

Tacit collusion, sometimes called conscious parallelism, happens when competing firms set their prices at a profit-maximizing level after recognizing their shared economic interests and interdependence related to pricing. It is done without an implicit or explicit agreement between the competing firms. It typically results in higher prices for consumers.

There are numerous examples of tacit price collusion across multiple markets, including "airline tickets, gasoline, cellular phone text messaging and roaming rates, interest rates on bank accounts, credit card interchange fees, movie tickets, recorded music, breakfast cereals, real estate and travel agent commissions, electricity prices in deregulated markets, and air cargo fuel surcharges."[xxvii]

Given that, it is important to carefully protect data that helps to maintain a competitive market and ensure it is never released publicly. As Mekki warns, such information sharing would likely

damage the private market: "A softening of competition through tacit coordination, facilitated by information sharing, distorts free market competition in the process."

In an environment where the DOJ feels compelled to pull back 30-year-old guidance because of increasing concerns about the anti-competitive impact of information sharing in the health care industry (including via tacit collusion), it seems imprudent to mandate increased information disclosures that could create the kinds of anti-competitive harms that the DOJ has identified, including tacit collusion amongst the drug companies.

In 2004, the Federal Trade Commission (FTC) spoke out against over-exposing information about private business dealings because such an approach is deeply damaging to a competitive marketplace, stating, "If pharmaceutical manufacturers learn the exact amount of the rebates offered by their competitors (either because the safeguards on subsequent disclosure by purchasers and prospective purchasers are insufficient or because the mandated disclosure to prescribers provides sufficient information for pharmaceutical manufacturers to calculate these amounts) then tacit collusion among manufacturers is more feasible. Consequently, the required disclosures may lead to higher prices for PBM services and Pharmaceuticals."[xxviii] Likewise, in 2009 the FTC noted that there are limits to the benefits of transparency and unintended consequences can result.[xxix] And again in 2014, the commission noted it had conducted numerous reviews on state laws mandating transparency to evaluate their likely effect on competition. At that time, staff noted two main concerns, "(1) mandatory disclosure requirements may hinder the ability of plans to negotiate an efficient level of disclosure with PBMs; and (2) if such disclosures publicly reveal previously proprietary and private information about discounts negotiated with PBMs, disclosure may result in less aggressive pricing by, or even collusion among, pharmaceutical manufacturers."[xxx]

Additionally, the CBO has framed the transparency and disclosure considerations clearly in this often-quoted statement:

> *The disclosure of drug rebates could affect Medicare spending through two principal mechanisms. First, disclosure would probably make rebates less varied among purchasers, with large rebates and small rebates tending to converge toward some average rebate. Such compression, for reasons discussed below, would tend to reduce the rebates that PDPs received and thus would raise Medicare costs. Second, for a range of medical conditions, drugs appropriate for treatment are available from only a few manufacturers; disclosure of drug-by drug rebate data in those cases would facilitate tacit collusion among those manufacturers, which would tend to raise drug prices.*[xxxi]

PCMA encourages the Committee, as it reviews how to improve the prescription drug market to help lower costs for patients, taxpayers, and businesses, to focus its efforts on actionable transparency and information disclosure that reduces drug costs, rather than the over-exposure of the type of proprietary information that raises drug costs.

Conclusion

Pharmacy benefit companies exist to reduce drug costs for plan sponsors and, most importantly, for the patients our companies serve. In doing this work, pharmacy benefit companies generate tremendous value for society, estimated at $145 billion annually,[xxxii] and save plan sponsors and patients an average of $1,040 per person per year.[xxxiii] Much of this value is generated by the savings pharmacy benefit companies negotiate with pharmaceutical manufacturers and

pharmacies. Pharmacy benefit companies also lower prescription drug costs by promoting the use of generic medications, encouraging better pharmacy quality, and offering things like home delivery of medications. Through their work, pharmacy benefit companies lower the cost of health coverage, reduce drug costs, and support better and more affordable prescription drug access for patients, which means more people can get on and stay on the medications they need. For many years, evidence has shown a return of 10:1 on investments in pharmacy benefit company services for their private sector and government partners.[xxxiv] As a result, pharmacy benefit companies will lower the cost of health care by $1 trillion over the next ten years.[xxxv]

On behalf of the industry, thank you for inviting me to testify. As I have indicated, PCMA welcomes the opportunity to further engage with the committee and looks forward to working collaboratively with Congress and other stakeholders to build on the existing private market framework to address prescription drug affordability challenges and improve functionality for patients.

---

[i] Visante. 2023. https://www.pcmanet.org/wp-content/uploads/2023/01/The-Return-on-Investment-ROI-on-PBM-Services-January-2023.pdf.
[ii] AAM. 2021. https://accessiblemeds.org/sites/default/files/2021-10/AAM-2021-US-Generic-Biosimilar-Medicines-Savings-Report-web.pdf.
[iii] FDA. 2021. https://www.fda.gov/drugs/buying-using-medicine-safely/generic-drugs.
[iv] Pharmacy Benefit Management Institute (PBMI). 2020. https://www.pcmanet.org/wp-content/uploads/2021/01/Solving-America%E2%80%99s-High-Drug-Cost-Problem_whitepaper_FINAL2.pdf. PBMI. 2017. www.pbmi.com/research. PBMI. 2016. www.pbmi.com/research.
[v] Foley Hoag. 2019. https://foleyhoag.com/publications/ebooks-and-white-papers/2019/march/the-history-of-rebates-in-the-drug-supply-chain.
[vi] CBO. 2020. https://www.cbo.gov/system/files/2022-01/57050-Rx-Spending.pdf.
[vii] Ibid.
[viii] PCMA. 2023. https://www.pcmanet.org/wp-content/uploads/2023/05/Pharmacy-Benefit-Companies-Save-Employer-and-Labor-Unions-Plans-Patients-124-Billion.pdf
[ix] PCMA. 2021. Available at https://www.pcmanet.org/wp-content/uploads/2021/04/PBM-Landscape-2021.pdf.
[x] PricewaterhouseCoopers. 2021 Health and Well-being Touchstone Survey.
[xi] PSG. 2022. Customer Satisfaction Report. https://www.psgconsults.com/research.
[xii] PSG. Trends in Drug Benefit Design Report 2023.
[xiii] Lawton Robert Burns. What history tells us about your prescription costs and the new 'bad boys' of health care. 2023. https://thehill.com/opinion/healthcare/3869127-what-history-tells-us-about-your-prescription-costs-and-the-new-bad-boys-of-health-care/
[xiv] Casey Mulligan. 2022. https://www.nber.org/papers/w30231.
[xv] Ibid.
[xvi]Visante. 2023. https://www.pcmanet.org/wp-content/uploads/2023/01/The-Return-on-Investment-ROI-on-PBM-Services-January-2023.pdf. https://www.pcmanet.org/wp-content/uploads/2023/01/The-Return-on-Investment-ROI-on-PBM-Services-January-2023.pdf.
[xvii] PCMA. The PBM Marketplace is Highly Competitive. March 2019. https://www.pcmanet.org/wp-content/uploads/2019/04/Competitive-PBM-Marketplace.pdf
[xviii] PCMA. 2023. https://www.pcmanet.org/the-pbm-marketplace-is-more-competitive-not-less/.
[xix] FTC. 2005. https://www.ftc.gov/news-events/news/press-releases/2005/09/ftc-issues-report-pbm-ownership-mail-order-pharmacies.
[xx] FTC. 2014. https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-erisa-advisory-council-u.s.department-labor-regarding-pharmacy-benefit-manager-compensation-fee-disclosure/140819erisaadvisory.pdf.
[xxi] Health Evaluations. 2021. https://www.pcmanet.org/wp-content/uploads/2021/01/PSAO-Report_Health-Evaluations.pdf.
[xxii] PCMA. 2023. https://www.pcmanet.org/the-independent-pharmacy-marketplace-is-stable-2023/.
[xxiii] Drug Channels. 2022. https://www.drugchannels.net/2022/02/five-things-to-know-about-state-of.html.
[xxiv] NCPA. 2022. https://ncpa.org/newsroom/news-releases/2022/10/02/ncpa-releases-2022-digest-report.
[xxv] Health Evaluations. 2021. https://www.pcmanet.org/wp-content/uploads/2021/01/PSAO-Report_Health-Evaluations.pdf. See also: Milliman. 2020. https://cdn.ymaws.com/www.floridapharmacy.org/resource/resmgr/docs_2021_legislative_session/milliman_report.pdf; Ohio Medicaid. 2018. https://www.gongwer-oh.com/public/130/pbmredacted.pdf.; Ohio Department of Medicaid. 2019. https://medicaid.ohio.gov/wps/wcm/connect/gov/2ef5a8b4-0f15-4ef4-8883-11fd6238e101/ODM-HDS-Summary.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=ROOTWORKSPACE.Z18_K9I401S01H7F40QBNJU3SO1F56-2ef5a8b4-0f15-4ef4-8883-11fd6238e101-nAkMJJ4.
[xxvi] DOJ. 2023. https://www.justice.gov/opa/speech/principal-deputy-assistant-attorney-general-doha-mekki-antitrust-division-delivers-0.
[xxvii] University of San Francisco. 2010. https://digital.sandiego.edu/cgi/viewcontent.cgi?article=2677&context=sdlr.
[xxviii] FTC. 2004. https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-comment-hon.greg-aghazarian-concerning-ca.b.1960-requiring-pharmacy-benefit-managers-make-disclosures-purchasers-and-prospective-purchasers/v040027.pdf.
[xxix] See FTC Staff Comment to the Honorable James L. Seward Concerning New York Senate Bill 58 on Pharmacy Benefit Managers (PBMs), FED. TRADE COMM'N. March 2009. Available at

https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf
[xxx] FTC. 2004. https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-comment-hon.greg-aghazarian-concerning-ca.b.1960-requiring-pharmacy-benefit-managers-make-disclosures-purchasers-and-prospective-purchasers/v040027.pdf.
[xxxi] CBO. March 12, 2007.
[xxxii] Casey Mulligan. 2022. https://www.nber.org/papers/w30231.
[xxxiii] Visante. 2023. https://www.pcmanet.org/wp-content/uploads/2023/01/Pharmacy-Benefit-Managers-PBMs-Generating-Savings-for-Plan-Sponsors-and-Consumers-January-2023.pdf.
[xxxiv] Visante. 2023. https://www.pcmanet.org/wp-content/uploads/2023/01/The-Return-on-Investment-ROI-on-PBM-Services-January-2023.pdf.
[xxxv] Visante. 2023. https://www.pcmanet.org/wp-content/uploads/2023/01/The-Return-on-Investment-ROI-on-PBM-Services-January-2023.pdf.

Chairman GOOD. Thank you, Mr. Scott. Finally, we will hear from Mr. Baker.

STATEMENT OF MR. GREG BAKER, CEO, AFFIRMEDRX

Mr. BAKER. Good morning, Chairman Good, Ranking Member DeSaulnier, and distinguished members of the House Subcommittee. I would like to thank you for the invitation to speak here today and discuss this increasingly important topic of competition and transparency in healthcare.

My name is Greg Baker. I am first and foremost a pharmacist. I am also the CEO of AffirmedRX, which is a transparent PBM I founded, and we are headquartered in Louisville, Kentucky. I have spent 30 years working in different areas of healthcare, mostly pharmacy. The last 11 of which, working directly with jumbo self-funded employers who do design and develop their own pharmacy benefit programs.

Our goal at AffirmedRX is to partner with these employers to deliver patient-centric pharmacy benefits with a mission to improve healthcare outcomes by bringing clarity, integrity, and trust to pharmacy benefit managing. As a pharmacy benefit management company though, and consistent with our corporate values, we are not members of PCMA.

PCMA does not represent who we are as an organization. We have founded a new not-for-profit organization with numerous other PBMs, who also do not want to be represented by PCMA, called Transparency RX. Just as transparency offers a better way on managing prescription drug benefits, Transparency RX represents a step forward to sound policy solutions, galvanizing true affordable prices as a counterweight to the status quo and the stale and outdated ideas of traditional PBMs and their lobby.

At a high level then, this may come as a surprise to some at the outset. I would like to embrace many of the much needed reforms gaining steam in Congress on a bipartisan basis. PBMs, especially traditional ones, and especially the big three, deserve scrutiny and reform.

More importantly in my opinion, their approach is a central feature to sustaining unnecessarily high drugs costs in America. We have a broken system which hides profits and inflates prescription costs, harming the interest of diverse communities, working families, and seniors.

With my expertise being in the pharmacy benefit space, I will focus my comments on competition and transparency within this industry here today. I have thoroughly read the testimoneys of my fellow witnesses. I find it interesting that many of us call out the increase in cost and the decrease in quality of healthcare.

While some of the fellow witnesses here also talk about the savings that PBMs always generate. We save 145 billion dollars as an industry, supposedly, over the course of the next 10 years. I always think about that in the context of my wife going shopping. I love my wife to death, she always goes shopping and comes home and tells me how much money she saved me, which I know really means she cost me a lot of money in the first place. I am sure she really enjoyed that thing she bought, but when you leave with savings I worry.

I always worry about organizations that want to talk about how much you save. Additionally, there is a lot of conversation around these savings saying we promote generic drugs as an industry. That also is a falsehood. You can look at any traditional PBM formulary that is publicly available online, and consistently see where brand drugs are put in place on the formulary over generic drugs.

When you consider the fact that of the 160 plus Americans who take private insurance, 55 percent of those people have a coinsurance or a high deductible plan. That means they are subject to a higher cost at the pharmacy counter. That is not acceptable in our opinion.

Biosimilars is a very consistent theme within the pharmacy benefit industry today as well. We consistently see a lot of the traditional PBMs picking higher cost biosimilars, over the lower cost versions as well. Last, it has been noted that there is a transparent and highly competitive marketplace out there for these jumbo and self-funded employers to pick their benefits.

I challenge that contention as well. There is an awesome article that Bob Herman and Staten News put out just yesterday talking about the collusion that could exist between benefit consultants who are helping these benefit employers and their PBMs based off of back-end payments that are not transparent.

In closing, I would like to go back to my Kentucky roots. I started practicing in Kentucky in the late 90's. That is when Oxycontin came out. It was a great drug, we thought at the time, because we had been told that for years.

Twenty years down the road, we all know how bad Oxycontin was for our society. At the same time, opioids kill about 80,000 people in America today. Over 100,000 people in America die every year because they are not adherent to their medicines. The No. 1 reason people are not adhering to their medication is because of cost.

I look forward to having further conversation working with the Committee to bring more transparency and competition to this PBM marketplace and look forward to your questions today. Thank you, Chairman.

[The Statement of Mr. Baker follows:]

AffirmedRx
PUBLIC BENEFIT CORPORATION

affirmedRx.com

House Committee on Education and The Workforce
"Competition and Transparency: The Pathway Forward For A Stronger Health Care Market"
June 21, 2023

Written Testimony of Greg Baker, BS Pharm
CEO of AffirmedRx

Chairman Good, Ranking Member DeSaulnier, and distinguished members of the House Subcommittee, I would like to thank you for the invitation to speak with you on the necessity of increasing competition and transparency in health care.

My name is Greg Baker. I, first and foremost, am a pharmacist. I am also the CEO of AffirmedRx which is a transparent PBM I founded, headquartered in Louisville, KY. I have spent the past 30 years working in different areas of pharmacy with the past 11 years dedicated to collaborating directly with jumbo self-funded employers to help define and develop their pharmacy programs. Our goal at AffirmedRx is to partner with employers to deliver patient-centric pharmacy benefits with a mission to improve health care outcomes by bringing clarity, integrity and trust to pharmacy benefit management.

With my expertise in pharmacy benefits, I will focus my comments on competition and transparency within this industry. While there are around 70 PBMs currently doing business in the United States, only three large PBMs control up to 80% of the market in the USA. These PBMs are not constrained by any obligation to be transparent on their pricing and what they pay their own pharmacy versus what they pay other community pharmacies. They are not transparent in what their corporately owned and newly conceived group purchasing organizations (GPOs) receive in total manufacturer revenue versus what they pay back out to employers to help drive down the total cost of care.

hello@affirmedRx.com | 10200 Forest Green Blvd., Suite 112, Louisville, Kentucky, 40223

They do not share global claims data or per claim level rebate amounts. They are not transparent on why they prefer branded medications over lower-cost generic medications which, for the 55% of self-funded patients with high deductible or co-insurance plans, increases their out-of-pocket costs at the pharmacy counter.

Additionally, over the past 5 years, through mergers and acquisitions, these PBMs have become part of large, vertically integrated systems. We have been told for years how this vertical integration will improve outcomes and lower the cost of health care. It is our view that instead of helping they have used their significant market position and profit-focused business practices to secure outsized margins for the services they provide. This has led to higher costs, lower medication adherence, lower condition control and has increased morbidity and mortality of U.S. citizens.

Let us consider these facts on the state of the pharmaceutical industry today:

- Medications can be a key component to reduce health risk, control chronic disease and treat illnesses. In the U.S., illness and death from non-optimized medication therapy cost $528.4 billion annually – equivalent to 16% of total U.S. healthcare expenditures.
- Patients starting new prescriptions as prescribed by their physicians abandoned 94 million prescriptions at pharmacies in 2022 with increasing frequency as costs rise.
- A JAMA article published in June 2021 suggest that while drug manufacturers may increase list prices in order to offer larger rebates to insurers, such increases were associated with increased out-of-pocket costs to patients:
    - This study found that between 2014-2018 list prices from manufacturers grew 13.3% while rebates paid to PBMs increased 24.4%.
    - With the manufacturers raising list prices they also found that every $1 increase in list price equated to an increase of $2.09 in patient out-of-pocket costs. While we have had much debate over the list

hello@affirmedRx.com | 10200 Forest Green Blvd., Suite 112, Louisville, Kentucky, 40223

price increases by pharmaceutical manufacturers, these numbers clearly show how PBMs are retaining the most value and the American public continues to suffer greater drug affordability issues.

- Finally, the report sadly pointed out that every $10 increase in patient out-of-pocket costs led to lower adherence rates. This is particularly concerning amongst individuals with lower incomes and older adults as increasing prescription cost sharing can be associated with increased emergency department use, more frequent hospitalizations and other poor health outcomes.

These numbers illustrate at a high level how current market behaviors are having negative impacts on the system. PBMs operate in the middle of the entire distribution chain for prescription drugs and control all the rules. For example, they decide what pharmacies are allowed to fill medications for their members. Many times, for specialty and chronic medications, PBMs are mandating prescriptions be filled by pharmacies they own. In these situations, they get to decide what they pay themselves and, as we pointed out in our House Oversight and Accountability written testimony from May 23, 2023, that number can drive significant corporate profits while increasing costs for plan sponsors and their members.

Beyond this, they decide what medication a physician can and cannot prescribe and are increasingly excluding more and more medications from their formularies as called out by a January 10, 2023 article in Drug Channels. This article appropriately calls out the fact these exclusionary formularies are used "as a powerful tool for PBMs to gain additional negotiating leverage against manufacturers."

Additionally, there has been discussion about rebates and the relationship between the pharmaceutical manufacturers and PBMs. I am not here to defend or hold manufacturers harmless when we are talking about why we have a drug affordability issue in our country. They are by no means innocent, but the PBMs

hello@affirmedRx.com | 10200 Forest Green Blvd., Suite 112, Louisville, Kentucky, 40223

bear a significantly larger responsibility for the problem than they do. There are hundreds of brand manufacturers and only three main rebate aggregators. These three aggregators are each owned by one of the "big three" PBMs. They not only negotiate rebates for those traditional PBMs, but they now provide these rebate services to almost every other PBM in the industry. These aggregators are Ascent - created in Switzerland by Express Scripts in 2019 and now owned by Cigna, Zinc - created by CVS in 2020 and Emisar - started in Ireland in 2022 and owned by United Health Care. Ascent and Zinc each contract for over one hundred (100) million American lives and Emisar contracts for sixty five (65) million. They use their scale to create competition between manufacturers.

If a manufacturer does not negotiate a high enough rebate and ends up on the ever-expanding list of medications found on the exclusionary drug list, they will lose access to be able to sell their medications to tens of millions of lives. For this reason, they are forced to pay higher and higher amounts in total revenue to these GPOs in order to maintain their formulary placement. The difference between list price increases as defined by manufacturers and the manufacturers' net revenues after paying all rebates and discounts has been coined the gross-to-net bubble by Drug Channels. In their April 4, 2023 article, they point out this difference has grown from $167 billion in 2016 to $223 billion in 2022. While I do agree that manufacturers are increasing their prices, this is only half of the story. We can publicly see list price increases from the manufacturer. It is time for PBMs and their GPOs to list how much total revenue they obtain from pharma to show what the total net prices should be to plan sponsors and patients, but the PBMs continue to fight against this level of transparency.

Two specific examples point to how PBMs influence manufacturer pricing decisions. These examples also show how the upcoming flood of new biosimilars may not have a significant impact in reducing pharmacy costs as plan sponsors have been hoping for. Semglee is the biosimilar to the blockbuster diabetes medication Lantus. When the FDA originally approved Semglee in July 2021, the manufacturer Viatris indicated it would price a vial at about $98 – much below

hello@affirmedRx.com | 10200 Forest Green Blvd., Suite 112, Louisville, Kentucky, 40223

the price of $285 a vial for Lantus at the time. By November 2021, Viatris changed their strategy by offering two versions - a branded version of Semglee priced at $270 per vial (with a rebate) and an unbranded version at $98 with no rebate. Amgen watched this play out and when they became the first biosimilar to hit the market for Humira earlier this year they followed the same pricing strategy to have one with a 5% discount to Humira with a higher rebate and another version at a 55% discount with a much lower rebate. If you look at most PBM formularies, they have picked up the higher priced, higher rebate version on their formulary. This negatively impacts plan sponsors – who are not getting claim-level data to ensure they are getting the lowest cost option – and patients who are having to pay a higher amount for a more costly medication.

Finally, it will be important in future policy to call out how the term "rebate" is defined. The industry has pushed this concept of passing through 100% of their rebate dollars over the past few years. While a portion of the funds they get from manufacturers is contractually called a "rebate," the GPOs are adding an ever-expanding list of fees which PBMs keep as profit. See the example below for a list of those fees and whether they are included or excluded in the monies shared with plan sponsors. This list is an example of 3 unnamed industry PBMs. All sources listed should be considered rebate revenue, yet many PBMs exclude them in the monies shared with plan sponsors.

Pharma Revenue Streams Included in Rebate Offer			
Source	**PBM #1**	**PBM #2**	**PBM #3**
Administrative Fees	Excluded	Excluded	Excluded
Clinical Program Fees	Excluded	N/A	Excluded
Consulting Fees	Excluded	N/A	Excluded
Credits	Excluded	Included	Excluded
Discounts	Excluded	Excluded	Excluded
Education Program Fees	Excluded	N/A	Excluded
Financial Incentives	Excluded	N/A	Excluded
Formulary Placement or Access Fees	Excluded	Included	Excluded
Implementation Fees	Excluded	N/A	Excluded
Market Share Based Payments	Excluded	Included	Excluded
Price Concessions	Excluded	N/A	Excluded
Promotional Allowances	Excluded	N/A	Excluded
Pull Through Program Fees	Excluded	Included	Excluded
Rebates	Included	Included	Included
Rebate Submission Fees	Excluded	N/A	Excluded
Software Licensing Fees	Excluded	N/A	Excluded
AWP Inflation Coverage	Excluded	Excluded	Excluded
All Other Payments From Pharma	Excluded	Excluded	Excluded

In closing, I would like to point to the *Consolidated Appropriations Act, 2021* (CAA). As pointed out in a article from Pharmaceutical Commerce in May 2023, the CAA has been designed to level the playing field between PBMs and plan sponsors. It will ensure that as a fiduciary to the plan all PBM revenue is disclosed, all data for that plan is shared with the plan sponsors, all compensation – both direct and indirect – brokers receive is fully disclosed and we will have a health care system that is more transparent and allows for more competition to drive down costs while improving quality and the lives of all Americans.

Thank you, members of the committee, for the opportunity to speak today and I look forward to your questions.

hello@affirmedRx.com | 10200 Forest Green Blvd., Suite 112, Louisville, Kentucky, 40223

For more information, here are links to articles aimed at educating purchasers about the PBM industry:

https://affirmedrx.com/how-gpos-work/

https://affirmedrx.com/how-pbms-make-money/

https://affirmedrx.com/what-is-a-pbm/

https://affirmedrx.com/8-things-every-employer-should-know-about-their-pharmacy-benefit-manager/

https://affirmedrx.com/how-do-pharma-pbm-contracts-play-role-in-rebate-leakage-part-1/

https://affirmedrx.com/how-do-pharma-pbm-contracts-play-role-in-rebate-leakage-part-2/

Chairman GOOD. Thank you, Mr. Baker. Under Committee Rule 9, we will now question witnesses under the 5-minute rule. I will wait to ask my questions at the end and therefore recognize Mr. Walberg from Michigan for 5 minutes.

Mr. WALBERG. Thank you, Mr. Chairman, and thanks to the panel for being here. As I understand it, Mr. Chairman, you have a document from our colleague Representative Buddy Carter to submit to the record on this issue. I will leave that to you.

The United States spends more on healthcare as a percentage of the economy than any other developed nation, and CBO projects that spending will continue to grow. A recent NFIB survey showed that while employers by and large believe offering health benefits is important, 98 percent of small businesses are concerned that healthcare costs will become unsustainable within the next five to 10 years, if they are not already.

I thank the Committee for holding this bipartisan hearing today on what the Federal Government can do about the high cost of healthcare. Mr. Baker and Mr. Scott, many employers say they are not able to obtain accurate cost and pricing information despite laws which mandate that third-party entities provide this information to plan sponsors.

Many PBMs say that employers can receive cost and quality information at any time through an audit. What is the disconnect? Mr. Scott first, then I will go to Mr. Baker.

Mr. JC Scott. Thank you for choosing one to go first, so we did not just sit here for 5 minutes. Thank you for the question. I would start by saying at PCMA, all PBMs, all pharmacy benefit companies, are welcome at our table as long as there is alignment around the mission of preserving the free market and the approach that does not have government dictating terms or asking Congress to come in and prefer one business model over another.

We have a fairly simple set of principles, where we are not here to advocate for one company to get a favorable approach over another. One thing that is consistent across our members is that they are hired by employers who choose to use them under no obligation, and that they want those employers to have all the information that they need to make informed choices about how to design their benefits, so that they can best serve the patients that they represent.

All of that is built into the request for a proposal, or RFP process, and I still have not fully understood where the RFP process may be failing some employers who are expressing that sentiment to you, Congressman. That is how PBMs compete, when they put in those RFPs, the kind of information that a given employer may need.

If there is more work to be done in that space to make sure the client is informed, we would be happy to work with the Committee on that.

Mr. WALBERG. Mr. Baker.

Mr. BAKER. Yes. Thank you for your question, and I think you are spot on. In general, we consistently work with jumbo self-funded employers who do not have access to their data. I do not know of one employer who knows at the claim level how much they are getting back in rebates from the pharmaceutical manufacturers.

While I do appreciate the comments of my esteemed colleague, Scott, I do not agree that there is a competitive marketplace that is working today. I think the status quo has existed for the last 15 or 20 years. I think that consultants and PBMs are focused on how they continue to drive profit at the detriment of the American public, and that data that you are asking for we agree should be present to all self-funded employers and it is not today.

Mr. WALBERG. Okay. Thank you. Dr. Sachdev, would you care to comment as well since you mentioned in your written testimony that employers have trouble accessing their own price and quality data. Then second, how are third party entities circumventing current data sharing requirements?

Ms. SACHDEV. Thank you so much for the question. I would concur with Mr. Baker that none of our employers have seen any pharmaceutical claims data at the drug level. When they get rebate information, they get it in aggregate, so that is not helpful to the employer because then they cannot shop for it.

They are told if you want to change the formulary, and this might be a little in the weeds here, but if you want to change the formulary, then you are going to, you know, that might impact the rebates that we give you. They might have, let us say I do not know, 500 drugs that they are covering, maybe more, and we would want to see what the rebates are at the drug level.

We do not get that level of information at the drug level. No employer I know gets that level of information from the largest PBMs. Regarding your question about audits, the audit—the language in these contracts is confusing, and they put a lot of restrictions on the audit. Yes, you can do an audit, but they might, and it can vary depending on the contract, that they might restrict audits, so the audits need to be unfettered access.

If the employer has fiduciary responsibility to do what is in the best interest of the client, they should be able to audit their own claims data all day long as many times as they want. They have restrictions on who the auditor can be, how many times per year they can do an audit. Maybe it is just once a year, or maybe twice a year.

How far back they can even look at their claims data. Maybe only 1 year back, so they cannot compare data over time. What drug classes they can even look at, et cetera, et cetera. There are just all these restrictions.

Mr. WALBERG. I thank you all for your answers. I have further questions that I will submit for the record, and I yield back.

Chairman GOOD. Thank you, Representative Walberg. Our Ranking Member DeSaulnier has also elected to defer to the end, so we will recognize Representative Wild from Pennsylvania.

Ms. WILD. Thank you, Mr. Chairman. Greetings everybody. There has been a lot of discussion for decades now about pharmaceutical prices generally, but recently the even more common subject of discussion is shortages of medications.

Adderall has been written about in all the major newspapers. I just looked online, there is a list of hundreds of medications that are apparently in short supply. What I have been told by a number of my constituents, and by the way, I am in Pennsylvania. Pennsylvania 7 in the Lehigh Valley, but it is probably typical across the

country, is that they find that when they go to the local pharmacy with their script, and the pharmacy says, "I'm sorry, we're out of that medication, we're not going to be able to fill it until we don't know when", they are then advised by their insurance company that if they get their medications by mail order, they will likely be able to fill it, and indeed. Optum RX, I believe, is the PBM for United Healthcare. CVS, I think is affiliated with either Aetna or Cigna. First and foremost, and I am going to ask you first, Mr. Baker, why is it that PBMs are able to supply medications when local pharmacies cannot, when there is a shortage?

Mr. BAKER. Yes, thank you for the question. I cannot specifically address that. I am not exactly sure. Usually the pharmacy supply chain, the bigger actors might get more limited quantities than say a small independent would, so it could be the fact that they just got a tighter supply relationship with the wholesaler.

Ms. WILD. The bigger pharmacies may get a smaller supply. Is that what you said?

Mr. BAKER. The bigger. No. The bigger pharmacies would have better access to the wholesalers limited amount of medication.

Ms. WILD. Okay. Are you saying that a PBM is sort of the biggest pharmacy of all, and therefore they are likely to have more?

Mr. BAKER. That would be my contention, yes ma'am.

Ms. WILD. Mr. Scott, what are your thoughts on that?

Mr. JC SCOTT. Yes. I agree with your concern. I would reflect my mom lives down in Pensacola, Florida and suffers from depression and has encountered exactly the situation that you have just described. It is a real issue. As Mr. Baker implied, I think it does get to the wholesaler relationship with the pharmacy, what is the acquisition, how much are they purchasing and making available in terms of that supply.

Ms. WILD. It is the reason that say Walmart is able to have large supplies. I am not even going to talk about medications, of certain products that a smaller retailer might have trouble buying.

Mr. JC SCOTT. It is all about that relationship with the wholesaler.

Ms. WILD. It is all about that relationship. The result of that, if I am correct, is not only that the consumer is then forced into the mail order or PBM model, but also that it continues the problems of the small, local independent pharmacies staying in business, which let us face it, small, local independent pharmacies are almost a thing of the past.

I can tell you that in my district many of them have closed much to the sadness and detriment of many consumers around my district who had personal relationships with their local pharmacist and were able to talk to him or her about interactions, and that kind of thing, which of course, when you are doing mail order, you do not have.

That just really concerns me, and I am trying to figure out—based on your answers, PBMs have greater purchasing power, right? That is because they have so many.

Mr. JC SCOTT. Some pharmacies have greater purchasing power than others, and it depends on the relationship with the wholesaler, and the pharmacy services administrative organization, the

PSAO, that represents about 83 percent of independent pharmacies.

Ms. WILD. Who exactly is a client or customer of a PBM? Is it the ultimate consumer, or is it the employer who holds the insurance plan?

Mr. JC SCOTT. The employer or retiree plan, government program, union plan is who hires the pharmacy benefit company to do the work to serve the patients they represent.

Ms. WILD. Let me just ask you then the Consolidated Appropriations Act of 2021, which we passed last year. I was proud to vote for it, indicates that pharmacy benefit managers are described as covered service providers who must provide information to responsible plan fiduciaries. You are familiar with that requirement?

Mr. JC SCOTT. Yes, Congresswoman.

Ms. WILD. Do you believe that PBMs provide plan fiduciaries, meaning somebody within the employer, with enough information to ensure that the compensation they are paying is reasonable?

Mr. JC SCOTT. Yes. I believe our companies all comply with the requirements of the law.

Ms. WILD. Now you are shaking your head. How about you?

Mr. BAKER. I think it was a carefully worded answer that they are complying with law, yes. What they are doing is they are aggregating numerous employers' data and they are sending it in to comply with CAA. That data is not going to the employer to make the right decision.

Ms. WILD. Thank you. Unfortunately, my time has run out. I have many more questions I would love to submit, and with that I yield back.

Chairman GOOD. Thank you, Ms. Wild. Now we will recognize Mr. Allen from Georgia for 5 minutes.

Mr. ALLEN. Thank you, Mr. Chairman, and thank you for holding this important hearing, and thank you to our witnesses for providing us the expertise that we need to address this critical situation. Obviously, there is no private healthcare system in this country.

The government has its fingers in every area of healthcare. What is happening to our healthcare system, it has become a complex, expensive made, fueled, a heavy-handed regulation, provided consideration and a lack of transparency. You are going to hear that over and over again today. The growth in healthcare spending is expected to outpace growth in gross domestic product over the next 10 years, forcing insurance premiums and out of pocket costs to remain too expensive for working families.

We cannot sustain what is happening with the costs, rising costs of healthcare. Dr. Sachdev, many in Congress, and you are going to hear more. We are going to drill down here about PBMs, and the consolidation of PBMs. This consolidation is taking away options for plan sponsors and patients. This includes what seems to be a push toward practices like mail order prescriptions, and the use of larger retail pharmacies, rather than on local community pharmacies.

While that may work for many Americans, I value options, and I think the American people want options in healthcare, the healthcare market, because they have actually a relationship with

their pharmacist. Do employees have flexibility when designing their prescription drug benefit programs?

Ms. SACHDEV. Thank you so much for the question. Was your question, just to clarify, do employers have options when yes, designing their drug benefit programs?

Mr. ALLEN. Yes.

Ms. SACHDEV. They do have options. Self-funded employers have benefit options, the options have become limited now because there's been so much consolidation in the PBM space, as Chairman Good mentioned, three big PBMs represent 80 percent of the market right now.

In some, because there has been so much consolidation between PBM and insurance companies and mail-order pharmacies, and physician groups, some insurance companies', PBMs say, if you are going to use our insurance company, you have to use our PBM. That is a real problem.

Mr. ALLEN. Yes. That is what I wanted to hear.

Ms. SACHDEV. While there appears to be choice, there are limited choices.

Mr. ALLEN. Of course, what choices do employers have when working with pharmacy benefit managers, meaning that those pharmacy benefit managers can dictate to the employee if you want this cost of health insurance you have to use my mail order service.

Ms. SACHDEV. That is correct.

Mr. ALLEN. Okay. Dr. Tripoli, or Ms. Tripoli, one of the main drivers of rising healthcare costs is increasing consolidation among hospitals and hospital systems, including horizontal, vertical, and cross market integration. In fact, hospital care services make up about 31 percent of our national healthcare expenditures, and hospital spending growth is projected to accelerate 9.3 percent in 2023.

That is precisely why one of my main goals of the Healthy Future Task Force last Congress was to increase choices through competition, which meant addressing matters such as site neutral rules, physician on hospitals and consolidation. What impact does consolidation among hospitals have on prices and access to care?

Ms. TRIPOLI. Thank you very much for the question. I would say the single biggest driver right now of rising premiums and increased cost sharing for consumers is increased consolidation, particularly among in the provider market among hospitals, that directly drive-up prices and results in higher costs to the employers, which of course gets shifted onto employees and consumers in the form of stagnant wages, and higher premiums and cost sharing.

Mr. ALLEN. A large part of my district is rural. What has this hospital consolidation—has—it impacted our rural communities?

Ms. TRIPOLI. I would say it has a very similar impact in terms of consolidation. We are seeing consolidation across the country, across U.S. healthcare markets within them. 90 percent of metropolitan statistical areas are now considered highly concentrated hospital markets. All for the same purpose of increasing prices and generating the highest priced volume of services that hospitals can.

Mr. ALLEN. Okay. I have some additional questions, and Chairman I will submit that to our panel later.

Chairman GOOD. Thank you, Mr. Allen. We will now hear from Ms. Jayapal from Washington. Are we—actually, we will go with Ms. Manning for 5 minutes.

Ms. MANNING. Thank you, Mr. Chairman. Mr. Scott, I represent Caswell County, a rural county in North Carolina that has only one pharmacy for the entire county. A small, independent pharmacy that is family run, and is struggling to stay open because they make so little money on the prescriptions they fill.

I understand that PBMs negotiate with insurance companies over how much patients pay for their medications at the checkout counter, and also how much pharmacists make for the prescriptions that are filled. Generally, chain and corporate pharmacies have better buying power, and receive better reimbursements from PBMs. Is that true? Do PBMs negotiate how much pharmacies get paid per prescription filled?

Can independent pharmacies get paid less per prescription than the big chain pharmacies?

Mr. JC SCOTT. PBMs negotiate with pharmacies to incentivize higher quality and lower cost, and about 40 percent of pharmacies that are part of PBM networks on average are independent pharmacies. What we have seen, the data we have seen, is that often the independent is getting paid slightly more than the chain.

Ms. MANNING. You are saying that what I have read in articles that affect independent pharmacies is not true. That independent pharmacies get paid more than chain pharmacies.

Mr. JC SCOTT. On average that is the data that we have seen.

Ms. MANNING. Why is it that from 2003 to 2018, more than 1,200 independently owned rural pharmacies closed in the United States?

Mr. JC SCOTT. The data from the community pharmacy lobby, NCPA, actually shows that across the country there has been a steady increase over the last 10 years in the number of independent pharmacies. Now, I would recognize—

Ms. MANNING. Not necessarily in rural areas?

Mr. JC SCOTT. That is across the country. I think the rural question is the one to focus on because often times, not only is that the only pharmacy, it is the only access point of care for patients, and it seems certainly for our industry, we believe we need to empower pharmacies to do more for patients, be able to practice at the top of their license.

We experienced some of this during COVID. That they can deliver more value to the patient, and as a side effect of that, develop more revenue stream for the pharmacy.

Ms. MANNING. If we had more transparency, we would be able to tell whether large chain pharmacies get more per prescription filled than small, independent pharmacies?

Mr. JC SCOTT. That data is available. I guess the point I am making is we need to adjust the law to allow the pharmacies to do more for patients.

Ms. MANNING. Okay. That does not really go to how much pharmacies get paid per prescription filled. That is a separate issue. What you are saying is let pharmacies do more, so they can make money other ways.

Mr. JC SCOTT. Correct.

Ms. MANNING. That does not really address the question of whether small, independent pharmacies actually get paid less than large pharmacies.

Mr. JC SCOTT. I would be happy to followup with you on that data that we have seen.

Ms. MANNING. Okay. Let me ask you another question. In your testimony, you detail a variety of services that your member PBMs provide beyond negotiating for lower drug costs. For example, you said that PBMs provide clinical support in the form of services to plan and release, provide internal clinical expertise to support business operations, and assemble clinical experts to evaluate drug therapies, and make coverage recommendations to plan sponsors.

Are these all duplicative services that simply add to the costs of our healthcare system? For example, when you say that you assemble clinical experts to evaluate drug therapies and make coverage recommendations to plan sponsors, doesn't the FDA already evaluate the safety and effectiveness of every drug before they approve a drug for use?

Mr. JC SCOTT. That is correct. We are adding to that value proposition of what the FDA does, and often times the pharmacy benefit company, for a given patient, who I think of my dad's experience at the end of his life. Alzheimer's, cancer, multiple doctors, multiple medications, doctor's offices not always communicating with each other.

The PBM was able to act to see if there's going to be any problematic medication interaction for him as the patient.

Ms. MANNING. The PBM does that, not the pharmacy?

Mr. JC SCOTT. Often times the pharmacy may not have visibility into every place the patient has gone to fill a script, or a medication has been prescribed.

Ms. MANNING. Are doctors——

Mr. JC SCOTT. The payer may.

Ms. MANNING. Are doctors already evaluating which medications they want their patients to use?

Mr. JC SCOTT. Absolutely, we provide information to empower them, but my dad's cancer doctor, and my dad's doctor who was helping him treat Alzheimer's at the end of his life may not be communicating across all the prescriptions that they are refilling.

Ms. MANNING. I am glad your dad had a good experience, but I have to tell you when I was using an eye medication that I had gone through multiple trials with my doctor to get used to save my sight, and my pharmacy benefit manager told me I could not use that drug until I failed forward. That was not a good result for me, and people all across the country have the same experience. My time is expired, I yield back.

Chairman GOOD. Thank you, Ms. Manning. Now we will go to Mr. Burlison from Missouri for 5 minutes.

Mr. BURLISON. Thank you, Mr. Chairman. Thank you for having this hearing. I think it is very important. I think the American people want to understand why their healthcare costs are sky high. Sadly, I think, and I will say this. I think their healthcare costs are sky high because of this place.

This place regulates the hell out of the healthcare industry to the point where there is no choice, right? We talked about the driving

costs that we have consolidation. Well normally, if people are making obscene profits in any marketplace that would be a great opportunity for a new entrant.

We have regulated the healthcare industry to such an extent that no one can enter into the market to compete and provide more choices. Now, the one thing that I have seen, because I served on a board at Missouri Consolidated, where it was my responsibility as the board to buy the health insurance for over 100,000 lives. You know what?

What we did, we found that using a PBM dramatically drove down our costs for the entire group, okay? I have heard testimony here that it is a false choice. I can tell you when you are actually writing the checks, it is not a false choice. It did save money. It is good to hear that there are choices.

Mr. Baker, I am going to ask you. Your PBM model works differently. Can you describe that?

Mr. BAKER. Yes. I think it is functionally three different things. One, we do think profits are a problem in driving bad decision-making in healthcare, so we are not a for-profit entity like a C corp or a public—

Mr. BURLISON. Do you think profits are evil or something?

Mr. BAKER. I think if everybody knows what you are paying for an item, and the American consumer can make a decision on that profitability that they are contributing to, that is fine. That does not exist in the pharmacy benefit space.

Mr. BURLISON. Okay. We can have a long conversation about that. My question at the end of the day is when a company like Missouri Consolidated, or other businesses are choosing a PBM at the end of the day, they just want to know what you cost, and what they are getting back from it.

Why are you—to me the question is if American Airlines were here and they were, you know, had one rate, and their mileage system is different than United, which it is. Can you imagine the scenario where American would have the temerity to come to Congress and say our mileage system is better and more transparent, therefore everyone should—all—the other airlines should have to move to our business model. Can you imagine that?

Mr. BAKER. I do not imagine that, but in the pharmacy space it is fundamentally different. I know if I want to buy a flight to come here to Washington, DC. I can look at American site, I can look at United's site and I can make a decision on costs.

Mr. BURLISON. I beg to differ. At the end of the day, Mr. Baker, you are competing with other PBMs, correct?

Mr. BAKER. Correct.

Mr. BURLISON. The businesses that are making these choices, they are deciding based on quality and costs, correct?

Mr. BAKER. I do not always agree with that statement.

Mr. BURLISON. To me, it is regulatory capture to come to Congress and abdicate that your competitors participate and run their businesses the exact same way. With that, Mr. Scott, let me ask this. We have talked about the consolidation. What kind of things can be done? I am intrigued by the idea that you had to let pharmacies do more. Can you elaborate on that?

Mr. JC SCOTT. Yes. Thank you for the question. Think back to all of our collective experience during COVID where we had to go to get our testing, where we had to go to get our vaccinations. The rules were eased to allow us to use the pharmacy as a site of care. There are so many things that a licensed pharmacist should be able to do, and particularly in rural counties where your doctor's office, your hospital may not be close, administering vaccines, administering shots, checking your blood pressure, some of those routine healthcare screenings where they can add value by interacting with the patient.

Mr. BURLISON. Right.

Mr. JC SCOTT. Instead of simply the revenue model being primarily the pill in the bottle, which remains critically important, but we think there is so much more they can do, which adds revenue for them and value for the system.

Mr. BURLISON. My time is getting close, but it appears to me that just the common theme is that centralization causes skyrocketing costs. In my opinion, decentralization could be the answer, but with that we have to trust mid-level providers to do more. We have to trust pharmacists to be able to administer some of the healthcare that patients need.

Then my last question, Ms. Tripoli, has to do with transparency. If I am going to go shop for where I am going to have dinner tonight, I can see on Yelp amazing information, costs, the value, the ratings of different restaurants. Why can we not get to that point in healthcare?

Ms. TRIPOLI. Part of the reason is because of the way that prices are negotiated, and the way they are set is in closed-door negotiations between plans and providers. That price, the negotiated rate, is buried in the proprietary contract, never to be seen by the public. Now, with these regulations, transparency in coverage and hospital price transparency, we are seeing for the first time what the actual underlying price of a healthcare service is, so now we can actually get the data and look at it, pull it down and understand where are prices needlessly high, where are they competitive, and we can make more informed policy decisions.

Mr. BURLISON. Thank you. Sadly, my time has expired.

Chairman GOOD. Thank you, Mr. Burlison, and now we will hear from Ms. Jayapal from Washington.

Ms. JAYAPAL. Thank you, so much Mr. Chairman. Recently, two of the largest health clinics serving my district were bought by United Health Group, a prime example of consolidation of our healthcare system. United Health then demanded a significant increase in payments from another health insurer, during tense negotiations in a highly consolidated health market.

As a result, over 19,000 of my constituents were notified that they would likely lose access to their doctor. As hospital consolidation in situations like this are becoming more common nationwide, it is just important that we take a look at the impacts of hospital consolidation on people's health and medical cost.

Seattle is not alone in experiencing these hospital mergers, and we have seen a concerning increase of mergers across the country. A recent report by the New York Times found that areas with the

highest rate of hospital consolidation had prices go up between 11 and 54 percent.

Ms. Tripoli, can you describe what typically happens when there is a high rate of hospital mergers in a region?

Ms. TRIPOLI. Absolutely. It really comes down to when you see increased concentration in a market, it gives greater negotiating power over being able to set prices, essentially. What we have seen in the hospital business model is a complete shift, and it is based on two things. Buying up local competition, so you can gain more negotiating leverage over how to demand higher prices and generating high volumes of high-priced services.

The result of course, the prices get passed on, particularly in the commercial market, to employers. We see stagnant wages. We see increased premiums and cost sharing for consumers, and we are stuck with unaffordable healthcare care. Rising levels of medical debt.

Ms. JAYAPAL. One of the things that we hear from the hospital industry, they often claim that hospital mergers increase the quality of care. Is that true?

Ms. TRIPOLI. I think what the data shows us is that that typically is a claim, but the data shows us that quality either stays the same, or in many cases gets worse.

Ms. JAYAPAL. It is really not true at all. Hospitals also claim that mergers lead to lower healthcare costs. Is that true?

Ms. TRIPOLI. That is definitely not true.

Ms. JAYAPAL. Definitely not true. Ms. Monahan, these hospital practices often lead to people losing access to their medical providers. What do experts say about the impact of losing access to your care provider and then having to find new providers, new specialists?

Ms. MONAHAN. I think it is a huge problem for consumers, and one thing that we see, for example, it is kind of this intersection of hospitals merging and acquiring physician practices, and then how the insurers have to respond. One example is that you know, insurers are trying to lower costs, and so they will say, you know, if you go to an independent practice, it will cost you less than if you go to this now hospital owned location.

That puts the consumers in a really tight spot because they may want to prefer to continue to see the doctor they have been seeing, maybe they are in the middle of a course of chemo. They now have to pay maybe several hundred dollars more for every time that they go in because the hospital owns this practice now and is charging a lot more for that.

Ms. JAYAPAL. It really reduces freedom of choice to see the doctors and specialists that you want. Representative Spartz and I have championed bipartisan efforts to expand antitrust enforcement to nonprofit hospitals through our legislation, the Stop Anticompetitive Healthcare Act. Ms. Tripoli, can you tell me a bit about how increased antitrust enforcement would affect competition in the healthcare system?

Ms. TRIPOLI. Yes, and thank you for your legislation. It is very exciting to see. As I understand it, the FDC currently does not have the ability to intervene and investigate mergers and acquisitions among non-profit hospitals in particular. As far as consolida-

tion, we are seeing increased consolidation across all types of hospitals, non-profit, for profit.

Giving FDC the authority to actually be able to investigate would go a long way in helping us to address the parts of the markets that are still not consolidated.

Ms. JAYAPAL. I really appreciate that, and I invite all of my colleagues on both sides of the aisle to join our bipartisan legislation. Hard-working Americans are bearing the brunt of increased healthcare costs from hospital consolidation, and I think it is really important that we work to prohibit these anticompetitive practices in healthcare.

Also go further, in my view, and enact a universal single payer healthcare system that would remove insurance middlemen who often perpetuate anti-competitiveness. I have that bill of course, it is Medicare for All Bill. The only competition in healthcare should be providers competing to provide the best possible care for their patients.

That should be the only objective, the only goal. I thank you all for your work, and I yield back Mr. Chairman.

Chairman GOOD. Thank you, Ms. Jayapal. Now we will recognize Ms. Houchin from Indiana.

Ms. HOUCHIN. Thank you, Mr. Chairman. Thanks to the witnesses for coming to testify before us today. This is an important opportunity for us to focus on issues pertaining to transparency in the cost of healthcare. Dr. Sachdev, as a fellow Hoosier, you know, that Indiana has recently passed important legislation as you noted in your opening statement, such as AGA 1004.

Requiring at least 85 percent of each drug rebate, which is probably defined to include fees and other remuneration, to go to certain patients at the point of sale at the pharmacy counter, or ERISA exempt employers get 100 percent of the rebates.

You mentioned in your testimony several policy ideas addressing PBMs. Could you talk through your ideas that you think this Committee should consider legislating, and how Indiana is leading in this regard?

Ms. SACHDEV. Thank you so much. Yes, we passed a PBM legislation is in SEA 8, so that is where that particular language comes from. We need to codify the Transparency in Coverage Act and include the pharmacy information in that. Prohibiting gag clauses with all parties, including insurers, but now that they have merged it has to be all parties, including those group purchasing organizations, those GPOs that they contract with.

A lot of the legislation around the country at the State level is focused on PBMs and the rebates that they have negotiated with the drug manufacturers. Now there is this other entity over here called the GPO and they are negotiating. If you are just targeting the PBM you miss the GPO, so that is an opportunity.

Spread pricing is a huge problem. We have heard about pharmacies, independent pharmacies getting paid less. There are issues you can pay a pharmacy a certain amount, but then the PBM can claw it back, which is like I paid you 100 bucks, but now you have got to pay me 50 back. We need some insight into claw backs.

This is a particularly shady process, where they will pay the pharmacy a price for a certain drug claim, but they will charge the

employer much more for it. That is why we need total transparency through the whole supply chain, so the employer can do that audit all the way through.

Merger and acquisition oversight, and because we have seen all of this vertical integration, we really need to think about how to prohibit self-dealing. You know, I am the insurance company, I am the PBM, I am the pharmacy, but the employer and the patient pays for everything, so I am just taking money out of one pocket, and putting it in the other.

They really should not be allowed to self-deal.

Ms. HOUCHIN. Thank you. Like you, I continue to be frustrated. I hear from constituents a lot on concerns about the practices of pharmacy benefit managers, how consolidation of PBMs has taken away options for plan sponsors and patients. Do employers have flexibility when designing their prescription drug benefit programs?

Ms. SACHDEV. They have limited flexibility. Sometimes the PBMs will say if you—here is your drug formulary. If you want to make any changes to it, you can, but we are going to charge you a huge fee to make any changes. When they do the math, they are like gosh, I just wanted to take a few drugs off, or get biosimilars on because there are no biosimilars on the formulary.

Now you are going to charge me a million dollars to do that. That is ridiculous. They should not be able to charge fees because you are really handcuffing employers by doing that if you are not going to say hey, you can do this, but then these fees, and they have so many fees really for doing anything.

Ms. HOUCHIN. Thank you. I think that is why this transparency piece is so important.

Ms. SACHDEV. Yes.

Ms. HOUCHIN. I have heard from constituents that they can no longer get long-term supplies. They can only get a month's supply of their prescription drugs, and then the cost is three times higher than if they had a 3-month supply. We are currently investigating if it is a PBM issue, or another issue that is causing their prescription prices to go up.

When we have increased costs of healthcare like going to a different facility, you know, buying a facility, going across the street, and then it costs more, consumers know that there is something not right about that. That it is incumbent upon us to try to contain these costs when possible. Nearly every healthcare related constituent meeting someone brings up PBMs, so I look forward to this Committee considering serious legislation addressing PBMs, and their role as the middleman. Thank you for being here today, I yield back.

Chairman GOOD. Thank you, Ms. Houchin. Now we will recognize Mr. Scott from the great State of Virginia.

Mr. BOBBY SCOTT. Thank you, thank you, Mr. Chairman. Ms. Tripoli, you responded to a previous question by saying that the costs did not go down when there are mergers. By costs, do you mean charges, or costs of providing services?

Ms. TRIPOLI. I mean the underlying price of healthcare. After there is a merger and acquisition, particularly in the hospital setting, we see prices go up.

Mr. BOBBY SCOTT. You are talking about the charges, not the costs of providing the services.

Ms. TRIPOLI. The charges, of course, the charges to the patient, the out-of-pocket costs of course depend on whether they are insured, what type of insurance.

Mr. BOBBY SCOTT. Yes, but I mean the costs of the hospital providing the services could go down, but the charges could go up?

Ms. TRIPOLI. The price of medical services after markets consolidate, after two hospitals merge together, goes up.

Mr. BOBBY SCOTT. The price?

Ms. TRIPOLI. The price does.

Mr. BOBBY SCOTT. The charges. Okay. We are dealing with costs of services, we are dealing with surprise billing, and it seems that when you land in an emergency room, providers could charge whatever they want. We heard one service was $1,000.00, or $2,500.00 in the same hospital, or $8,000.00 down the street. There used to be a term called UCR, usual, customary, and reasonable. Is that still a limitation on what you can charge? Anybody want to answer that?

No? Can you still just make up whatever you want unrelated to anything?

Ms. TRIPOLI. Just to make sure I understand the question. Is the question about the charge master price where hospitals are essentially setting, pretty much a price, they are building to price, and then is that what you are asking?

Mr. BOBBY SCOTT. Yes. I mean, if I take my car to a mechanic and say change the oil, he cannot come back and say well I will charge you $750.00, and I am going to keep your car until you pay. It has got to be a reasonable price.

Ms. TRIPOLI. It should be a reasonable price. I think what we are seeing as a result of heavily consolidated markets is that the underlying price is not reasonable. It is not only high, and increasing, but there is incredible variation across the market. In one hospital system you can, depending on your plan, on your health insurance plan, the MRI can be $1,000.00, or it can be $3,500.00.

That MRI should be one price because it is an MRI. It is the same service. It is the same across the whole country.

Mr. BOBBY SCOTT. That is not the case right now.

Ms. TRIPOLI. Exactly.

Mr. BOBBY SCOTT. One of the—we have had a lot of complaints of PBMs and TPAs, how much of this could be solved if they were considered fiduciaries?

Mr. BAKER. Thank you for the question. I think it would have frankly limited value for the reasons that Dr. Sachdev brought about earlier, because of self-dealing. You could say PBM you have to be the fiduciary, but within the corporate umbrella of that PBM, they also own their mail pharmacy, their specialty pharmacy, the GPO, there is all of these other corporate entities that they could still bury these profits in.

I think it is important to really look at the global entity, and make sure that you are putting regulation in place that makes sure that all of the entity needs to be driving the best interest of its clients.

Mr. BOBBY SCOTT. Do you want to answer that?

Ms. MONAHAN. On the fiduciary question. I think there is potential for value in having PBMs or TPAs be fiduciaries, but we want to just think about it from kind of the functional sense of kind of, what service is being provided here, what activity are they performing. Then with respect to that activity, is there something that we think is really very important that they be acting in the best interest of the plan members.

I totally recognize these are really complex companies and structures, and so I do not—I think the idea here is that we want them to be working and to contain costs, and not just be acting in their own self-interest. I do not think it is necessarily like clean, put the label on. Done. Thinking through, like yes, there might be some value in thinking of them as fiduciaries as well.

Mr. JC SCOTT. I would just add the fiduciary label in law implies that there is decisionmaking authority, and ability to control the other entities' decision and financing. A great example, the PBM does not hold that decisionmaking authority on behalf of the employer, and a great example is the conversation we just had about rebates where the employer is making the choice whether that goes to the point of sale at the pharmacy counter, to defray premium, to make the benefit more robust, or to apply it elsewhere in the employer's finances.

The PBM does not control that decision. As you look at that fiduciary label, that decisionmaking authority does not exist.

Mr. BOBBY SCOTT. Let me try to get in one other question. What is the rationale for facility fee to determine whether the procedure is performed in a hospital or a physician's office, particularly when they are charging these facility fees in a corporate owned physician's office?

Ms. TRIPOLI. I think there is very little rationale for facility fees for a certain group of services. Ultimately what is happening is you're seeing large healthcare corporations buying up physician practices, rebranding so that they can get a higher reimbursement. How that plays out in the commercial market is that consumers are experiencing a facility fee.

In the story of the woman I told, Ms. Tesso and her son, they did a 1-hour videoconference, and they got a $1,000.00 bill facility fee, but they never stepped foot in the hospital-based setting.

Mr. BOBBY SCOTT. Thank you, Mr. Chairman.

Chairman GOOD. Thank you, Mr. Scott. Now we will go to Chairman Foxx from North Carolina.

Mrs. FOXX. Thank you, Mr. Chairman, and thanks to our witnesses for being here today. Dr. Sachdev, the Employers Forum of Indiana has continued to push for change in Indiana, which has among the most hospital consolidations in the country. Kaiser Family Foundation has discussed challenges with hospital price transparency data.

How has your organization surmounted these challenges?

Ms. SACHDEV. Thank you for the question. I am not sure that we have fully surmounted those challenges, but we are doing our very best. It is beginning with transparency. We are requiring financial transparency of all the hospitals in the State, they have to submit all of their finances. We have hospitals that have between 2 billion and 7 billion dollars in cash and reserves, and so when they come

to legislators claiming poverty, they have the data, and we were able to supply that.

It needs to be more readily available to them.

Mrs. FOXX. How has the recently passed legislation prohibiting hospital off-campus facilities fees been implemented?

Ms. SACHDEV. We looked. We did not want a blunt instrument across all of the hospitals. We want to make sure all of our rural hospitals are successful. It did not apply to all hospitals. It applied to certain hospitals, and those were our largest hospital systems, and they simply do not fill out a hospital facility fee form, they just fill out an independent form.

Mrs. FOXX. Thank you. Ms. Monahan, the No Surprises Act prohibited gag clauses in contracts between health plans and third-party administrators to ensure that plan sponsors can access cost and quality data. Despite this, plan sponsors still struggle to access needed information. What can be done to allow plans to access cost and quality data.

Ms. MONAHAN. I think we need to revisit the gag clause prohibition and think about kind of where the burden falls. Right now, the TPAs are kind of looking at this and responding saying it is on the employer to kind of negotiate a contract where they get rid of the gag clauses.

There is no kind of real hook on the TPAs themselves to be eliminating these.

Mrs. FOXX. Thank you. Mr. Baker, I would like to pose the same question to you. What can be done to improve plan sponsors access to their own cost and quality data?

Mr. BAKER. I think the Consolidated Appropriations Act has been a very good start. It is really trying to put more data out there, but that law really says the data needs to go to the Federal Government, and it can be done in an aggregate fashion. Where these employers see exactly their data, know exactly their costs, and where their money is going would be incredibly helpful.

Mrs. FOXX. Thank you very much. Mr. Scott, many in Congress believe that large pharmacy benefit managers are not transparent and are driving higher drug prices through the use of rebates and spread pricing. Do you agree that plan sponsors should be able to audit their plan data without interference, and should they be made aware of any indirect compensation the PBM receives for its contracted services?

Mr. JC SCOTT. Yes. I would agree. We need our clients and employers to have all the information they need to make informed decisions.

Mrs. FOXX. Thank you very much. Mr. Chairman, I yield back.

Chairman GOOD. Thank you, Dr. Foxx. We will now recognize Ms. Hayes from Connecticut for 5 minutes.

Mrs. HAYES. Millions of Americans across the country are hit with unexpectedly high medical bills because of increased hospital consolidation. Studies show that consolidation has consistently produced higher prices for care. According to the American Hospital Association, between 1998 and the end of 2021, there were 1,887 hospital mergers, reducing the number of hospitals from 8,000 to just over 6,000.

This consolidation includes hospitals acquiring independent physicians' offices and converting them to hospital outpatient departments. Under the current system, these departments can fully charge facility fees, and receive higher reimbursements than freestanding physicians' offices than other lower cost settings.

There is little evidence that the quality of care is higher, and that in many cases physicians' practices were brought by hospitals, and designated part of the outpatient department, just to take advantage of this rule. Ms. Monahan, you discussed hospital billing practices that make it difficult to determine which setting is providing the service.

This includes when a service is provided in what is effectively a doctor's office but is billed at the hospital rate. While the plan has no way of distinguishing the setting in which the care took place, can you tell us a little bit about if you do not know the location of where care is provided, how is a plan supposed to determine the rate of payment?

Would providing accurate information on the site of service improve transparency?

Ms. MONAHAN. Absolutely providing this would improve transparency, and the payers as well as State officials, State regulators, Federal regulators, looking at this really just cannot see the actual location where care took place, and they cannot make their decisions to say this is an off campus, a physician's office that is miles off campus. It looks like a hospital to us, and figuring out what to pay then becomes much more difficult.

If you want to adjust, this is a lower quality practice that a hospital now has acquired and maybe we do not want to contract them, or we do not want to pay them as much if we cannot see that that is where the care is being provided, rather than it all just looks like it is on a main hospital campus. It makes it a huge challenge to implement reforms.

Mrs. HAYES. Can you just help us understand a little why it would make a difference, I think to Mr. Scott's question, if a service is being provided. Does the setting, should the setting determine the rate of reimbursement for that service, whether it be an MRI, an ultrasound, or whatever.

Ms. MONAHAN. Ideally, no. I think that is a system we want to move to where for care that can be safely and effectively provided in a physician office, we should not be paying more when it is being provided in a hospital owned setting. Right now, what you see is states trying to do, like Indiana, to say at least off campus physician, or a physician's offices. Let us not pay more, let us not pay facility fees there.

Payers may have difficulty implementing that if they cannot see where the care was provided.

Mrs. HAYES. Thank you. Ms. Tripoli, in your testimony you discussed the lack of transparency concerning the business practices of PBMs, or pharmacy benefit managers. As you know, in 2022, 80 percent of all equivalent prescription claims were processed by three companies. CVS Health, Express Scripts through Cigna, and Optum RX through United Healthcare Group.

What are some of the problems that may arise because of how PBMs are currently compensated, and how would transparency help in these issues?

Ms. TRIPOLI. Thank you very much for the question. I think the first thing to say is the reason we have a drug affordability crisis is because of price gouging from drug companies. It is also important to note that PBMs, of course, have a role to play. There is just an incredible amount of opaqueness around the PBM business practices and contracting practices.

They are, to your point, three major PBMs owning 80 percent of the market. Giving them this market power gives them increased negotiating leverage with the drug companies, to get price concessions. The result of pricing structures that are not always in the interests, in the financial interests and health interests of the American people.

Increased transparency, pulling back the curtain, understanding what is happening around the rebates, the actual negotiated rates is going to empower employers to actually be able to negotiate to get a better deal for the employees.

Mrs. HAYES. Thank you. That was one of the things that Democrats tried to do was Medicare negotiating the price of prescription drugs, increasing competition in many of these workplaces. How does the lack of competition impact an ability to better deal with PBMs in 15 seconds?

Ms. TRIPOLI. The main thing that I have not said is that PBMs can actually steer patients to their own pharmacies, taking away choice from consumers, which is hugely problematic for their access to pharmaceuticals.

Mrs. HAYES. Pretty basic. Thank you. That is all I have. I yield back.

Chairman GOOD. Thank you, Mrs. Hayes. Now we will go to Representative Chavez-DeRemer from Oregon.

Mrs. CHAVEZ-DEREMER. Thank you, Mr. Chairman, and thank you for the witnesses for being here today. We have heard a lot about pharmacy benefit managers, PBMs, and so just for a quick refresher, while we asked several questions over and over again. I think it is fair to the American people to hear it over and over again what your answers are.

PBMs decide which medications are covered by health insurance plans, which pharmacies patients can use, and all are owned by insurance companies who in turn also own the pharmacies. The discounts acquired by PBMs notice rebates are often not passed down to the patients.

In other words, a PBM could get $100.00 rebate from a pharmaceutical company, pass along the $15.00 to a patient, and pocket the remaining $85.00. Meaning the insurance company is forcing a larger copay on a patient, so they can pay themselves more than if there was no rebate at all.

It is really a system beating down on the patients, and that is who we hear from. Mr. Baker, how could we require PBMs to pass through the discounts from rebates onto the patients, and avoid insurance companies jacking up the premiums because they are losing profits from these rebates?

Mr. BAKER. That is a great question. I think it goes back to the theme of the conversation here today, transparency and data—to make sure that at that claim level the ultimate plan sponsor can see exactly what is being charged, what they are getting back in rebate dollars from the pharmaceutical manufacturers in aggregate.

I think you also bring up another very important point about the PBMs owning their own pharmacies and having that control. Just for perspective, a drug cost is not a drug cost, and this is where we have got to look at that major corporate umbrella that these PBMs are part of.

For example, Mark Cuban's cost plus drug company, there is a drug called Imatinib. You can buy it from him for a year's supply for $866.00. There's one PBM that works with four large State health plans. If you are part of the State health plan of Kentucky, that drug is going to cost you $26,000.00. If you are part of Louisiana's health plan, it is $57,000.00.

If you are part of Georgia's health plan it's $170,000.00, and if you are unfortunate enough to be a taxpayer in Tennessee, you are paying $212,000.00. Exact same drug, exact same PBM, the price changes depending on how they want to do that and the arbitrage that is in the middle, how they want to move that money around.

Mrs. CHAVEZ-DEREMER. I appreciate the answer, especially being here today given that you are a competing industry dominated by the monopoly. How can Congress disrupt this vertical integration in the industry so that insurance companies cannot distort our healthcare system and force devastating costs on what I would call vulnerable Oregonians?

Mr. BAKER. I think the vertical consolidation has been 5 years on and is very obviously not helping. Costs continue to go up, and quality continues to go down. You know, I think really delinking how PBMs make their profit from a percentage of acquisition costs and sales costs because then if I am a PBM and I make 7 percent, do I want to make 7 percent off of $5,000.00 drug or off of a $50.00 drug?

Again, these are large corporations who are driven to profit. I think it starts with creating the right incentives, getting the right data out there, and then making sure that all of that is completely visible.

Mrs. CHAVEZ-DEREMER. Thank you, Mr. Baker. Let us move now to the relationship between PBMs and employers. A whole lot of employers have said they are not able to get accurate costs and pricing information as was stated earlier, from PBMs, despite laws which mandate the sharing of this information. PBMs deny this claim and say that employers can receive cost and quality information at any time through the audit.

It seems almost coy, really, for certain PBMs to say if you want to know whether we are following the law, audit us. Knowing small businesses do not have that kind of time, let alone really the resources to do so. With that disconnect, Mr. Baker, answer me this. How can we bridge this issue so that there is seamless transparency between the PBMs and the employers?

Then to followup to that, Ms. Monahan, what can Congress do to make sure that PBMs comply with the law, and meet their re-

porting requirements, insuring the disclosure of direct and indirect compensation for their services? I will wait for those, because I will be running out of time, so make it quick.

Mr. BAKER. I will go very quickly. I think it goes to the status quo. Basically, PBMs say you cannot audit, but then they say only certain auditors can come in, and only certain data is available. The term audit is very loose, and it is not as comprehensive as it needs to be, and it should be able to be done by anybody that the employer chooses.

Mrs. CHAVES-DEREMER. Thank you, Mr. Baker, Ms. Monahan?

Ms. MONAHAN. This Committee sent a letter last December encouraging DOL to issue guidance clarifying that the service provider compensation disclosures applied to PBMs and TPAs. At this point that guidance has not happened, but so further action may be warranted to make sure that is clear.

Mrs. CHAVES-DEREMER. Great. That was quick. Thank you. Dr. And Ms. Tripoli, but I do not think we are going to have time. If PBMs disappear tomorrow, how do you believe employer health plans would be able to negotiate those drug prices with pharmaceutical companies? I know the answer will be long, so I will go ahead and ask this question to the Chair, submit it, and I appreciate I just wanted to get that for the record, and with that I yield back my time.

Chairman GOOD. Thank you. We will now go the Ranking Member, Mr. DeSaulnier, for his questions.

Mr. DESAULNIER. Thank you, Mr. Chairman. I want to followup on the Chairman's, Chairman Foxx's questions about the prohibition on gag rules. Starting with Ms. Monahan, and then Dr. Sachdev. If we required a plan's data to be treated as a plan asset under ERISA, how might that help with getting the information that Dr. Foxx was talking about?

Ms. MONAHAN. That would effectively kind of flip the framework we currently have on its head, so rather than the PBMs and TPAs kind of owning the data and setting the terms by which an employer can access it. It would say this is the employer's data, and the employer can then set terms, or Congress could set terms under which, you know, the TPAs, or PBMs could be using that. There are certain important functions that they would perform, so we would want to make sure that would still happen in some sense.

The employer, that would be their data, and they could have access to it. The one thing I would want to make sure is that there are the appropriate privacy protections to protect the plan members whose health information would be accessible.

Mr. DESAULNIER. Doctor, any comments?

Ms. SACHDEV. Yes. In addition to the gag clause where you say we are going to remove this, there is—it is one thing to say the gag clauses are gone. It is another thing, there is a lot of stalling that happens and getting the data to the employer.

It can take, you can make the request that they might give you the wrong data, it may take 18 months to get the data. I would really encourage you to think about a timeframe by which they have to give the data back. In Indiana, we put 15 business days in statute.

Again with the audits, we have a law now that says 85 to 100 percent of rebates have to go to patients or employers. How do we know that 100 percent or 85 percent, or any percent is actually getting? We have to have those audits at the drug level, not in aggregate.

I think what would be perhaps most transformational is with the Transparency in Coverage Act, all the insurance information, all the PBM direct pricing information, as these insurance companies have to put those prices on their machine-readable files on their own websites, the hospitals have to put it on their own websites.

They should all send a copy to you. You could put it in a master data base. You would be able to see how prices compare when policies change, monitor it, look for compliance. Also give the public access, and researcher's access. That way we would all be making evidence-based decisions in a policy manner, in a purchasing manner.

As mentioned, as you mentioned, employers do not have a lot of resources to do all this deep dive data analysis, so the Federal Government just getting a copy of these machine-readable files could really go a long way to help them.

Mr. DESAULNIER. Thank you. Ms. Tripoli, would you talk a little bit more about hospital facility fees and the cost to hospitals? It is interesting listening to this happening many years ago, 20 plus years ago, being on the governing body of a public hospital clinic in an area in the San Francisco Bay area, the east bay where Kaiser is very, a closed system, is dominant.

We were trying to move the high cost of what we called the aircraft carrier of the hospital, and so it was Kaiser, and so was Sutter, and so was Anthem is affiliated, into primary care, and into community-based clinics.

Now I am listening to this testimony, I am reading, and the hospitals seemed to have changed that model to sort of capture even lower cost at a higher cost reimbursement. Is that accurate?

Ms. TRIPOLI. That is. That is accurate. I completely agree. I think we want to make sure, as was mentioned earlier, that services are provided in the most safe and effective location possible, but what we are seeing is a complete shift to outpatient care where it is higher priced, higher cost services, to take advantage of a higher reimbursement.

Mr. DESAULNIER. Ms. Monahan, as a consumer, as personally as a consumer, as a survivor of cancer, and non-curable cancer, trying to navigate this is basically just giving up to a certain degree, and trusting your primary care doctor. Fortunately, I have a really good one. He has to advocate and figure out where are we sending you.

To get started on the pharmaceutical industry and going to Walgreens as opposed to a personal local pharmacy is just a hugely different world. Sticking to the just—the access to the facility. What does this mean for the consumer? I know my perspective; you just really count on your primary care physician.

Ms. MONAHAN. Very much so, and I think it really means that consumers are going to be paying a lot more because so many physician practices are now being purchased by hospitals and large health systems, and it is not really necessarily up to the physician, you know, but when they go and they see you out at this location

that is owned by the health system, the health system is going to tack on a bill.

That bill, how it is being processed under your insurance will often mean you are paying a lot more when you would go to see your physician. You might just have a copay, but now you have an additional hospital bill, and that might be a coinsurance charge, or you are paying for all of it under your deductible, so it is a lot more money just to go to your doctor.

Mr. DESAULNIER. Yes, it is awful for the consumer. Thank you, Mr. Chairman. I just want to mention my oncologist, in case he was listening, I rely on him too. I yield back.

Chairman GOOD. Thank you, Mr. DeSaulnier. Now we will go to Representative Comer from Kentucky.

Mr. COMER. Thank you, Mr. Chairman. Mr. Scott, it is good to see you. Following PCMA's statement regarding our recent oversight hearing on this topic, which criticized having a new entry to the market, Mr. Baker testified about the challenges he has faced. I wanted to give you a chance to answer a few of the same questions that were discussed during that meeting, during that hearing.

However, I first want to acknowledge that the Chief Financial Officer of CVS Caremark Aetna was quoted on May 31st at an industry conference when asked about potential reforms proposed in Congress as saying, "There's other ways in the economic model that we could adjust if one of those things changes." Advised his peers to "not worry about Congress."

Now your presence before us today and insistence on being the only voice testifying to Congress on potential reforms, leads me to believe you might have a different opinion of the importance of Congress. Mr. Scott, this poster shows Imatinib, a generic chemotherapy drug used to treat Leukemia.

Can cost the patient at CVS more than $17,000.00 for a 30 day supply. An identical prescription, a 30 day supply of Imatinib would only cost $72.00 at Cost Plus Drugs. Obviously, Imatinib does not cost $17,000.00 if Cost Plus Drugs can sell it for $72.00.

How would you explain to any patient or payer such as the Federal Government the benefit in CVS charging $17,000.00 for a drug that can be sold for only $72.00?

Mr. JC SCOTT. It is good to see you Chairman Comer, and I appreciate the opportunity to visit with you again. We have spent time together before, and I am glad that Mr. Baker is here, and has been able to testify in other forums, because I do believe to your point it is important we hear from a variety of voices.

PCMA certainly celebrates every new entrant into the market because we want a very competitive marketplace with a lot of choices. We have heard a lot today about frustration from employers that they cannot get the information they need from their current PBM. That is great. I can assume that they can flock to different business models as those develop in the marketplace.

I believe Congress has an incredibly important role to play, which is why I am here, and why we want to engage, because we all need to be working together toward trying to bring down the cost of prescription drugs. I cannot speak as to what the CVS representative was saying to his shareholder audience, other than to say I recognize that as policy change occurs, the importance of hav-

ing a pharmacy benefit company in existence to help employers and other plan sponsors manage their prescription drug cost, that value proposition is going to continue to be present.

That work needs to be done because if you disaggregate that, you lose that value of scale and being able to negotiate and harnessing group purchasing power. It is only going to increase costs if every employer and every plan sponsor has to do that on their own.

For your example on the chart, I cannot speak to the specific example with not having more knowledge of the patient's health plan, the cost sharing, the benefit design.

Mr. COMER. It is the same example I used in the oversight hearing on the PBM. Let me ask another question because my time is running short. Mr. Scott, CVS Caremark underwent a system enhancement last week, which removed the plan cost column, including for our example here, Imatinib.

Plan sponsors were previously able to see the total cost of the medication, and the total cost to their plan. Unfortunately, as PBMs professed to want transparency, and have a focus on providing plan sponsors with information, they are actively suppressing information available to plan sponsors.

Thankfully, this information magically became available again last night right before this hearing. Mr. Scott, I am having trouble reconciling these two things. We continually hear about how PBMs would like to provide transparency, but then see intermittent or incomplete information provided to plan sponsors.

Can you provide some insight into voluntary actions PBMs could take right now to provide this data to PBM clients?

Mr. JC SCOTT. Yes, sir. If a pharmacy benefit company is not providing the information that a client is requesting when they're drawing up their RFP, when they are designing their contract, then that client is going to move to another PMB. It is in the interest of the PBM to make sure they are providing the data.

Mr. COMER. Well, why have they not taken those actions? They talk about transparency, and that is what we have got other committees looking into this. We are going to have legislation to be more transparent. The Secretary testified in a committee hearing; transparency is the answer. Well, why will not the industry just be transparent?

Mr. JC SCOTT. I believe the industry is transparent.

Mr. COMER. I disagree. Respectfully.

Mr. JC SCOTT. I understand that. If the companies are not providing what the client is asking for, the client is going to move elsewhere. That is why we see new business models able to enter into the marketplace and differentiate in the kinds of contracts they're willing to offer.

Mr. COMER. The problem with the client is the industry is exhibiting vertical and horizontal manipulation of the pharmaceutical market. That is the problem, and that is what Congress is going to have to do, Mr. Chairman, to fix the problem. Transparency is a great political talking point, but Congress has been talking about that for years, and nothing is happening. I appreciate this Committee hearing. I look forward to working in a bipartisan way to try to get resolution to this problem. With that, Mr. Chairman, I yield back.

Chairman GOOD. Thank you, Mr. Comer, and again thanks for all of our witnesses here today. I represent a predominantly rural district, and I regularly hear, as I am sure many of my colleagues do about the importance of local, independent pharmacies, and how they're under attack from big pharma, and dying out, or struggling to survive.

Mr. Scott, your testimony cites data that would seem to disagree with what I am hearing from my constituents, and why do you think that is, or how would you counter that argument about the impact on local pharmacies?

Mr. JC SCOTT. Yes, sir. It is not our data, or not our data alone, this comes from the NCPA, the community pharmacy lobby. That is documented that we continue to see a stable marketplace when it comes to independent pharmacies across the country. What we've talked about a little bit here before during the course of the hearing is isolating those rural pharmacies, right?

Not the independents, the 83 percent independents, who are serviced by wholesalers through their pharmacy services and administrative organizations, or PSAOs that do a lot of negotiating work on their behalf. You have got these stand-alone rural pharmacies, often the only point of care where we really have to focus on making sure that they are able to have a sustainable business model, so that they can be there to serve patients.

That gets to the conversation we were having earlier about making sure there is a lot of different ways they can provide value to patients.

Chairman GOOD. One of the things that a lot of people in my district talk about is how Express Scripts, in particular, is offering a reimbursement rate that's so low that it is unaffordable for these small pharmacies to fulfill Tri-Care prescriptions. What would your response be to that?

Mr. JC SCOTT. A lot of this gets to the setting of pharmacy networks, so just like you said, a provider network on the hospital side. We work with our clients—our companies work with our clients to develop networks of pharmacies. Always with the goal of making sure that there is an access point nearby the patient's home where they can get access to their medications at a retail pharmacy.

In the Tri-Care system, the Department of Defense is involved in helping to set very specific network adequacy requirements that dictate like how far they have to be, as it is in the Medicare program, and in the commercial marketplace. That's the objective of the plan sponsor, is to develop a robust network to serve the patients that they represent.

Chairman GOOD. I switched gears in the interest of time to Mr. Baker here. Mr. Baker, some have claimed that increased transparency, which we talked a lot about today, actually causes prices to increase, and can result in collusion because it inhibits a payer's ability to privately negotiate discounts. What's your opinion on this?

Mr. BAKER. I think that transparency would do nothing but drive down costs. I think it is a fear tactic. I find it very interesting that we want to continue to point to the system as working, but again, costs have gone up every year. Quality is going down every year.

What we have been trying, and how we have allowed the gate keepers to run is not working.

This lack of transparency is driving a lot of those poor outcomes. I think people being able to really see like the poor State of Tennessee. I am paying $212,000.00 for this drug that your neighbor to the north, Kentucky, only gets $26,000.00. If that information is out there, and people then can say I do not want to pay $400.00 for a gallon of milk at, you know, my grocery store.

I am going to go over here because I know what a gallon of milk should cost, we are going to see a significant drop in pricing.

Chairman GOOD. There is no question. Your company's business model is to provide a transparent, cost-effective PBM option for employers. You have talked about how yours is different. What benefits have you seen to the industry and consumers from what your PBMs offer?

Mr. BAKER. I would say three things. One, we have seen decreasing costs for all of the clients that we work with, so because we are transparent, and we sit down and have deep conversations with them about the decisions they should make in the best interest of their plan, their costs go down.

Two, technology matters. We talk a lot about healthcare, and the poor technology in healthcare, and that is the same thing in the PBM industry. Most PBMs are still dealing in 35-year-old DOS based technology which makes reporting very limiting, makes the ability to customize very hard.

Technology then gives employers much more flexibility, and then finally, we inject a lot of pharmacy technicians and pharmacists that we hired from community pharmacy back into the system. PBMs have created a tremendous amount of exclusionary formularies and utilization management criteria.

Basically, what those words mean is they do not let the doctor write for the drugs that the doctor wants. They say no, doc, you cannot write for that drug. We, PBM, will not cover it. That puts a significant administrative burden on physician practices to try to figure out oh, Express Scripts has this drug. CVS has this drug.

We want to make sure that we help those physician offices out by saying here are the right drugs, and then work with the member to stay on that drug through the course of their therapy.

Chairman GOOD. Well again, I want to thank all of our witnesses today, and for your investment of time to be with us today, and I would like, without objection, there being no further business, the Committee stands adjourned. Thank you.

American Hospital Association™
Advancing Health in America

Washington, D.C. Office
800 10th Street, N.W.
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100

Statement

of the

American Hospital Association

for the

Committee on Education and the Workforce

Subcommittee on Health, Employment, Labor, and Pensions

of the

U.S. House of Representatives

"Competition and Transparency: The Pathway Forward For a Stronger Health Care Market"

June 21, 2023

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to submit this statement for the record as the Education and Workforce Subcommittee on Health, Employment, Labor, and Pensions examines a number of ways to strengthen the health care market.

MERGERS AND ACQUISITIONS HELP HOSPITALS MANAGE CURRENT FINANCIAL PRESSURES

Hospitals and health systems have faced historic challenges in the last several years. Mergers and acquisitions are important tools that some hospitals use to manage financial pressures and increase access to care for patients.

A recent report released by the AHA details the extraordinary financial pressures continuing to affect hospitals and health systems, as well as access to patient care. The

report found expenses across the board saw double-digit increases in 2022 compared to pre-pandemic levels, including for workforce, drugs and medical supplies and equipment. Hospitals and health systems have seen input cost increases for other essential operational services, as well, such as IT, sanitation, facilities management, and food and nutrition.

In addition, a major source of financial pressure for hospitals are the costs of complying with a complex web of local, state and federal regulations, excessive commercial payer administrative requirements, and chronic underpayments by the Medicare and Medicaid programs. It is well documented that neither Medicare nor Medicaid covers the cost of caring for its beneficiaries, and hospitals often struggle to make up for these financial losses. Exacerbating this pressure is the fact that Medicare and Medicaid account for most hospital utilization. In fact, 94% of hospitals have 50% of their inpatient days paid by Medicare and Medicaid, and more than three quarters of hospitals have 67% Medicare and Medicaid inpatient days.[1]

Merging with a hospital system can help some hospitals ease these financial burdens and improve patient care by providing scale to help reduce costs associated with obtaining medical services, supplies and prescription drugs, and enable health systems to reduce other operational costs.

Perhaps most important, mergers can allow struggling hospitals to remain open. Without mergers, some hospitals could shutter, patients could lose access to care and communities could suffer. This is particularly important for rural hospitals, where mergers and acquisitions have played a critical role in preserving access to care for patients and communities. An AHA analysis of the UNC Sheps Center rural hospital closure data between 2010 and 2020 showed that even though most rural community hospitals are affiliated with a health system, less than half of the hospitals that have been closed were system affiliated. This would indicate that of all the challenges facing rural hospitals that contribute to closures, being part of a system is likely not one of them. Health systems typically acquire rural hospitals when these hospitals are under financial distress. Research has shown that rural hospitals are less likely to close after acquisition compared to independent hospitals and that mergers have improved access and quality of care for rural hospitals.[2]

BENEFITS OF HOSPITAL MERGERS AND ACQUISITIONS

Hospital mergers and acquisitions can bring measurable benefits to patients and communities, including lower health care costs, improved quality and better access to health care.

---

[1] https://www.aha.org/system/files/media/file/2022/05/fact-sheet-majority-hospital-payments-dependent-on-medicare-or-medicaid-congress-continues-to-cut-hospital-reimbursements-for-medicare.pdf
[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9250050/

Lower Health Care Costs

Acquisitions and mergers can help reduce health care costs and create a fiscally sustainable environment for health care delivery for patients and communities. Mergers with larger hospital systems can provide community hospitals the scale and resources needed to decrease costs by increasing administrative efficiencies and reducing redundant or duplicative services. A Charles River Associates analysis for the AHA shows that hospital acquisitions are associated with a statistically significant 3.3% reduction in annual operating expenses per admission at acquired hospitals, along with a 3.7% decrease in net patient revenue per adjusted admission.[3]

The same report shows that additional substantial savings come from improved IT systems and advanced data analytics. Consolidated hospitals can often better invest in IT infrastructure for both clinical and financial data that can be used to identify best practices for more cost-effective, integrated and streamlined care. These data systems have substantial but largely fixed costs, making them effectively inaccessible to independent hospitals.

Improved Quality

Emerging research has demonstrated a clear association between consolidation and quality improvement. For example, one study found that a full-integration approach is associated with improvements in mortality and readmission rates, among other quality and outcome improvements.[4] Another study found significant reductions in mortality for a number of common conditions — including acute myocardial infarction, heart failure, acute stroke and pneumonia — among patients at rural hospitals that had merged or been acquired.[5]

Better Access to Care

Mergers and acquisitions can help some hospitals improve access to care by expanding the types of specialists and services available to patients. According to an analysis by the health care consulting firm Kaufman Hall, nearly 40% of affiliated hospitals added one or more services post-acquisition. Almost half of all hospitals acquired by an academic medical center added one or more service. Patients at hospitals acquired by academic medical centers or large health systems also gained improved access to tertiary and quaternary services.[6]

Mergers and acquisitions also are a vital tool that some health systems use to keep financially struggling hospitals open, thereby averting bankruptcy or even closure. When

---

[3] https://www.aha.org/guidesreports/2021-08-18-hospital-merger-benefits-econometric-analysis-revisited-executive-summary
[4] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2787652
[5] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2784342
[6] https://www.aha.org/system/files/media/file/2021/10/KH-AHA-Benefits-of-Hospital-Mergers-Acquisitions-2021-10-08.pdf

hospitals become part of a health system, the continuum of care can be strengthened for patients and the community, resulting in better care and decreased readmission rates.

This is particularly true in rural and underserved communities. Partnerships, mergers or acquisitions can be a means for creating more cohesive care, making it easier for patients to access specialists or services in the acquiring system. In this way, consolidation can ensure that care remains in the community.

INSURERS LEVERAGE THEIR VERTICAL AND HORIZONTAL MARKET POWER

The AHA appreciates that the subcommittee is examining various aspects of the health care industry in this hearing. To help reduce prices and increase quality, we urge the subcommittee to review how large, national commercial insurers have affected the health care system through rapid consolidation, particularly the increased vertical and horizontal integration that the commercial insurance market has experienced in recent years. For example, according to the Medicare Payment Advisory Commission (MedPAC), although initially thought to bring down costs, the vertical consolidation of insurers with providers (such as a nationally dominant Medicare Advantage plan purchasing large physician practices throughout the country) may not generate taxpayer savings.[7] Additionally, earlier this month the USC Schaeffer Center for Health Policy and Economics found that overpayments to Medicare Advantage plans now exceed 20% or $75 billion annually.[8] This example illustrates broader consolidation concerns within the commercial insurance market — where certain commercial insurers today rank in the top seven of the Fortune 500 list of largest companies by revenue. It also underscores the urgent need for reform.

Hospitals and health systems face significant pressure from these health insurance companies and private equity firms, which are leveraging their market power to drive up hospital and health system costs. For example, in nearly half of all markets, a single health insurer controls at least 50% of the commercial market.[9] Health insurers can use this market power to implement policies that compromise patient safety and raise costs, such as prior authorization delays, denying medically necessary coverage, or forcing patients to try potentially ineffective treatments or therapies.[10]

Moreover, commercial insurers have spent billions of dollars acquiring physician practices and other sites of care, amassing major market power through vertical

---

[7] https://www.beckerspayer.com/payer/meet-americas-largest-employer-of-physicians-unitedhealth-group.html
[8] https://healthpolicy.usc.edu/research/ma-enrolls-lower-spending-people-leading-to-large-overpayments/
[9] https://www.ama-assn.org/delivering-care/patient-support-advocacy/competition-health-care-research
[10] https://www.aha.org/white-papers/2022-07-28-commercial-health-plans-policies-compromise-patient-safety-and-raise-costs

integration and steering patients to sites of care that they increasingly own through insurance benefit design that may not align with the best interests of patients.

UnitedHealth, under its subsidiary Optum, has acquired, for example, Crystal Run, Kelsey-Sebold and Atrius Health in the past three years and is now the largest employer of physicians nationwide, with over 70,000 employed or affiliated physicians.[11] In 2023 alone, CVS Health has announced plans to spend over $15 billion to acquire both Signify Health and Oak Street. Studies have shown that highly concentrated insurer markets are associated with higher premiums and that insurers are not likely to pass on to consumers any savings achieved through lower provider rates.[12] Though many contend that insurers like UnitedHealth Group (over $324 billion in revenue in 2022, covering over 46 million Americans) and Elevance (over $155 billion in revenue over the same period, covering over 47 million Americans) are helpless in their dealings with local hospitals and health systems, that is far from the truth.

MEDICARE SITE-NEUTRAL PAYMENT REDUCTIONS

The AHA strongly opposes additional site-neutral payment policies and appreciates the opportunity to clarify that the notion that hospitals engage in "dishonest billing" practices to optimize higher reimbursement rates is inaccurate and intentionally misleading. Hospitals cannot lawfully obfuscate the location of care delivery on their bills. Hospitals and other providers bill according to federal regulations, which require them to bill all payers — Medicare, Medicaid and private payers — using codes that indicate the location of where the service is provided. Additionally, current Medicare regulations require that beneficiaries who are treated in an off-campus hospital outpatient department (HOPD) receive a notification of their expected financial obligations and be informed that they will receive bills from both the doctor and hospital. This is not "dishonest billing" — it is simply following current federal regulations.

Existing site-neutral payment cuts have already had a significantly negative impact on the financial sustainability of hospitals and health systems and have contributed to Medicare's chronic failure to cover the cost of caring for its beneficiaries. According to MedPAC, overall Medicare hospital margins were negative 6.3% in 2021 after accounting for temporary COVID-19 relief funds. Without these funds, the overall Medicare margin for 2021 remained depressed at negative 8.2% after hitting a staggering low of negative 12.3% in 2020. On average, Medicare only pays 84 cents for every dollar hospitals spend providing care to Medicare beneficiaries. Moreover, overall median hospital operating margins were negative throughout 2022 and into the beginning of 2023. Site-neutral cuts have already contributed to these shortfalls and any further expansion of these policies will exacerbate this situation and threaten patients' access to quality care.

---

[11] https://www.beckerspayer.com/payer/meet-americas-largest-employer-of-physicians-unitedhealth-group.html
[12] https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.0548

Site-neutral policies also fail to account for the fundamental differences between HOPDs and other sites of care. The cost of care delivered in hospitals and health systems takes into account the unique benefits that they provide to their communities. This includes the investments made to maintain standby capacity for natural and man-made disasters, public health emergencies and unexpected traumatic events, as well as deliver 24/7 emergency care to all who come to the hospital, regardless of ability to pay or insurance status. This standby role is built into the cost structure of hospitals and is supported by revenue from direct patient care — a situation that does not exist for any other type of provider. Expanding site-neutral cuts to HOPDs and the outpatient services they provide would endanger the critical role they play in their communities, including access to care for patients.

Furthermore, hospital facilities treat patients who are sicker and have more chronic conditions than those treated in physician offices or ambulatory surgical centers.[13] Hospitals are better equipped to handle complications and emergencies, but this often requires the use of additional resources that other settings do not typically provide. Hospital facilities also must comply with a much more comprehensive scope of licensing, accreditation and other regulatory requirements compared to other sites of care.

Some groups have suggested that hospitals are acquiring off-campus physician practices so that the hospital can "flip the sign" and receive a higher Medicare reimbursement for providing a similar service. However, this is a deliberate misrepresentation of the facts. Under current law, any off-campus HOPD that was not billing Medicare before November 2015 is no longer paid at the hospital outpatient prospective payment system rate. Instead, this HOPD is already paid at a site-neutral rate under the Medicare physician fee schedule (PFS) for nearly all services it furnishes.

Site-neutral policies are based on the flawed assumption that PFS payment rates are sustainable rates for physicians. However, the truth is much different. According to the American Medical Association, "Medicare physician payment has effectively been cut 26%, adjusted for inflation, from 2001–2023. …The discrepancy between what it costs to run a physician practice and actual payment combined with the administrative and financial burden of participating in Medicare is encouraging market consolidation and threatens to drive physicians out of rural and underserved areas."[14]

Additionally, physicians are increasingly turning to hospitals, health systems and other organizations for financial security, and to focus more on clinical care and less on the administrative burdens and cost concerns of managing their own practice.[15] The

---

[13] https://www.aha.org/guidesreports/2023-03-27-comparison-medicare-beneficiary-characteristics-report
[14] https://www.ama-assn.org/practice-management/medicare-medicaid/advocacy-action-leading-charge-reform-medicare-pay
[15] https://www.merritthawkins.com/uploadedFiles/merritt-hawkins-2021-resident-survey.pdf

administrative and regulatory burden associated with public and private insurer policies and practices, coupled with inadequate reimbursement rates, are important barriers to operating an independent physician practice. A recent survey of physicians conducted by Morning Consult on behalf of the AHA found that over 90% of physicians think it has become more financially and administratively difficult to operate a practice and that 84% of employed physicians reported that the administrative burden from payers had an impact on their employment decision.[16]

These factors are creating unworkable environments forcing physicians to prioritize administrative duties over caring for patients. The result is increased burnout among physicians, and there are no signs of it stopping anytime soon.[17] Physicians are searching for alternative practice settings that reduce these burdens and provide adequate reimbursement, while allowing them to focus on patient care. Hospitals and health systems are a natural fit to help physicians alleviate many of these burdens.

CONCLUSION

The AHA appreciates your efforts to examine how to create a stronger health care market and looks forward to continuing to work with you to address these important topics on behalf of patients and communities.

---

[16] https://www.aha.org/fact-sheets/2023-06-07-fact-sheet-examining-real-factors-driving-physician-practice-acquisition
[17] https://www.uhcprovider.com/en/resource-library/news/2023/new-requirements-gastroenterology-services.html

June 16, 2023

The Honorable Bob Good
Chairman
Subcommittee on Health, Employment,
Labor and Pensions
Committee on Education & the Workforce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Mark DeSaulnier
Ranking Member
Subcommittee on Health, Employment,
Labor and Pensions
Committee on Education & the Workforce
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Good and Ranking Member DeSaulnier:

The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN), the American Gastroenterological Association (AGA), the American College of Gastroenterology (ACG) and the American Society for Gastrointestinal Endoscopy (ASGE) write on behalf of our members out of concern and desperation. Together, our four societies represent virtually all practicing gastroenterologists in the United States. We have received an increasing number of disturbing reports from our physician members regarding the obstacles and restrictions their patients are experiencing when attempting to gain access to prescribed, lifesaving biologic and small molecule therapies for gastrointestinal (GI) disease and disorders.

We commend your Subcommittee for scheduling a hearing for June 21 on competition and transparency in the health care market. During that hearing, we strongly encourage the Subcommittee to examine the practices of pharmaceutical benefit managers (PBMs) and insurance companies that are resulting in delayed or denied access to biologics to great inflammatory bowel diseases (IBD). We hope the information contained in this letter will be a useful resource to you as consider how Congress should respond.

PBMs, insurance companies, and drug manufacturers have created an elaborate and opaque system to control and manipulate drug prices. Irrespective of this process, newer biologic therapies and small molecules used to treat IBD are expensive. As a result and in an effort to control costs, insurers and PBMs have implemented a series of roadblocks under the guise of "drug utilization management," increasing administrative costs for physicians, and delaying delivery of medically necessary treatments to patients. The use of utilization management tactics, including "step therapy" (or "fail first" protocols), prior authorization, and insurance company decisions that require patients to switch biologics

when they are stable on current therapy, are all becoming increasingly common with detrimental effects on patients with IBD.

Four recently published stories[1,2,3,4] shine a bright light on the extent to which insurance companies are making health care decisions over the recommendations of treating physicians to the significant detriment of patient health and outcomes. These types of scenarios have become commonplace for physicians who treat children and adults with IBD, which include Crohn's Disease and Ulcerative Colitis. Our medical societies have met in recent years with major insurance companies in an attempt to protect children and adults living with IBD who have been subject to changes in coverage policies and formularies that require patients to switch their biologic medications even though they are currently stable on their authorized treatment. Insurers often make formulary changes without effective communications to patients and providers.

Our societies have made numerous appeals to insurance companies to provide an exception to non-medical switching for patients stable on their approved biologic therapy. When payers have made exceptions, they are typically narrow, require physicians to appeal and seek authorization to keep their patient on existing treatment, or result in greater out-of-pocket costs to patients. The process of reauthorization for patients who are stable on existing therapy is often accompanied by delays and disruption in care.

Drug utilization management protocols also restrict access of new medicines to children and adults. For example, early onset of IBD in children is a risk factor for more severe course of disease and, therefore, requires timely initiation of biologic therapy, often at higher doses than older children and adults. Under the current drug development system, drugs are first tested and approved in adults through expensive clinical trials. After approval in adults, pediatric studies of the same medication are then performed, but such studies can often take a decade or more to complete. For example, the drug vedolizumab, an essential tool in the treatment for Crohn's Disease and ulcerative colitis, was approved by the Food and Drug Administration (FDA) in 2014, but clinical trials in children have yet to be completed. Thus, it is often medically necessary for pediatricians to use these drugs "off label" in children. To quote the American Academy of Pediatrics, "the term 'off-label' does not imply an improper, illegal, contraindicated, or investigational use. Therapeutic decision-making must always rely on the best available evidence and the importance of the benefit for the individual patient." However, insurers and PBMs frequently automatically deny care on the basis of age alone. This constitutes a direct form of discrimination against children that can have terrible consequences for a sick child.

---

[1] "I wrote about high-priced drugs for years. Then my toddler needed one." *Washington Post*, Jan. 30, 2023. https://www.washingtonpost.com/wellness/2023/01/30/high-priced-drugs-step-insurance-policies/

[2] "UnitedHealthcare Tried to Deny Coverage to a Chronically Ill Patient. He Fought Back, Exposing the Insurer's Inner Workings." *ProPublica*, Feb. 2, 2023. https://www.propublica.org/article/unitedhealth-healthcare-insurance-denial-ulcerative-colitis

[3] Insurance requirements for prior authorization may prompt 'devastating' delays. Lauren Sausser, Kaiser Health News, March 10, 2023. https://www.cnn.com/2023/03/10/health/prior-authorization-khn-partner/index.html

[4] How Cigna Saves Millions by Having Its Doctors Reject Claims Without Reading Them; Patrick Rucker, Maya Miller and David Armstrong March 25, 2023. https://www.propublica.org/article/cigna-pxdx-medical-health-insurance-rejection-claims?utm_medium=social&utm_source=twitter&utm_campaign=TwitterThread

Considerable integration in the PBM industry has compounded the issue. Today, the three biggest PBMs are integrated or owned by a major health insurance provider. Therefore, we support thorough examination of PBM practices by Congress and the Federal Trade Commission. Congressional hearings have largely focused on the role of PBMs and the cost of prescription drugs to consumers. In addition to contracting with PBMs to negotiate prices of prescription drugs, insurance companies use PBMs to design their drug benefits and process claims. PBMs extract discounts on drug prices by increasing volume for preferred manufacturers and suppliers; they do this by restricting patient choice of drugs. The more restrictive the drug formularies are, the bigger the discounts the PBMs extract from drug companies and suppliers.

We acknowledge that policies included in the *Inflation Reduction Act* have the potential to lower the prices of biologic products and, perhaps eventually, will obviate the need for prescription drug utilization management tools, but this will take time and our patients simply cannot wait.

In many respects, by virtue of their integration, investigation into PBMs puts insurance companies under the microscope as well. However, the growing and egregious use of utilization management practices by PBMs, which is being endorsed by the insurance companies with which they are contacted or affiliated, are having detrimental effects on patient care and safety. Our societies call for the investigation and oversight of insurance companies who control and direct treatment coverage decisions for their enrollees and their use or endorsement of utilization management practices that result in denials of or delays to medically necessary care, and we ask Congress to enact common sense legislation — such as the *Safe Step Act* (H.R. 2630) — this year that prioritizes patient care and safety over insurance company profits.

The recently published final rule by the Centers for Medicare and Medicaid Services (CMS) to put guardrails in place for prior authorization processes used by Medicare Advantage plans does not include prior authorization and step therapy for Part B drugs, which include biologics used by IBD patients.[5] Likewise, a proposed rule that would automate and standardize the prior authorization process across public and private payers and require more timely reviews and more transparency is a good step in the right direction; however, this proposed rule also excluded Part B drugs, which are crucial for our patients' care and long-term management.[6] It is clear congressional intervention is needed to prioritize the interests of patients living with IBD and other diseases and disorders that require treatment with biologic and small molecule therapies.

Evidence of Patient Harm

A retrospective study of 190 pediatric patients with IBD published in *Pediatrics* found that prior authorization and complicated prior authorizations (requiring appeal, step therapy, or peer-to-peer

---

[5] Medicare Program: Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, etc. Posted by the Centers for Medicare&Medicaid Services on April 5, 2023. https://public-inspection.federalregister.gov/2023-07115.pdf. This document is scheduled to be published in the Federal Register on 04/12/2023 and available online at federalregister.gov/d/2023-07115, and on govinfo.gov.

[6] Administrative Simplification: Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard. Posted by the Centers for Medicare&Medicaid Services on Dec 20, 2022https://www.regulations.gov/document/CMS-2022-0204-0001

review) did not deter the use of certain medications, but were associated with 10.2-day and 24.6-day delays in biologic initiation time, respectively. This is clinically significant because delays in care in IBD increase the risks of penetrating complications, future need for surgery, and corticosteroid-related toxicities, including growth failure, fractures, thromboembolism and infections.[7] The study concluded there is roughly one potentially avoidable health care utilization outcome for every eight patients requiring prior authorization.

Many insurance companies use "step therapy," or "fail first," protocols where treatment with an older, less effective, but cheaper medication is required before use of a more expensive medication. In IBD, step therapy may require documented nonresponse to an older agent, known to be inferior with a worse adverse effect profile, before a biologic can be prescribed.[8] These insurance companies are dictating medical care and clinicians are being forced to prescribe medications that they do not feel are appropriate. Equally problematic is that the majority of these policies are inconsistent with current evidence-based IBD treatment guidelines.[9]

It is common for patients who are doing well on their therapy to receive a denial of care by an insurance company that changes the patient's treatment as biologic products move on and off formulary. Switching of biologic therapies, particularly in pediatric patients, have been associated with adverse patient outcomes.

Patients, in particular children, may also require higher doses of a biologic than those approved by the FDA; yet, insurance companies are increasingly rejecting dosing of medications above their FDA approved dose. This type of scenario was detailed in a recently published story about UnitedHealthcare's refusal to approve off-label or higher dosing regimens for a patient with a severe case of ulcerative colitis.[10]

An abstract was presented at a major GI scientific conference this May with the results of a nationwide survey of 373 gastroenterologists regarding the effect of prior authorization for biologics to treat IBD on patient outcomes, medical decision making and provider burden.[11] Of the respondents, 97 percent reported prior authorizations somewhat-to-greatly worsen care, with 82 percent reporting that prior authorizations moderately-to-greatly limit their ability to provide optimal care. The vast majority of physicians (83%) reported that prior authorizations delayed biologic initiation and contributed to a hospitalization or surgery. Ninety-five percent reported the clinical burden of prior authorization has increased over the past five years. The administrative burden is important to highlight as this is likely contributing to the burnout crisis the medical field is currently experiencing.

---

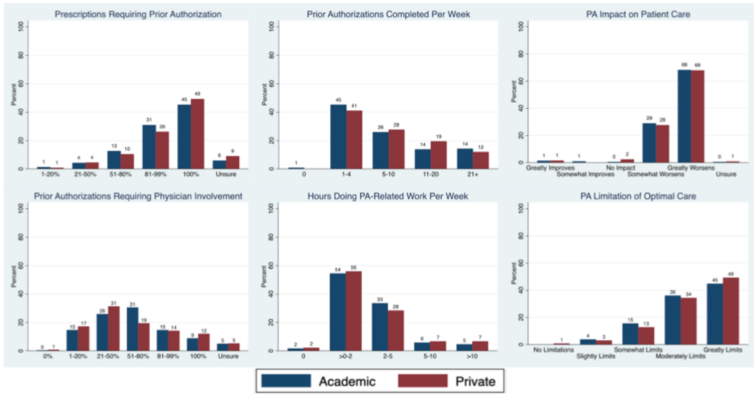
[7] Constant BD, de Zoeten EF, Stahl MG, et al. Delays Related to Prior Authorization in Inflammatory Bowel Disease. Pediatrics. 2022;149(3):e2021052501

[8] Kahn SA, Bousvaros A. Denials, Dilly-dallying, and Despair: Navigating the Insurance Labyrinth to Obtain Medically Necessary Medications for Pediatric Inflammatory Bowel Disease Patients. J Pediatr Gastroenterol Nutr. 2022 Oct 1;75(4):418-422. doi: 10.1097/MPG.0000000000003564. Epub 2022 Jul 15. PMID: 35836325.

[9] Ibid.

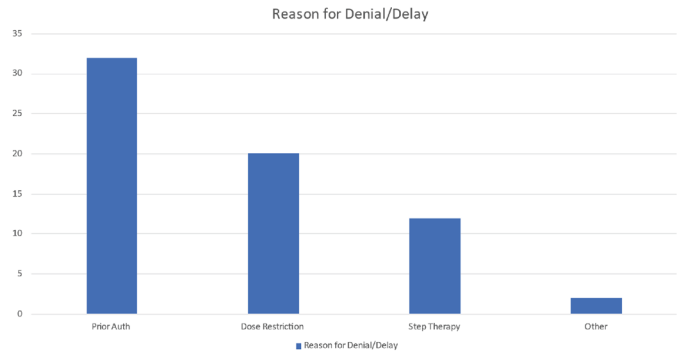
[10] "UnitedHealthcare Tried to Deny Coverage to a Chronically Ill Patient. He Fought Back, Exposing the Insurer's Inner Workings." ProPublica, Feb. 2, 2023. https://www.propublica.org/article/unitedhealth-healthcare-insurance-denial-ulcerative-colitis

[11] Constant BD, Albenberg L, Mitchel E, et al. Prior Authorizations for IBD Biologics Delay Therapy, Impact Decision Making, and Lead to Serious Adverse Events: 2022 Nationwide Provider Survey. 2023 Digestive Disease Week Annual Meeting, Chicago, IL, USA.



In an effort to better document the use of prior authorization, step therapy and other utilization control tactics in pediatric IBD patients on an ongoing basis, physician members of NASPGHAN and Improve Care Now (ICN) recently created a survey to be completed by physicians every time there is an issue with a payor or PBM, for example a denial, delay of care, or extra administrative time. The results of this survey will eventually be published.

Of the physician responses collected to date, the median delay of medication approval was 19 days. Twenty-three percent reported their patient had an adverse outcome due to delay, and 22 percent of patients had a hospitalization or extended length of hospital stays. In the majority of cases, treatment was eventually approved. However, delays and denials occurred across all major insurance companies, as well as Medicaid and TRICARE.



Survey results collected between March 8-23,

The commentary being collected through the survey highlights the suffering pediatric patients are needlessly enduring as a result of insurance company tactics. Examples include:

- 17-year-old girl in Massachusetts was hospitalized and received IV antibiotics and endoscopy after insurance company-induced prior authorization delays. Access to treatment delayed by 20 days.

- 17-year-old male in New York denied coverage to prescribed biologic therapy because he had not first "failed" on steroids or immunomodulating agents. The patient's quality of life was impacted and resulted in a four-day hospitalization. Coverage of the prescribed biologic was eventually approved. Access to treatment delayed by 60 days.

- 15-year-old male in California was in remission with current biologic administered every four weeks for two years. The patient has a complicated history of fistulas and developed antibodies to two other biologics. At the beginning of 2023, his insurance company denied his every four-week treatment. The physician made multiple attempts to contact the insurance company and a letter of medical necessity was written with no reply. At the time of the report, the patient was still waiting approval for treatment at four-week intervals.

- 13-year-old female in Washington required prior authorization for her physician-recommended treatment. Delays in approval resulted in deterioration of the patient's condition. The prior authorization peer-to-peer review was scheduled for seven days after initial denial with no option to expedite it. Due to significant anemia and fatigue, the patient collapsed, falling and hitting her head. The result was hospitalization and subsequent admission where her recommended treatment was ultimately initiated. Treatment delayed by 18 days.

While the examples above highlight how children are being hurt by these policies, adult patients face similar challenges, including when they require doses at higher levels or at more frequent levels than approved by the FDA. When insurers deny a medically necessary therapy, the physician practice spends an extraordinary amount of time modifying orders, completing prior authorizations, conducting peer-to-peer reviews, and writing letters of medical necessity which detracts from the care of other patients. Prior authorization, step therapy and other utilization controls result in unnecessary delays in patient care, often with deleterious effects to the patient's overall health, while shifting costs onto physicians who are uncompensated for the administrative time and staff required for authorization and appeals when coverage of a prescribed treatment is initially denied.

Our societies request an opportunity to meet with you in an effort to work toward increased oversight of insurance companies and polices that will protect IBD patients by ensuring that insurance plan policies do not delay or deny access to medically necessary care. For more information and to schedule a meeting, please contact Camille Bonta at cbonta@summithealthconsulting.com or (202) 320-3658.

Sincerely,

Jenifer Lightdale, MD
President
North American Society for Pediatric Gastroenterology Hepatology and Nutrition

Jennifer A. Christie, MD, FASGE
President
American Society for Gastrointestinal Endoscopy

Barbara H. Jung, MD, AGAF
President
American Gastroenterological Association

Daniel Pambianco, MD, FACG
President
American College of Gastroenterology

Committee on Education and the Workforce
Subcommittee on Health, Employment, Labor, and Pensions

"Competition and Transparency:
The Pathway Forward for a Stronger Health Care Market"
June 21, 2023

JC Scott, President and CEO
Pharmaceutical Care Management Association

Supplemental Statement

According to pharmacy count data from the National Council for Prescription Drug Programs (NCPDP) – the gold standard for this type of data – over the last ten years, the number of independent retail pharmacies nationwide increased by 1,638 stores or 7.5%. While we see fluctuations in the number of independent pharmacies in some areas, overall the marketplace is stable. Between 2022 and 2023, both the NCPDP data and IQVIA data put out by NCPA shows that the number of independent pharmacies increased by 0.4%.

Julia Bogue

Director
Innovation and Human Resources

June 20, 2023

The Honorable Bob Good
Chairman
Subcommittee on Health, Employment, Labor and Pensions
Committee on Education and the Workforce
U.S. House of Representatives
Washington, DC 20515

The Honorable Mark DeSaulnier
Ranking Member
Subcommittee on Health, Employment Labor and Pensions
Committee on Education and the Workforce
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Good and Ranking Member DeSaulnier

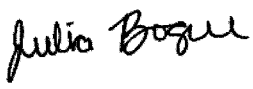
The National Association of Manufacturers is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturing employs nearly 13 million Americans and contributes $2.90 trillion to the U.S. economy annually. Manufacturers pay workers over 18% more than average for all businesses and 99% of manufacturers offer health benefits to employees. Manufacturers go to great lengths to provide robust health insurance offerings to employees and welcome the subcommittee's hearing on "Competition and Transparency: The Pathway Forward for a Stronger Health Care Market."

Large and small manufacturers continue to cite rising health care expenses as one of their top business concerns. In a recent survey of NAM members, 95% described the costs associated with offering health care to employees as expensive. Manufactures support applying free enterprise principles to all aspects of health care policy reform such as protecting IP, encouraging transparency, opposing price control-oriented solutions and avoiding costly Medicare for All.

Transparency is particularly vital when analyzing pharmacy benefit managers, companies first established to manage the cost of prescription drugs that are contributing to soaring health care costs and driving up the price of medications. Manufacturers support reforming the PBM model to ensure that savings are passed through to employer health care sponsors and consumers.

Manufacturers support policies that will promote innovation and value by encouraging reforms that are in step with the next generation of health care delivery. Below you will find our recommendations on a variety of health care reforms and related issues that are consistent with these principles and would support a stronger economy and healthier country. These principles were previously submitted to the subcommittee as well as the Healthy Future Task Force in December 2022. The NAM stands ready to work with you as this effort continues.

Sincerely,



Julia Bogue

Health Care Reforms to Improve Outcomes

Improving Transparency in Health Care

Manufacturers appreciate ongoing efforts to improve transparency in health care. Our industry has experienced the impacts of cost variation related to a range of health care services. These impacts can make health coverage more frustrating and expensive, for both consumers and employers who sponsor coverage. Price variations range from state to state, county to county and even within a city's limits. Price and service comparisons under the current paradigm are often impossible or overly complicated. Making an informed decision is challenging because health care information important to and associated with addressing a health event is not always in one place and not easily understood by the layman. Manufacturers support transparency, better value in health services that are paid for by employers and delivered by health care partners, improved and more efficient payment arrangements and—most importantly—better health outcomes.

Our members provide coverage for millions of Americans, and the ability to access data and appropriately harness relevant information will improve health care decision-making at all levels. Claims data provide valuable information to employers and the federal agencies responsible for managing multiple health coverage programs for various populations. Regulatory barriers to leveraging and exchanging standardized data hamper the health care system's ability to drive continuous improvements and innovations in medical research and care delivery. Such constraints—many self-imposed by federal regulators and Congress—are deterrents to innovation that can help solve some of the most pressing medical and fiscal challenges. However, collecting data for the sake of data is not purposeful, and manufacturers urge approaches that serve an important consumer-driven purpose (i.e., reduced costs, improved quality, etc.) that also balance the burdens of collecting and reporting data.

Of note, several states have explored and pursued health care pricing transparency initiatives and state-based all-claims databases that include hospital and provider pricing of services. Approaches and tools to address transparency have varied, and results have been mixed. Ultimately, a range of experts and studies have found that how information is conveyed to consumers will influence how consumers behave when presented with the opportunity to price shop and assess the quality of health care services. Manufacturers believe that the private sector is well-positioned to advance consumer-friendly platforms. The private sector is also well-suited to analyze and assess public and private data to make information actionable. However, the challenge of collecting raw data, accessing claims made by both public and private payers and discerning what data are most helpful to determine and ultimately improve the quality of care is worthy of a full public debate so long as a clear goal is articulated, and market-based principles are maintained.

Manufacturers also support the advancement of pharmacy benefit manager reform and a further examination of pharmaceutical pass-through savings. Public-private structures help achieve both success and savings, but misaligned incentives must be changed so that plan sponsors and consumers can fully realize the benefits of savings. As health care costs continue to escalate, bending the cost curve without sacrificing access and quality care remains a priority for manufacturers.

Health Information Technology

Manufacturers believe that an interoperable health system should not be an elusive goal, and that it holds great promise to transform the delivery, quality and cost of health care. The technology is available, and businesses have the capability to deliver and realize the potential of a fully connected health care system. However, the regulatory framework that exists today remains fragmented and was designed before the digitization of our economy. Privacy laws and regulations need updating so that the deployment and adoption of new innovations to improve connectivity in our health care system can flourish. For example, the current approach does not allow for the rapid sharing of information or make data more accessible to aid in broader public health goals and improved health outcomes. To unleash a new wave of consumer-driven health care innovation and enhance the patient–provider experience, we need a revised privacy framework that recognizes the strengths of the Health Insurance Portability and Accountability Act and includes opportunities for better information sharing for health care coordination. This can be accomplished without sacrificing patient privacy and by maintaining critical protections of personal data that are currently safeguarded under HIPAA. Ultimately, a patient receiving care should be able to walk into any provider facility and have medical records seamlessly uploaded so that providers are offering the best and most informed care for the patient.

Reducing Patient Out-of-Pocket Spending

Health savings accounts allow employees to have more control of their health care spending, and employers are increasingly offering consumer-driven high deductible health plans paired with HSAs. Increasing HSA limits and modernizing the rules governing HSAs would encourage savings for future health care expenses and provide the flexibility patients need to have greater control over their own health care decisions. As the demand for HSAs grows, greater flexibility is needed to ensure that consumers can take full advantage of changes and innovations in the delivery of health care. Since HSAs were established close to 20 years ago, there have been significant advancements in health benefits outside of traditional medical insurance policies. These include the use of care coordination and medical homes, telemedicine, direct primary care, onsite and near site primary medical care sponsored by employers, retail clinics and incentives such as fitness memberships to promote wellness. Additionally, management of chronic disease is an increasing priority, and further efforts should be made to provide greater flexibility for chronic disease reimbursement with HSAs. While HSAs are one tool to prepare for out of pocket health costs, and manufacturers urge Congress to advance legislation that modernizes and aligns the utilization of HSA accounts with today's health care landscape while providing employers added flexibility to design best-in-class benefits for their employees, Congress should also consider other tools which would allow Americans to put aside income in a dedicated account for health expenses regardless of the health coverage they receive and that functions similar to a Roth savings account.

Ensuring the Full Potential of Value-Based Arrangements

Manufacturers are encouraged by the potential for health care innovation through outcomes-based health care arrangements. These arrangements would align incentives across a range of parties—health care providers, employers, patients, insurers and pharmaceutical and life sciences manufacturers—so that delivery of care, payment arrangements and clinical outcomes are achieved in an efficient manner. Collaboration and improved benefit design hold the promise to change how health care is paid for and delivered. Improving data and modernizing relevant outdated regulations that prevent these value-based arrangements from realizing their full potential would help address rising premiums and pharmacy costs effectively.

This shift to reward value in health care delivery through value-based arrangements is truly transformational. Manufacturers are enthusiastic to realize the potential efficiencies that connect payment for a medicine to patient outcomes. To that end, manufacturers see promise in efforts to advance VBAs for prescription drugs in federally sponsored programs as a market-based solution to price setting and value determination. Manufacturers are encouraged by the introduction of H.R. 2666, the Medicaid VBPs for Patients (MVP) Act by Representatives Guthrie and Eshoo and see the legislation as a step forward. There is concern however, around the vagueness surrounding the Medicaid Drug Rebate Status and reference to the Federal Register in the legislation.

Maintaining Association Health Plans

The Department of Labor had previously made reforming, advancing and strengthening association health plans a leading priority. Manufacturers are grateful for this past leadership, because small businesses in particular experience challenges in offering affordable health coverage to employees. Manufacturers have urged this administration to maintain a similar posture around association health plans to provide ongoing regulatory certainty. However, manufacturers also believe legislation is needed to better ensure the longevity and sustainability of AHPs as an affordable health insurance coverage option. Small employers value this accessibility to a broad range of health insurance products (both fully insured and self-insured) for their employees as well as the opportunity to achieve greater efficiencies in managing health benefits over the long term. This affordable insurance option should enjoy regulatory consistency and be affirmed by Congress.

Continuing to Advance the Potential of Wellness Programs

In order to support voluntary wellness programs, the various regulations guiding these programs should be consistent and predictable. The Equal Employment Opportunity Commission withdrew new proposed rules issued in early 2021 that would have set important parameters in place to guide these incentive programs. Today, conflicts remain between the Affordable Care Act and nondiscrimination statutes. As employers work through these challenges and continue to seek clarity, Congress should not add to existing confusion or regulatory burdens. Manufacturers believe that participation and engagement in workplace wellness programs will improve employee health, reduce absenteeism and promote productivity with the potential to lower health care premiums. This is an important area of employer-sponsored health care that will need continued review and attention in light of litigation and changes in leadership at the EEOC.

Addressing Competition

While manufacturers strongly support increased access to affordable prescription drugs, consumer safety should always be our paramount public policy concern. Importation and reimportation could expose consumers to counterfeit and adulterated therapies. Drug importation creates a needless risk to public health. Maintaining important strides in consumer protection and safeguarding the reputation of quality drugs approved by the Food and Drug Administration for marketing in the United States are clear priorities that we urge Congress to continue recognizing.

Manufacturers are concerned with the changes to the Medicare Part D program as a result of the Inflation Reduction Act (IRA). The open marketplace has been a hallmark of the Medicare Part D prescription drug program, and the public interest is well-served without the

interference of the federal government determining drug prices. The introduction of price-control oriented policies will ultimately challenge the development of new drugs and therapies and discourage innovation.

Due to the government's new policies that restrict the market-based principles of the original Medicare prescription drug program, the opportunity cost to invest in the research and development of new cures will have to be reevaluated and reassessed with a new price control purchasing model. Specific provisions within the IRA will have deleterious impacts to innovation and the pharmaceutical supply chain, including but not limited to hindering the utilization of follow-on indications for orphan drugs, meaning secondary applications of treatments that benefit a wider range of patients will be more limited, and lessening the intellectual property protections of small molecule medicines over large molecule drugs. A strong and productive pharmaceutical manufacturing sector is critical in the U.S. to continue to lead and develop lifesaving therapies and steps must be taken to address these deleterious impacts of the IRA.

***

Congress of the United States

Washington, DC 20515

Statement for the Record

The Committee on Education and the Workforce

"Competition and Transparency: The Pathway Forward for a Stronger Health Care Market"

Subcommittee on Health, Employment, Labor, and Pensions

June 21, 2023

Chairman Good, Ranking Member DeSaulnier, and Members of the Committee,

Thank you for the invitation to offer this Statement for the Record and for holding this important hearing on health care competition and transparency and the misaligned incentives that distort the market and make it more difficult for patients to get lower cost medications.

As a pharmacist for over four decades, I have seen firsthand the rising costs of prescriptions drugs and the impact it has on patients and families. I was the one who was on the other side of the counter who had to tell the patient how much their insulin costs. I was the one who watched the senior citizens trying to decide whether they were going to buy insulin or buy groceries. I was the one who watched a mother cry because she couldn't afford the medication for her child. I was the one who watched all this happen, and I knew behind the curtain that Pharmacy Benefit Managers ("PBM") are the root cause of high prescription drug costs and inaccessible health care.

PBMs act as middlemen between pharmacies, drug manufacturing companies, and health insurance plans to administer prescription drug benefits. They have vertically integrated, creating health care conglomerates that control pricing with little competition. The three largest PBMs - CVS Caremark, Express Scripts, and OptumRx - control over 80% of the market. Using their size, leverage, and negotiating power, PBMs play a large role in determining which prescription drugs are covered by insurance plans and how much they cost, while keeping themselves mostly hidden from the American public.

PBMs have stated that their role in the marketplace is to control costs. However, over the past thirty years the cost of health care has steadily risen by almost 5% annually. Employers experienced a 1,553% increase in drug benefit costs over that same time for employer-sponsored insurance benefits offered to employees. Fast forward to 2021, health care costs eclipsed $4 trillion annually, amounting to roughly $13,000 per person. If PBMs argue they keep drug costs low, then the question naturally arises: why have drug costs gone up so much?

As many experts have noted, PBMs are not really just PBMs anymore. They have been allowed to consolidate and reach into almost every aspect of our health care system at the expense of patients. PBMs are mail-order pharmacies. PBMs own prescribers and physician practices. PBMs own specialty pharmacies. In the case of a company like CVS Caremark, they are a retail pharmacy.

The chart below from the Drug Channels Institute shows the extent of the vertical integration involved. Note that the integration includes mergers with health providers too, not just insurers and pharmacies. This integration presents opportunities for PBMs to lock competing pharmacies, insurers, or even providers out of the market. With less competition, PBMs can continue raising prices and stealing profits from other entities, again leading to increased drug costs.

PBMs have also merged with specialty pharmacies, which were established to manage the extreme growth of specialty medication use and the extra precautions required to dispense them. Specialty medications are complex drugs that treat chronic, difficult-to-treat, or rare conditions. These medications have driven large spikes in health spending in recent years. They often have high prices and usually require special handling, storage, additional training for pharmacists, and intensive patient monitoring.

PBMs that own specialty pharmacies participate in a little-known practice called "patient steering," where the PBM forces patients, through their insurance network, to use a specialty pharmacy the PBM owns. The PBM unilaterally decides what medications will be covered as part of a patient's drug formulary. This presents an opportunity for PBMs to spike costs because patients have limited options to access the medication elsewhere.

We've heard countless stories about how these middlemen drive up drug prices and steer patients to use their own pharmacies, forcing independent pharmacies out of business. Last year, my office rushed to action when we heard that Cigna/Express Scripts was planning to remove almost 15,000 local independent pharmacies out of the military's TRICARE network, depriving our servicemembers and veterans of access to their trusted local health care provider. Plain and simple, PBMs' market consolidation and integration has enabled these unfair and deceptive practices, resulting in decreased competition and higher prices.

The consolidation and vertical integration of our health care system is not limited to PBMs. Rather, our entire health care has become consolidated. Hospitals, physicians, and health insurer markets have become increasingly consolidated. There have been almost 1,800 hospital mergers between 1998 and 2021, leading to about 2,000 fewer hospitals throughout the country. Larger health systems are also buying physician practices at record rates. More than 80,000 physician practices were acquired in 2018, a marked increase over the more than 35,000 acquired in 2012.

Take UnitedHealth Group as an example. This conglomerate has a stronghold on every type of health care service. It is the single largest employer of physicians, while also one of the biggest insurance companies, meaning it gets to choose how much to pay the doctors who rival its own. It also controls its PBM, its own mail-order pharmacy, and recently acquired a hospice and home health service provider.

Undoubtedly, these companies will say their moves to acquire other businesses and grow are intended to save money. However, I recently asked the Director of the Congressional Budget Office, Phill Swagel, to name one example of a health care consolidation that has benefited patients and taxpayers. His response, "Sir, I cannot think of one example."

It's past time for Congress to examine how more competition can help lower health care costs.

I want to again thank Chairman Good, Ranking Member DeSaulnier, and the members of this Subcommittee for holding this hearing today. I believe this is a perfect opportunity to show the American people that we care about them and are working towards solutions that increase the accessibility, affordability, quality of health care.

Sincerely,

Earl L. "Buddy" Carter
Member of Congress

Statement for Hearing on
"Competition and Transparency: The Pathway Forward for a Stronger Health Care Market"

House Committee on Education and the Workforce
Subcommittee on Health, Employment, Labor, and Pensions

June 21, 2023

Employer-provided coverage delivers affordable access to care, effective ways to improve health, and financial security. From comprehensive health insurance coverage and income protection to dental and vision benefits, Americans have real choices and real control in the care and protection they receive through work. Nearly 180 million people – about half the total U.S. population - are covered by employer-provided coverage and 89% of all American workers are employed by a company that offers health benefits.[1] As the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day, we are committed to market-based solutions that make employer-provided coverage better and more affordable and accessible for everyone.

Where there is robust competition – for example, when there are several local hospitals, or generic alternatives for prescription drugs – private negotiations work to make health care more affordable, spur innovations such as value-based agreements and integrated care models, and provide Americans with more choices for their care.

True competition requires transparency – so people can make better and more informed decisions as they seek and receive care. Health insurance providers offer price transparency tools that enable hardworking Americans to make health care decisions that deliver better health care at lower costs, and they are continually improving them.[2]

At the same time, Americans continue to see health care prices escalate year after year – a challenge that can be tied directly to health care markets where there is little to no competition. This calls for a comprehensive effort to spur the robust competition that is essential to providing Americans with more choices, better quality, and lower costs. AHIP commends the

[1] https://www.ahip.org/documents/CaW_EPC_Primer.pdf
[2] https://www.ahip.org/documents/202206-AHIP_IB_Price_Transparency.pdf

subcommittee for looking at ways to increase competition and transparency to create a more patient-friendly, and pocketbook-friendly, health care system for Americans, and offers the following solutions.

Health Insurance Providers are Committed to Meaningful Price Transparency
AHIP and our member health insurance providers fully support the goals of providing Americans with information about the cost and quality of health care services, so they can make better-informed, decisions that take into consideration cost and value of health care. We are fully committed to providing personalized, accurate information on enrollees' estimated out-of-pocket costs, all while protecting patients' personal privacy and the security of their personal health information.

Health insurance providers have demonstrated their commitment to price transparency by providing meaningful cost estimates through tools that help people shop for affordable services. Ahead of regulatory deadlines in June 2021, 94% of commercial health plans were providing patients with access to meaningful price transparency by offering cost estimates through Internet-based self-service cost calculator tools.[3]

These tools provide personalized estimates of an enrollee's out-pocket costs for services and procedures including elective outpatient surgery/procedures, inpatient surgical services, inpatient non-surgical services, physician services, outpatient laboratory services, radiology services, prenatal care, and delivery and postpartum care, based on the enrollee's benefits, deductible, out-of-pocket maximum and the plan's cost-sharing features. Moreover, many of these tools offer quality and other information that can be helpful in shopping for services.

Health insurance providers are fully committed to providing people with information about their out-of-pocket costs prior to seeking health care services through advanced explanations of benefits (AEOB), which allow them to request a precise estimate of their expected out-of-pocket costs before a scheduled service. An AEOB will provide personalized, accurate cost information based on the particular provider, at a specific site (e.g., hospital inpatient or physician's office), based on a set of tailored billing codes, and reflective of that individual enrollee's benefits. Thus, AEOBs have the potential to be the most valuable transparency tool for Americans.

Recommendations

1. The subcommittee should work with stakeholders to ensure that any new reporting requirements are not duplicative and include directions to the federal agencies to streamline reporting to reduce burden.
2. Policy solutions should ensure that health care information is personalized, accurate, and easy to understand – focusing on treatments and services for which people can actually shop and make choices about.

[3] https://www.ahip.org/documents/202206-AHIP_IB_Price_Transparency.pdf

Strengthening Negotiating Power to Drive Down Prescription Drug Costs
Everyone deserves access to affordable prescription drugs, but Americans are paying increasingly more for the medications they need. Drug manufacturers continue to raise prices every year without any improvement in a drug's efficacy while launching new drugs at ever higher prices and manipulating patent rules to block competition from generic medications. Yet these manufacturers provide no transparency to their manufacturing or research costs to demonstrate how they would justify their monopoly prices. We agree that transparency is critical to ensure drugs are priced at levels that reflect their innovation and value. Patients benefit from seeing honest drug prices that reflect the actual value medications provide, not the highest prices the market will bear.

Absent this transparency from drug manufacturers, patients need an advocate to negotiate lower drug prices. Pharmacy benefit managers (PBMs) negotiate drug prices on behalf of patients, leveraging competition for prescriptions and keeping prices down. These private entities are a powerful tool in securing savings for patients, promoting safety in the system, and providing an important check drug manufacturers' power. Pharmaceutical manufacturers sets the prices for their drugs, including frequent price increases not associated with a change in value or outcome of the drug. PBMs are an essential negotiator for lower drug costs and protect patients from out-of-control prices.

Health insurance providers remain committed to price transparency and have made additional strides to increase transparency for the people they serve. For instance, some are implementing innovative solutions like new copay plans capping out-of-pocket copays on prescription drugs, fully transparent price models, and enhanced disclosure practices.[4] Other initiatives include increasing the interoperability between systems so that PBMs can proactively and transparently share patient benefit information with prescribers to ensure continuity of care and show out-of-pocket costs for prescription medications.[5] Additionally, health insurance providers and PBMs report substantial amounts of data on health care and drug spending to the federal government through the Prescription Drug Data Collection (RxDC).

Recommendations
AHIP supports additional standardized reporting by PBMs to plan sponsors on the following, which would empower employers to compare benefit packages:

1. Gross spending on prescription drugs
2. Net spending on prescription drugs after manufacturer rebates
3. Total drug utilization
4. Fees and compensation paid to brokers and consultants

However, to increase the overall transparency around prescription drugs, AHIP recommends Congress look at policies that require drug manufacturers to publicly disclose pricing information to the public and justify price increases for their high-priced drugs.

[4] https://newsroom.thecignagroup.com/express-scripts-further-advances-transparency-and-affordability
[5] https://payorsolutions.cvshealth.com/insights/strategic-initiative-to-create-greater-transparency-and-access

Site-Neutral Payment Reforms Would Increase Affordability and Transparency
Enacting site-neutral payments across outpatient sites of service can help drive improved affordability for everyone. Historically, Medicare has paid a higher amount for comparable services when performed in hospital outpatient departments versus physician offices. In addition to higher reimbursement rates, hospital-owned locations can charge a facility fee along with professional service fees for even low-complexity services that can be safely performed at physician offices for a lower cost. Patients should not pay more for the same service furnished with the same quality of care simply because a hospital owns their physician's office.

Payment differentials across sites of service create two problems for health care affordability. First, it results in increased costs to patients and their health insurance providers for individual services at the point of care. Second, the prospect of higher reimbursement rates paid to hospital-affiliated practices is seen as a contributing factor to consolidation, as hospitals have an economic incentive to purchase independent physician offices to receive higher rates at those locations.[6] Implementing site-neutral payments for outpatient care has the potential to drive savings across markets, drive affordability for consumers, and remove incentives to consolidate.

Recommendations
The subcommittee should work with other committees of jurisdiction on legislative solutions that permit comparable payment for comparable services encourage an efficient and competitive market that works for Americans, including:

1. Require separate national provider identifier enumeration for off-campus hospital outpatient departments to strengthen implementation of site neutral payment policies.
2. Remove the exception for grandfathered hospital-based locations such that these sites are subject to site neutral payments.
3. Prohibit the assessment of facility fees for outpatient care that can be safely performed at physician offices unless a special exception applies.
4. Narrow the definition of free-standing emergency departments to those that provide most services on an unscheduled basis and require patient disclosure notices.

Conclusion
Competition, transparency, and a strong ERISA market are essential to ensure that the nation's health care system focuses on patients and their access to affordable, comprehensive health insurance coverage. Therefore, attempts to weaken the ERISA preemption protections will jeopardize the robust employer-sponsored health plans millions of Americans rely on today and increase costs to employers across the country. We are committed to working with the subcommittee to prevent the degradation of these ERISA preemptions and continue strengthening the employer-sponsored health insurance market.

[6] https://www.gao.gov/assets/gao-16-189.pdf

better solutions
for healthcare™

Chairman Bob Good (R-VA)
Ranking Member Mark DeSaulnier (D-CA)
House Committee on Education and the Workforce
Subcommittee on Health, Employment, Labor, and Pensions

Dear Chairman Good and Ranking Member DeSaulnier:

As hospital prices continue their unreasonable and alarming rise year over year, we are calling upon policymakers to prioritize market-based solutions to address the affordability crisis impacting American patients and their employers. We appreciate the committee's ongoing work to increase transparency and improve affordability, and we call on Congress to take immediate action to rein in corporate hospital takeovers.

The escalating cost of healthcare services is a primary concern of businesses.[1] Since 2015, U.S. hospital prices have increased four times faster than workers' paychecks. Hospital services now represent the largest share of total healthcare spending, accounting for 44% of total spending for privately-insured Americans. When corporate hospital systems charge more for prescription drugs and treatments, healthcare costs go up. Some hospital markups prioritize bottom lines over patients' health. For example, patients can be charged either $150 or $950 for the same blood test, depending on the facility they choose.

As Congress works to solve America's healthcare affordability crisis, we applaud your focus on the role corporate hospital systems play in driving up healthcare costs for patients, their employers, public sector purchasers, and the government. A lack of market competition, pricing transparency, and price mark-ups have exacerbated significant market distortions and undercut the stability and sustainability of the system.

This is why we support legislative efforts that promote hospital competition through market-based solutions, enforce federal price transparency laws for hospital charges, rein in hospital price markups, and ensure honest billing practices by hospitals.

We look forward to working with you to drive the legislative proposals required to support our system's foundations, help fix areas that have become broken, and promote beneficial growth, innovation, and investment to protect the health of patients, employers, and their families across the country.

Sincerely,

Better Solutions for Healthcare

---

[1] "Health Insurance, Labor, and Taxes Remain Top Issues for Small Business Owners in NFIB's Every-Four-Year Study." *NFIB*, 13 August 2020, https://www.nfib.com/content/press-release/homepage/health-insurance-labor-and-taxes-remain-top-issues-for-small-business-owners-in-nfibs-every-four-year-study/.

PULLING BACK THE CURTAIN ON PBMS:

A Path Towards Affordable Prescription Drugs

Congressman
BUDDY CARTER
Georgia's First District

Contents

Key Terms

Step Therapy, Fail First: Requires patients to take one or more treatments for several weeks or months before deciding whether to pay for the one prescribed by their doctor.

Prior Authorization: Requires the patient to get permission from the health plan to use a medicine, device or treatment prescribed by their doctor. Often used in combination with step therapy.

Direct and Indirect Renumeration (DIR) Fee: Fees imposed by PBMs on pharmacies that are not itemized and can be charged a year or more after medications are dispensed to Medicare Part D beneficiaries — a practice that has since also been termed as "clawbacks."

Spread Pricing: The practice of PBMs charging payers more than they pay the pharmacy for a medication, and then keeping the 'spread' or difference as profit.

Patient Steering: The practice of PBMs pushing patients away from local pharmacies in favor of pharmacies or mail-order programs the PBM directly owns or is affiliated with.

The Harvard Journal on Legislation is the nation's premier legal journal focused on the analysis of legislation and the legislative process. The Journal publishes viewpoints from across various legislative perspectives, providing a forum for scholarship on legislative reform and on the efficiency and effectiveness of legislative decision-making. Publication does not constitute an endorsement by the Journal of any particular viewpoint.

Letter from Congressman Buddy Carter

Pharmacy Benefit Managers (PBMs) are the pharmaceutical supply chain's hidden middlemen that are driving up costs for prescription medications, delaying access to necessary treatments, and robbing hope from patients.

It's time we pull back the curtain on these insidious actors.

Before coming to Congress, I owned and operated Carter's Pharmacy in Georgia. Working in community pharmacy gave me the unique opportunity to help people in my neighborhood, from providing over-the-counter headache medications to vaccinations and life-saving prescriptions for chronic illness. The work that pharmacists do is, and pardon my pun, indispensable. There's a reason we are among the most trusted healthcare professionals in the country: accessibility. We are in patients' communities, and they rely on our expertise to alleviate their suffering.

Unfortunately, community pharmacies are waning, and it is in large part due to the vulturous vertical integration that is occurring in our healthcare system. The largest PBMs own the insurance company as well as the pharmacy, and now only three companies have a virtual triopoly over the entire prescription drug market.

Drug manufacturers are often maligned for their role in raising the cost of prescription medications, and they are not blameless. But they're also not Fortune 25 companies, they're not the ones deciding what patients pay out-of-pocket for prescription drugs, and they're not the ones who manipulate the market without providing any real value to the consumer. Those roles are filled by PBMs.

To raise awareness about the real-world impacts of PBMs' predatory practices, I interviewed patients from across the country about their struggles accessing and affording necessary treatments and prescriptions. While each of them has their own unique story, common themes run through them all: their essential medications would be easier to obtain, their prescriptions would be cheaper, and their health would improve if PBMs were reined in.

As Members of Congress, we can alleviate their suffering. I hope you take the time to read their stories, along with my article that was first published in the Harvard Journal of Legislation and is repurposed for you here, that details exactly how we can help patients without expensive, burdensome, and inefficient government programs.

Your friend from South Georgia,

Buddy Carter

FOR MORE INFORMATION, VISIT:
buddycarter.house.gov/pbmabuses/

I. Introduction

Over the next decade, the Centers for Medicare and Medicaid Services ("CMS") projects that spending for retail prescription drugs will be the fastest growing health category.[1] In 2019, 52% of American adults reported that healthcare costs have delayed their day-to-day activities.[2] During the 2020 presidential election, one survey found that 74% of Democratic voters in Blue Wall states believed a top priority of Congress should be lowering the cost of the prescription drugs.[3] During my experience running a pharmacy, I have also unfortunately witnessed families discussing how to cut costs on groceries to afford prescription medicine.

Pharmacy Benefit Managers ("PBMs") have grown into some of the largest, most profitable companies in our nation.[4] PBMs act as middlemen between pharmacies, drug manufacturing companies, and health insurance plans to administer prescription drug benefits.[5] Using their size, leverage, and negotiating power, PBMs play a large role in determining which prescription drugs are covered by insurance plans and how much they cost, while keeping themselves mostly hidden from the American public.[6]

This Essay identifies PBMs as a root cause of high prescription drug costs. Behind the curtain, PBMs play an outsized role in the perilous state of the current American prescription drug market. As everyone from pharmacy owners to patients to taxpayers are victimized by the predatory practices of PBMs, this is inherently a human issue. I hope to expose the hidden actor of PBMs to the American public and encourage Congress to address this problem.

Stories from patients, pharmacists, and doctors have already inspired some congressional action to rein in PBMs' predatory practices. For example, bipartisan coalitions introduced the Ensuring Seniors Access to Local Pharmacies Act,[7] which would require transparency of PBM contracts, prohibit patient steering to in-house or PBM associated pharmacies, and allow seniors in Medicare Part D plans to use pharmacies of their choice.[8] Additionally, the Pharmacy DIR Reform to Reduce Senior Drug Costs Act[9] would ensure that clawbacks, or price concessions issued by PBMs, are assessed at the point of sale to eliminate the retroactive nature of Direct and Indirect Remuneration ("DIR") fees.[10] Congress has also sent several letters to the Biden administration,[11] but no action has been taken to stop PBMs.

It is time to finally lower drug prices in America, and, together, we can make a difference.

---

1 Craig Hanna & Colo, *Prescription Drug Spending in the U.S. Health Care System*, AM. ACAD. ACTUARIES (2018), https://www.actuary.org/content/prescription-drug-spending-us-health-care-system [https://perma.cc/VL9Z-MZRX].

2 *See* Megan Leonhardt, *Rising Health-Care Costs Stall Americans' Dreams of Buying Homes, Building Families and Saving for Retirement*, CNBC (Nov. 4, 2019, 1:28 PM), https://www.cnbc.com/2019/11/04/health-care-costs-are-preventing-many-americans-from-hittinglife-milestones.html [https://perma.cc/REX5-BLWZ].

3 *See* ASHLEY KIRZINGER, CAILEY MUÑANA, MOLLYANN BRODIE, CHARLIE COOK, AMY WALTER, JENNIFER DUFFY & DAVID WASSERMAN, BLUE WALL VOICES PROJECT 27 (2019), https://files.kff.org/attachment/REPORT-Blue-Wall-Voices-Project [https://perma.cc/6HEEVYEW].

4 *See* PBM ACCOUNTABILITY PROJECT, UNDERSTANDING THE EVOLVING BUSINESS MODELS AND REVENUE OF PHARMACY BENEFIT MANAGERS 3 (2021), https://b11210f4-9a71-4e4ca08f-cf43a83bc1df.usrfiles.com/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf [https://perma.cc/YWR6-HHLZ].

5 *See id.*

6 *See id.*

7 H.R. 2608, 117th Cong. (2021).

8 *See id.*

9 S. 1909, 117th Cong. (2021).

10 *See id.*

11 *See, e.g.*, Letter from Earl L. "Buddy" Carter, U.S. Representative, House of Representatives et al. to Xavier Becerra, Sec'y, U.S. Dep't Health & Hum. Servs. (Mar. 16, 2022), https://buddycarter.house.gov/uploadedfiles/dir_reform_letter_to_hhs_3.16.22.pdf [https://perma.cc/95NR-G9QT].

For a $100 expenditure on pharmaceuticals, approximately $24 accrues to insurers and PBMs

Source: USC

"To get that letter in the mail saying that my specialty doctor wants me on this medication and my insurance company is saying 'no' is extremely frustrating... Prior authorization and step therapy have definitely delayed therapy or changed the order of my treatment."

Jessica Wofford
Registered Nurse

Jessica has been battling Crohn's Disease for over 15 years, for which there is no known cure. She says that her health has been adversely impacted by the prior authorization process and refers to it as her "biggest barrier to care." Beyond delaying access to necessary treatments, constant battles with insurance companies have taken a toll on her mental health. The stress has "worsened [her] condition" and makes it harder to focus on the one thing that matters: her health. She wants members of Congress to know that, at times, the system designed to treat her can be worse than her disease itself. Even as a nurse, Jessica says she "still feels lost in this process."

II. The Rise in Drug Prices

Drug prices in America are on the rise.[12] According to GoodRx Health, drug costs rose 33% between 2014 and 2020.[13] A recent report by the Congressional Budget Office shows the average net price of branded pharmaceutical products in Medicare Part D increasing from $149 in 2009 to $353 in 2018.[14] A study by the non-partisan, non-profit RAND Corporation suggests drug prices in the United States are 2.56 times higher than other modern nations.[15] And Americans are spending a larger percentage of their total income on healthcare and drugs than in years past.[16]

Insulin provides an illustrative example: diabetic patients pay an average of $300 for a vial of insulin.[17] A vial of insulin contains 1,000 insulin units, and, depending on the type of diabetes an individual has and his or her weight, he or she may require upwards of 100 insulin units a day.[18] Simple math suggests diabetic patients could spend over $1,000 a month on insulin alone. As a result, patients often must choose between their health and their wallets. No American should have to make that choice.

---

[12] *See* TAMARA HAYFORD & DAVID AUSTIN, CONG. BUDGET OFF., NO. 57050, PRESCRIPTION DRUGS: SPENDING, USE, AND PRICES 13 (2022), https://www.cbo.gov/system/files/2022-01/57050-Rx-Spending.pdf [https://perma.cc/9ELE-HTYS].

[13] *See* Tori Marsh, Prices for Prescription Drugs Rise Faster than Prices for Any Other Medical Good or Service, GOODRX HEALTH (Sept. 17, 2020), https://www.goodrx.com/healthcare-access/drug-cost-and-savings/prescription-drugs-rise-faster-than-medical-goods-or-services [https://perma.cc/NL2P-5QYY].

[14] *See* HAYFORD & AUSTIN, *supra* note 12, at 16.

[15] *See* ANDREW W. MULCAHY, CHRISTOPHER M. WHALEY, MAHLET GIZAW, DANIELSCHWAM, NATHANIEL EDENFIELD & ALEJANDRO U. BECERRA-ORTHENELAS, RAND CORP., INTERNATIONAL PRESCRIPTION DRUG PRICE COMPARISONS: CURRENT EMPIRICAL ESTIMATES AND COMPARISONS WITH PREVIOUS STUDIES 26 (2021), https://www.rand.org/pubs/research_reports/RR2956.html [https://perma.cc/8GS6-JBWA].

[16] *See* Danielle K. Roberts, *The Deadly Cost of Insulin*, AM. J. MANAGED CARE (June 10, 2019), https://www.ajmc.com/view/the-deadly-costs-of-insulin [https://perma.cc/3W8VHBW3].

[17] *See* David Lazarus, *Column: Soaring Insulin Prices Reveal Clout, and Greed of Healthcare Middlemen*, L.A. TIMES (Nov. 30, 2021, 6:00 AM), https://www.latimes.com/business/story/2021-11-30/lazarus-healthcare-insulin-prices [https://perma.cc/YPC6-6VER].

[18] *See* SingleCare Team, *Insulin Prices: How Much Does Insulin Cost*, SINGLECARE (Jan. 27, 2020), https://www.singlecare.com/blog/insulin-prices/ [https://perma.cc/ER65-4KM6].

Reducing drug prices has consistently polled as a top issue for American voters.[19] According to a poll released in October 2021 by the Kaiser Family Foundation, 83% of Americans say the costs of prescription drugs are unreasonable.[20] The same poll says 26% of Americans have a hard time affording their medications, and 78% of Americans think pharmaceutical companies are to blame for the high prices.[21] A different poll released by Morning Consult and Politico revealed that 50% of Americans think bringing down prescription drugs should be a priority.[22] Clearly, this is an important issue to Americans.

There are competing and complex explanations for why drug prices are so high. Many Americans think it is because pharmaceutical companies jack up prices and pocket those profits.[23] The above statistics might even suggest this to be true. But this argument blatantly ignores other entities within the American healthcare system and the tactics they use to increase prices and pocket greater profits. The American healthcare system is too complex to put the blame on a single entity. I've experienced the complexities of this system myself over my thirty years as a pharmacist, independent pharmacy owner, and now member of Congress on the House Energy and Commerce Health Subcommittee. There is more than meets the eye to this story, and I strive to reveal how hidden "middlemen" in the pharmaceutical supply chain are the ones to blame for these drastic price increases.

GENERIC DRUGS VS. BRANDED DRUGS

Where does the money come from?

Before examining the middlemen within the supply chain and how they raise drug costs, it is important to discuss the pharmaceutical marketplace, how generic drugs and branded drugs differ, and how the marketplace profits off of them.

Generic drugs are unbranded products that compete with the original, branded innovator drug when exclusivity and legal patents expire for the branded product.[24] In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman Act"),[25] which established a pathway for expedited drugs that are exact copies of branded products already on the market.[26] The FDA relies on its determination that the original branded product is safe and effective to approve new generic drugs.[27] Because the generic drugs are exact copies of the original product, the companies developing them avoid costly research and development investments, clinical trial costs, and the risk of a drug not being safe or effective.[28] Essentially, the Hatch-Waxman Act created competition in the marketplace by giving consumers a choice among different generic and brand-name products when in need of treatment.[29]

The Hatman-Waxman Act was a success: today, generic drugs account for most of the drugs

[19] *See* Liz Hamel, Lunna Lopes, Ashely Kirzinger, Grace Sparks, Audrey Kearney, Mellisha Stokes & Mollyann Brodie, *Public Opinion on Prescription Drugs and Their Prices*, KAISER FAM. FOUND. (Oct. 18, 2021), https://www.kff.org/health-costs/poll-finding/publicopinion-on-prescription-drugs-and-their-prices/ [https://perma.cc/K37C-DU7H].

[20] *See id.*

[21] *See id.*

[22] *See* Gaby Galvin, *Curbing Drug Costs Should Be a Top Priority for Congress, 1 in 2 Voters Say*, MORNING CONSULT (May 5, 2021, 6:00 AM), https://morningconsult.com/2021/05/05/drug-pricing-top-priority-congress-poll/ [https://perma.cc/KXA5-E835]

[23] *See* Marisa Fernandez, *Drug Companies Keep Raising Prices*, AXIOS (Jan. 14, 2021), https://www.axios.com/drug-price-increases-new-year-2021-cf1fce6d-3c82-456f-9a6c-6b5144b4f061.html [https://perma.cc/E2PN-84ZD].

[24] SUZANNE M. KIRCHHOFF, AGATA BODIE, KAVYA SEKAR & SIMI V. SIDDALINGAIAH, CONG. RSCH. SERV., R44832, FREQUENTLY ASKED QUESTIONS ABOUT PRESCRIPTION DRUG PRICING AND POLICY 2 (2021), https://sgp.fas.org/crs/misc/R44832.pdf [https://perma.cc/6J7Y-CPYY].

[25] 21 U.S.C. § 355(j)

[26] *See id.*

[27] *See* AGATA DABROWSKA, CONG. RSCH. SERV., IF11075, FDA AND DRUG PRICES: FACILITATING ACCESS TO GENERIC DRUGS 1 (2019), https://sgp.fas.org/crs/misc/IF11075.pdf [https://perma.cc/24VJ-CJQS].

[28] *See id.*

[29] *See id.*

sold in the United States—about 90% of all dispensed medications.[30] These generic products are usually very cheap, accessible at every pharmacy, and have lower out-of-pocket insurance costs for consumers compared to branded products.[31] The intense competition between generic drugs and branded drugs has caused generic drug prices to drop by more than 60% since 2008.[32] Thus, generic drugs are increasingly becoming very affordable.[33] But despite the high market share, generic drugs account for only 26% of total drug spending, meaning 74% of all spending on drugs is spent on branded drugs.[34] The high share of spending on branded drugs is explainable, and there is a good reason for it: branded drugs are often very new to the market. They require years, sometimes decades, of investments into research and development to create, and they treat specific, often rare, health conditions for a small subset of the population.[35]

New drug development does not come cheap. According to the Congressional Budget Office, the pharmaceutical industry spent $83 billion in 2019 on research and development.[36] That is ten times more than what the industry spent in the 1980s, when adjusted for inflation.[37] Drug companies can expect to spend between $1 billion and $2 billion for every new product they attempt to bring to the market.[38] A recent study published in the Journal of Health Economics estimates that it costs drug makers $2.6

CVS caremark™ Optum Rx®

PBMs are among the Fortune 25 companies - ranked higher than the drug manufacturers

Source: Fortune 500

"I've had so many surgeries that might have been prevented if I could just do what the doctors have implemented...It's because the doctor-patient relationship has been hijacked by insurance and PBMs."

Elisa Comer
Healthcare Administrator

Elisa has a term for the turmoil PBMs have put her through: hijacked healthcare. Even though she is a businesswoman herself, she says that she couldn't invent a system this convoluted if she tried. In addition to claiming 15-20 hours a week of her time, the equivalent of a part-time job, the endless sea of phone calls and treatment rejections has taken a toll on her mental health. "I've actually had to go in-and-out of medications for anxiety," says Elisa, because "the system is running your healthcare, not you and your doctor." Despite having a background in healthcare administration, this process has stolen her hope. "I don't know any other industry that gets to run their books this way. People are dying," Elisa says.

[30] HAYFORD & AUSTIN, *supra* note 12, at 10.
[31] *See* DABROWSKA, *supra* note 27, at 1.
[32] *See* U.S. DEP'T HEALTH & HUM. SERVS., UNDERSTANDING RECENT TRENDS IN GENERIC DRUG PRICES (2016), https://aspe.hhs.gov/reports/understanding-recent-trends-generic-drugprices [https://perma.cc/Y72T-7YVH].
[33] *See* Rachel Schwartz, *The Generic Drug Supply Chain*, ASS'N FOR ACCESSIBLE MEDS. (Oct. 16, 2017), https://accessiblemeds.org/resources/blog/generic-drug-supply-chain#:~:text=with%2089%20percent%20of%20all,the%20U.S.%20health%20care%20system [https://perma.cc/GE6C-Q9ZM].
[34] *See id.*
[35] *See* KIRCHOFF ET AL., *supra* note 24, at 29
[36] TAMARA HAYFORD & DAVID AUSTIN, CONG. BUDGET OFF., 57025, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 1 (2021), https://www.cbo.gov/publication/57126 [https://perma.cc/N26M-2NUP].
[37] *Id.*
[38] Jonathan Gardner, *New Estimate Puts Cost to Develop a New Drug at $1B, Adding to Long-Running Debate*, BIOPHARMA DIVE (Mar. 3, 2020), https://www.biopharmadive.com/news/new-drug-cost-research-development-market-jama-study/573381/ [https://perma.cc/LGH3-S8X9].

billion to get a drug to market.[39] Despite the billions of dollars drug makers invest in new products, there is no guarantee a new drug will ever make it to pharmacy shelves. The FDA approves only about 9% of all drugs that start clinical trials, proving new drug development to be an extremely risky venture.[40]

Drug companies must charge a price that recoups the billions of dollars in developmental costs, payroll, overhead, financial losses from non-approved drugs, and other expenses—all before taking any profit. These companies take immense risk to create life-saving medicines, experiencing a 91% fail rate on their investments. We must preserve the incentive of modest profits for these companies to take such risks—risks that bring us life-saving medicines.

Where does the money go?

Americans may assume most of the money they spend on drugs goes back to the drug manufacturer. That is not the case. In fact, drug manufacturers receive just 37% of dollars spent on prescription drugs.[41] This number has decreased by 17 percentage points since 2013.[42] Similarly, branded drug list prices have now declined for the fourth straight year.[43] This means, year after year, manufacturers are actually decreasing, not increasing, their listed drug prices.[44]

If drug prices listed by manufacturers continue to decrease, then what explains the increased drug costs for consumers at the pharmacy counter? The answer is middlemen, or PBMs. In 2020, total gross expenditures for branded medications reached $517 billion.[45] Brand manufacturers retained just 31% of this spending, while middlemen retained 69%.[46]

In 2006, PBMs took on expanded roles in negotiating drug prices. The result?
A 313% increase in the cost of prescription drugs.
Source: Journal of Law and Biosciences

"What prior authorizations do is take the decisions out of the hands of the physicians and put them in the hands of the insurance company and that is never appropriate or acceptable."

Nisha Trivedi
MBA Admissions Consultant

Nisha has been spared some of the healthcare industry's worst trials, but that does not stop her from advocating for others. As a patient, she knows first-hand that "it should not be this difficult to receive treatment." "Everyone deserves to be healthy and to not go bankrupt based on the cost of drugs," she says, recalling a time when she got a surprisingly high bill in the mail that would have been lower if she did not go through insurance at all. While affordability is a massive hindrance to many patients, Nisha notes that patients are "fighting battles every day. They're fighting battles with their condition, they're fighting battles to find treatment for their condition, and then they're fighting battles to get those medications approved." These barriers, bills, and repeated denials are part of a complicated web that leaves patients, many critically ill, in the dust. When discussing PBMs' predatory practices, Nisha describes them as "a manipulation of the healthcare system."

[39] *See* Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 20 (2016).
[40] *See* Press Release, Biotechnology Indus. Org., New Study Shows the Rate of Drug Approvals Lower Than Previously Reported (Feb. 14, 2011), https://archive.bio.org/media/press-release/new-study-shows-rate-drug-approvals-lower-previously-reported [https://perma.cc/3K7F-5YGX].
[41] Andrew Brownlee & Jordan Watson, *The Pharmaceutical Supply Chain*, 2013–2020,BRG (Jan. 7, 2022), https://www.thinkbrg.com/insights/publications/pharmaceutical-supplychain-2013-2020 [https://perma.cc/A5EN-MEVN].
[42] *Id.*
[43] *See* John A. Murphy, III, *Brand Name Drug Prices Fell in 2021 — Again.*, BIO (Jan. 7, 2022), https://www.bio.org/blogs/brand-name-drug-prices-fell-2021-again [https://perma.cc/H6DC-DDYQ].
[44] *See id.*
[45] Brownlee & Watson, *supra* note 41, at 5.
[46] *See id.*

To summarize, yes, drug prices at the pharmacy counter are rising. But the data shows drug manufacturers are dropping their drug prices, while middlemen in the supply chain are taking substantially more profits every single year. My experience as a pharmacy owner has led me to believe that the main culprits for the rise in drugs costs are PBMs.

The drug supply chain encompasses six main entities: manufacturers, distributors, retailers or pharmacies, PBMs, health insurance plans or government-run insurance, and patients.[47] Manufacturers make a drug, distributors purchase those drugs and ship them to retailers and pharmacies, and the medication is then dispensed to the patient by a pharmacist. These entities provide services that are visible to patients.[48]

Health insurance plans and PBMs operate as virtual entities in the supply chain. Health insurance plans pay a portion of the cost of the dispensed medication. They decide which pharmacies are part of their network—entities your health plan contracts with to provide you with medical benefits. Health plans make money by charging patients premium payments and yearly deductibles.

PBMs operate as middlemen, and they operate exclusively in the United States.[49] They were originally created to perform administrative functions for insurers related to consumer drug benefits.[50] Today, they negotiate costs and reimbursements with pharmacies, drug manufacturers, and insurance plans to establish drug formularies, or lists of generic and branded medications that insurers will cover and pay for according to a consumer's health insurance contract.[51] PBMs also manage the flow of financing in the drug supply chain by providing reimbursements and payments to all entities.[52]

PBMs claim they are directly responsible for lowering the costs of drugs.[53] The Pharmaceutical Care Management Association ("PCMA"), the PBM industry association that lobbies lawmakers in Washington, D.C., has an entire webpage dedicated to explaining the value of PBMs.[54] They claim discounts and rebates, paid by pharmaceutical companies, and negotiated by PBMs, ultimately lower patient costs.[55] They claim PBMs build pharmacy networks to provide drugs at discounted rates.[56] And they claim PBMs work to increase generic drug utilization and patient medication adherence.[57]

PBM lobbyists spread these messages throughout Congress' halls. In the first nine months of 2021, PBMs spent $5.9 million to convince lawmakers these claims are true.[58] This was a 20% increase over the same period in 2020.[59] They are spending this money for good reason. PBMs have been under increased scrutiny by states and the federal government for their business dealings.[60]

---

[47] *See* JULIE SOMERS & ANNA COOK, CONG. BUDGET OFF., NO. 2703, PRESCRIPTION DRUG PRICING IN THE PRIVATE SECTOR 5–11 (2007), https://www.cbo.gov/sites/default/files/110thcongress-2007-2008/reports/01-03-prescriptiondrug.pdf [https://perma.cc/68A7-9M6Q].

[48] *See id.* at 1–2.

[49] *See* Jeff Lagasse, *Pharmacy Benefit Managers Operate with Lack of Transparency, Expert Finds*, HEALTHCARE FIN. (Sept. 19, 2018), https://www.healthcarefinancenews.com/news/pharmacy-b

[50] *See* Cole Werble, *Pharmacy Benefit Managers*, HEALTH AFFS. (Sept. 14, 2017), https:// www.healthaffairs.org/do/10.1377/hpb20171409.000178/ [https://perma.cc/8FSC-4KZQ].

[51] *See* Ana Gascon Ivey, *A Guide to Medication Formularies*, GOODRX HEALTH (May 19, 2020), https://www.goodrx.com/insurance/health-insurance/medication-formulary [https://perma.cc/GU7W-BAS6].

[52] *Pharmacy Benefit Managers and Their Role in Drug Spending*, COMMONWEALTH FUND (Apr. 2019), https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacybenefit-managers-and-their-role-drug-spending [https://perma.cc/8C5F-NFQ3].

[53] *See The Value of PBMs*, PHARM. CARE MGMT. ASS'N, https://www.pcmanet.org/thevalue-of-pbms/ [https://perma.cc/ZL7H-2TL5].

[54] *Id.*

[55] *Id.*

[56] *Id.*

[57] *Id.*

[58] David McKay, *To Be, or Not to Be . . . a Fiduciary: That Is the Question for PBMs*, BENEFITS PRO (Feb. 14, 2022), https://www.benefitspro.com/2022/02/14/to-be-or-not-to-be-afiduciary-that-is-the-question-for-pbms/?slreturn=20220123185822 [https://perma.cc/A3SHGRHL].

[59] *Id.*

[60] Gaby Galvin, *Pharmacy Benefit Managers Are Feeling a Push from States to 'Turn the Lights on' to Their Business Practices*, OFF. MONT. STATE AUDITOR, COMM'R SEC. & INS. (Aug. 26, 2021), https://csimt.gov/news/pharmacy-benefit-managers-are-feeling-a-push-fromstates-to-turn-the-lights-on-to-their-business-practices/ [https://perma.cc/M3DJ-TC3G].

The three largest PBMs *exclude more than 1,150 medicines from their formulary*, essentially blocking them from the market.

Source: Xcenda

"Several of my medications are no longer on my formulary or have become more expensive so I can't take them anymore...Not being able to take medication when I need it means I am in excruciating pain. I am basically staying sicker because of this."

Yuri Cárdenas
Bay Area Resident, Dog Lover

Yuri received their first diagnosis at just five years old. For over nine years, they've fought near constant battles accessing necessary medications to manage their pain. Recently, a drug that they were on for more than seven years was denied by a PBM, with no warning or explanation. Without coverage, the pills are simply unaffordable. These inconsistencies are more than just frustrating - they are physically taxing. "I have had to skip doses to be able to afford the cost of my medications," says Yuri. "I sometimes cut my pills in half to be able to save the pills for as long as I need. I am restricted by the costs of medication that insurance is allowed to cover each year, and it changes." They believe PBMs are responsible for the exorbitant costs for their medication, saying that every year the prices rise. Yuri admits that each denial "chips away at a hope for a fruitful career or for ever getting [their] life back."

In 2021, over 100 bills were introduced across the country that targeted PBMs.[61] Congress and the Biden and Trump administrations have taken action on PBMs as well. I will discuss these actions in more detail later.

Unfortunately, the lack of transparency in PBM business practices has allowed them to institute practices that harm consumers' medication access and to increase drug costs.[62] The key to their lack of transparency: vertical mergers.

PBMs have vertically integrated, creating healthcare conglomerates that control pricing with little competition.[63] The three largest PBMs are CVS Caremark, Express Scipts, and OptumRx.[64] CVS Caremark is integrated with Aetna's insurance plan and CVS Pharmacy.[65] Express Scripts is merged with Cigna's insurance plans and Express Scipts' mail-order pharmacy.[66] OptumRx is merged with United Healthcare's insurance plan and runs its own mail order pharmacy.[67] The big three PBMs control almost 80% of the market.[68]

PBMs comprise the only entity in the drug supply chain that knows what everyone is paying and what everyone is profiting. Yet, they operate in a black box with no transparency. PBMs use this lack of transparency to take profits from the rest of the supply chain—resulting in much higher drug prices.

---

[61] *Id.*
[62] *See id.*
[63] Adam J. Fein, *Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?*, DRUG CHANNELS (Dec. 12, 2019), https://www.drugchannels.net/2019/12/insurers-pbms-specialty-pharmacies.html [https://perma.cc/6JF6-BTYR].
[64] *See* Matej Mikulic, *U.S. Prescription Market: Market Share of Pharmacy Benefit Managers 2020*, STATISTA (June 16, 2021), https://www.statista.com/statistics/239976/us-prescription-market-share-of-top-pharmacy-benefit-managers/ [https://perma.cc/2GUP-8EUM].
[65] Fein, *supra* note 63.
[66] *Id.*
[67] *Id.*
[68] Jake Frenz, *Industry Voices—Why It's Time for PBM Rebates to Come to an End*, FIERCE HEALTHCARE (Apr. 8, 2019, 10:42 AM), https://www.fiercehealthcare.com/payer/industry-voices-why-it-s-time-for-pbm-rebates-to-come-to-end [https://perma.cc/W9F2-BJBV].

Figure 1: Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies, and Providers 2021*

*This graphic has been changed since the HJL article was published to reflect the most up-to-date information

The chart above, from the National Community Pharmacists Association, shows the extent of vertical integration involved.[69] Note that the integration includes mergers with health providers too, not just insurers and pharmacies. This integration presents opportunities for PBMs to lock competing pharmacies, insurers, or even providers out of the market. With less competition, PBMs can continue raising prices and stealing profits from other entities, again leading to increased drug costs.

PBMs have also merged with specialty pharmacies, which were established to manage the extreme growth of specialty medication use and the extra precautions required to dispense them.[70] Specialty medications are complex drugs that treat chronic, difficult to treat, or rare conditions.[71] These medications are driving large spikes in health spending in recent years.[72] They often have high prices and usually require special handling, storage, additional training for pharmacists, and intensive patient monitoring.[73] Specialty medications accounted for 53% of all drug spending in 2020—up from 27% in 2010.[74] Roughly 75% of all drugs under development right now are specialty medications—mostly oncology and autoimmune medications.[75] PBMs have realized the potential for profitability with specialty medications. It is estimated that dispensing specialty medications accounted for nearly one-third of PBM profits in 2019.[76] In 2020, specialty pharmacies are estimated to have dispensed $176 billion in medications, an increase of 9.1% since 2019.[77]

CVS owns CVS Specialty, Express Scripts owns Accredo, and OptumRx owns BriovaRx.[78] In

[69] NCPA, THE PBM STORY (2021)

[70] *See* ANNA ANDERSON-COOK & JARED MAEDA, CONG. BUDGET OFF., NO. 54964, PRICES FOR AND SPENDING ON SPECIALTY DRUGS IN MEDICARE PART D AND MEDICAID 1 (2019), https://www.cbo.gov/system/files/2019-03/55011-Specialty_Drugs_WP.pdf [https://perma.cc/EZ88-DTME].

[71] Bijal Nitin Patel & Patricia R. Audet, *A Review of Approaches for the Management of Specialty Pharmaceuticals in the United States*, 32 PHARMACOECONOMICS 1105, 1105 (2014).

[72] *See* Rabah Kamal, Cynthia Cox & Daniel McDermott, *What Are the Recent and Forecasted Trends in Prescription Drug Spending?*, PETERSON-KAISER FAM. FOUND. HEALTH SYS. TRACKER (Feb. 20, 2019), https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/ [https://perma.cc/74PF-8J5K].

[73] *See* ANDERSON-COOK & MAEDA, *supra* note 70, at 1.

[74] MURRAY AITKEN & MICHAEL KLEINROCK, IQVIA INST., THE USE OF MEDICINES IN THE U.S. 4 (2021).

[75] CVS HEALTH, DRUG TREND REPORT 2019 8 (2020).

[76] *See* Fein, *supra* note 63.

[77] Adam J. Fein, *DCI's Top 15 Specialty Pharmacies of 2020: PBMs Expand Amid the Shakeout—While Walgreens' Outlook Dims*, DRUG CHANNELS (May 4, 2021), https://www.drugchannels.net/2021/05/dcis-top-15-specialty-pharmacies-of.html [https://perma.cc/7VD6-LCGU].

[78] *See* Adam J. Fein, *PBM-Owned Specialty Pharmacies Expand Their Role in—and Profits from—the 340B Program*, DRUG CHANNELS (July 21, 2020), https://www.drugchannels.net/2020/07/pbm-owned-specialty-pharmacies-expand.html [https://perma.cc/K5SP-8VAP].

2018, only 900 United States pharmacies had a specialty pharmacy accreditation.[79] It is estimated there are more than 60,000 pharmacies in the United States.[80] PBMs that own specialty pharmacies partake in a little-known practice called "patient steering," where the PBM forces patients, through their insurance network, to use a specialty pharmacy the PBM owns.[81] The PBM unilaterally decides what medications will be covered as part of a patient's drug formulary.[82] This presents an opportunity for PBMs to spike costs because patients have limited options to access the medication elsewhere.

Studies about specialty pharmacies in certain states have indicated that the big three PBMs are involved in this type of "steering" behavior. One report from the Florida Pharmacy Association and the American Pharmacy Cooperative in February 2020 studied the behavior of PBMs in relation to a diverse group of pharmacies in the state of Florida.[83] A *Pharmacy Times* review of the report found that PBMs often require "generic specialty drugs to be dispensed at their affiliated pharmacy and the reported payments to these pharmacies far exceeded their [cost of dispensing]."[84] The report also found that claims "dispensed at affiliated or specialty pharmacies are being reported with a weighted average margin over acquisition cost of up to $200 per claim" within Florida.[85]

Other states have studied this behavior and come to similar conclusions. The Ohio Pharmacists Association and 46brooklyn Research, a drug-pricing analytics firm, authored a 2019 report[86] discussing PBM operations in Ohio. Antonio Ciaccia, co-author of the report, commented that the data suggests that in Ohio:

> [i]n the case of specialty drugs and [Medicaid managed care organization ("MCO")]-owned specialty pharmacies, inappropriate profiteering and self-dealing are not just risks, but realities. When those entities who are tasked with containing costs also profit off the cost, it begs the question of whether or not there are adequate incentives to contain costs at all.[87]

The vertical integration of PBMs, insurers, and the rest of the healthcare delivery system increasingly presents opportunities to raise prices and increase profits.[88] In my opinion, PBMs are filled with conflicts of interest and incentives to raise prices, not decrease them.

The are some independently owned specialty pharmacies operating, and they present customers with a high degree of quality service and competitive prices.[89] In 2018, 44% of all independent pharmacies dispensed specialty drugs, but not all were accredited specialty

---

[79] *See* Adam J. Fein, *The Specialty Pharmacy Boom: Our Exclusive Update on the U.S. Market*, DRUG CHANNELS (Apr. 23, 2019), https://www.drugchannels.net/2019/04/the-specialty-pharmacy-boom-our.html [https://perma.cc/B9K9-TFLR].

[80] PETE HATEMI & CHRISTOPHER ZORN, PHARM. CARE MGMT. ASS'N, INDEPENDENT PHARMACIES IN THE U.S. ARE MORE ON THE RISE THAN ON THE DECLINE 2 (2020).

[81] *See Patient Steering*, NAT'L CMTY. PHARMACISTS ASS'N (2022), https://ncpa.org/patientsteering [https://perma.cc/84PE-AWZJ].

[82] Paul B. Ginsburg & Steven M. Lieberman, *Government Regulated or Negotiated Drug Prices: Key Design Considerations*, BROOKINGS (Aug. 30, 2021), https://www.brookings.edu/essay/government-regulated-or-negotiated-drug-prices-key-design-considerations/ [https://perma.cc/W3ZX-83WJ].

[83] *See* 3 AXIS ADVISORS, SUNSHINE IN THE BLACK BOX OF PHARMACY BENEFITS MANAGEMENT (2020), https://cdn.ymaws.com/www.floridapharmacy.org/resource/resmgr/docs_2020_legislative_session/fl_master_master_5.0_delieve.pdf [https://perma.cc/Z68U-7NEJ].

[84] Aislinn Antrim, *Florida Pharmacy Association Report Outlines Concerns About PBM, MCO Manipulations*, PHARMACY TIMES (Feb. 5, 2020), https://www.pharmacytimes.com/view/florida-pharmacy-association-report-outlines-concerns-about-pbm-mco-manipulations[https://perma.cc/2HPX-BUP7].

[85] 3 AXIS ADVISORS, *supra* note 83, at 9

[86] 46BROOKLYN RSCH., NEW DRUG PRICING ANALYSIS REVEALS WHERE PBMS AND PHARMACIES MAKE THEIR MONEY (2019), https://www.46brooklyn.com/research/2019/4/21/newpricing-data-reveals-where-pbms-and-pharmacies-make-their-money [https://perma.cc/R24KENCN].

[87] Darrel Rowland, *PBMs Accused of Exploiting Specialty Drugs*, COLUMBUS DISPATCH (Apr. 24, 2019), https://www.dispatch.com/story/news/politics/government/2019/04/24/pbmsaccused-exploiting-specialty-drugs/5347089007/ [https://perma.cc/F9DJ-YBUG].

[88] *See id.*

[89] Elizabeth Seeley & Surya Singh, *Competition, Consolidation, and Evolution in the Pharmacy Market*, COMMONWEALTH FUND (2021), https://www.commonwealthfund.org/publications/issue-briefs/2021/aug/competition-consolidation-evolution-pharmacy-market [https://perma.cc/4HE8-XN4P].

pharmacies.[90] Unfortunately, with PBMs' immense control over the specialty pharmacy business, it becomes harder every day for these community pharmacies to compete.

As a Member of Congress seated on the House Energy and Commerce Health Subcommittee, I have warned my colleagues repeatedly that vertical integration of PBMs, insurers, and other health entities is going to raise prices and limit medication access. Three years ago, I sent a letter to the Federal Trade Commission ("FTC") warning against the merging of these companies and tipped off the Department of Health and Human Services ("HHS") that these mergers were going to cause problems for consumers.[91] In that letter, I stated that PBMs maintain a number of conflicts of interest that inhibit their ability and incentive to keep drug costs low.

Congress established the FTC in 1914 through passage of the Federal Trade Commission Act.[92] The agency is tasked with investigating and preventing unfair competition, or lack thereof, and protecting consumers from lies and deceptive business practices.[93] The FTC is also tasked with enforcing various antitrust laws, or laws that regulate the organization of businesses to promote competition and prevent monopolies.[94]

Contrary to the FTC's congressionally mandated mission, it has allowed the mergers discussed previously to occur. In my letter, I pointed out to the FTC that PBMs control prescription drug coverage for over 238 million Americans.[95] The three largest PBMs

Just *three* PBMs control 80% of prescriptions filled in the US

Source: Xcenda

"It's incredibly frustrating to feel like my health hangs in the balance of a PBM or insurance company...PBMs have definitely robbed me of hope."

Grace Shults
Patient, Student

Grace describes her experience with PBMs and insurance companies in one word: traumatic. In fact, she says "going through the system was more traumatic than the actual diagnosis itself." While there are treatments and medications out there that could improve her quality of life, PBMs and insurance companies disagree with her physician, despite never meeting Grace in-person. This means she is left "living on samples" from her doctor and, at times, she even painfully admits to "borrowing essential prescriptions" from friends and family members when the costs get too high. She wants Members of Congress to know that "they have the power to make peoples' lives a little bit easier" by reining in PBMs. "It's scary to feel like you're hitting dead ends all the time," says Grace. "It doesn't have to be this way."

[90] *See* PDM Healthcare, *Independent Pharmacies, Chains Enter Specialty Pharmacy*, 7 PDM HEALTHCARE HEALTH INDUS. LINK 4 (2016), http://www.pdmhealthcare.com/HIL.aspx?story=HIL704_12 [https://perma.cc/4QTP-PYX6].

[91] *See* Earl L. "Buddy" Carter, Comment Letter to the Federal Trade Commission on Competition and Consumer Protection in the 21st Century Hearings, Project Number P181201; the State of Antitrust and Consumer Protection Law and Enforcement, and Their Development, Since the Pitofsky Hearings (Aug. 20, 2018), https://www.ftc.gov/system/files/documents/pu blic_comments/2018/08/ftc-2018-0048-d-0083-155238.pdf [https://perma.cc/3NLTS4NF].

[92] 15 U.S.C. §§ 41–58.

[93] *A Brief Overview of the Federal Trade Commission's Investigative, Law Enforcement, and Rulemaking Authority*, FED. TRADE COMM'N (May 2021), https://www.ftc.gov/about-ftc/mission/enforcement-authority [https://perma.cc/AE42-2S7N].

[94] *Guide to Antitrust Laws*, FED. TRADE COMM'N, https://www.ftc.gov/advice-guidance/competition-guidance/guide-antitrust-laws [https://perma.cc/5ZAP-R8UE].

[95] *See* Comment Letter, *supra* note 91, at 2.

control approximately 89% of those prescription drug benefits.[96]

PBMs have stated that their role in the marketplace is to control costs.[97] However, patients' out-of-pocket costs increased 169% from 1987 to 2008.[98] Employers experienced a 1,553% increase in drug benefit costs over that same time for employer-sponsored insurance benefits offered to employees.[99] Fast forward to 2018, recent data shows nationwide spending on prescription drugs reached $335 billion, up from only $30 billion in 1980.[100]

If PBMs argue they keep drug costs low, then the question naturally arises: why have drug costs gone up so much? PBMs have developed a complex business model of rebates, fees, gag clauses, and other practices that allow them to drive up prices and profits.[101] For example, if a drug manufacturer wants patients to have access to its product, it may be instructed by the PBM to set a higher list price on the medicine in order to deliver a bigger rebate to the PBM.[102] If the drug manufacturer refuses, the PBM could just exclude the medicine from its drug formulary—denying patients access.[103] PBMs also have no incentive to negotiate contracts with pharmacies outside of their integrated business. Independent pharmacists can try to negotiate business contracts with the PBM for network access, but they are often told by the PBMs that the contract is non-negotiable. I experienced this at my own pharmacy business.

These practices prevent competition from entering the marketplace and allow PBMs to further consolidate. Furthermore, PBMs are seated in the middle of the drug marketplace, allowing them to control the drug manufacturer rebate, plan formulary, fee paid to the pharmacists, and the price of drugs to the patients.[104] They maintain control of the flow of money with little to no transparency. PBMs have no fiduciary duty to employers, insurance plans, or patients. They are therefore able to negotiate all aspects of drug delivery without any responsibility to disclose any benefits they receive preventing patients, manufacturers, pharmacists, and even plans from determining their true value in the market. To this day, there are no laws or regulations that require PBMs disclose any of their business dealings, despite a HHS proposal to move forward with reforms that would address the growing impact of DIR fees on drug prices.[105]

The FTC received my letter but did not investigate PBM business practices. I never received a response from the agency. I followed up with FTC Chair Lina Kahn in December 2021 over the phone. The Chair told me the FTC would be conducting investigations and taking action against PBMs. As of January 2022, they still have not done so.*

**In June 2022, the FTC unanimously approved to launch an inquiry examining pharmacy benefit managers' (PBMs) unfair and deceptive business practices.*

---

[96] *Pharmacy Benefit Managers*, NAT'L ASS'N INS. COMM'RS (Mar. 16, 2021), https://content.naic.org/cipr_topics/topic_pharmacy_benefit_managers.htm [https://perma.cc/BRJ3-F4MA].

[97] *Pharmacy Benefit Managers and Their Role in Drug Spending*, *supra* note 52.

[98] NAT'L CMTY. PHARMACISTS ASS'N, THE PBM STORY 8 (2017), http://www.ncpa.co/pdf/PBM-Storybook-6pg.pdf [https://perma.cc/UDQ2-PKVL].

[99] *Id.*

[100] HAYFORD & AUSTIN, *supra* note 12.

[101] See Lauren Vela, *Reducing Wasteful Spending in Employers' Pharmacy Benefit Plans*, COMMONWEALTH FUND (Aug. 30, 2019), https://www.commonwealthfund.org/publications/issue-briefs/2019/aug/reducing-wasteful-spending-employers-pharmacy-benefit-plans [https://perma.cc/8AEE-CHXF].

[102] *See* MATHEMATICA POL'Y RSCH., INC., THE ROLE OF PBMS IN MANAGING DRUGCOSTS: IMPLICATIONS FOR A MEDICARE DRUG BENEFIT 16 (2000), https://www.kff.org/wpcontent/uploads/2013/01/the-role-of-pbms-in-managing-drug-costs-implications-for-a-medicare-drug-benefit.pdf [https://perma.cc/9FGC-34BY].

[103] *See id.*

[104] *See* Mark Meador, *Squeezing the Middleman: Ending Underhanded Dealing in the Pharmacy Benefit Management Industry through Regulation*, 20 ANNALS HEALTH L. 77, 78–79 (2011).

[105] *See* Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Correction, 87 Fed. Reg. 1842 (proposed Feb. 25, 2022) (to be codified at 42 C.F.R. §§ 422–23), https://www.federalregister.gov/documents/2022/02/25/2022-03966/medicare-program-contract-year-2023-policy-and-technical-changes-to-the-medicare-advantage-and [https://perma.cc/K95F76ZU].

III. PBM Predatory Tactics

Pharmacies are the nation's most accessible healthcare entities—95% of Americans live within five miles of a pharmacy.[106] There are two main types of pharmacies: independently owned "community pharmacies" and retail pharmacies that are integrated, or owned, by PBMs.[107] The best recognized and largest PBM-owned retail pharmacies are CVS, Express Scripts mail order, and OptumRx mail order.[108] The latter two are virtual pharmacies that ship medications to patients—they are not brick-and-mortar stores.[109]

Independent pharmacists continue to support their patients, but they are being driven out of the market by PBMs.[110] From December 2017 to December 2020, the United States lost more than 2,300 independent pharmacies, while PBMs consolidated more of the market for their own pharmacy business.[111] Every day that the FTC fails to stop PBMs' mergers and anticompetitive practices, more independent pharmacies are put out of business.[112]

PBMs use various tactics to limit patient medication access and increase drug costs to benefit their bottom line: issuing DIR fees, pocketing rebates, spread pricing contracts, and patient steering.[113]

DIR FEES

DIR fees were originally conceived in Medicare Part D as an incentive to lower costs for patients.[114] The original rule defined DIR fees as including: "discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits from manufacturers, pharmacies or similar entities."[115]

The idea was to bring prices down for Medicare patients through incentives. It has since morphed into a tool PBMs use to take more profits. PBMs require that pharmacies fulfill certain metrics when dispensing drugs—often called "performance fees."[116] PBMs are not transparent about how they grade pharmacies to issue these fees, but they are likely based on dispensing rates, medication adherence, and chronic disease management.[117] Pharmacies may be hit with DIR fees if they do not refill medications whether a patient asked for it or not, how many medications they dispensed, or if they dispense drugs that are not on the PBMs' preferred drug formulary list.

---

[106] *See* Rachel Balick, *HHS Releases Plan Aimed at Increasing Adult Immunizations*, PHARMACY TODAY (May 1, 2016), https://www.pharmacytoday.org/article/S1042-0991(16)30176-1/fulltext [https://perma.cc/WY2C-JU4M].

[107] *See* Patty Taddei-Allen, *Evolution of the Pharmacy Benefit Manager/Community Pharmacy Relationship: An Opportunity for Success*, 26 J. MANAGED CARE & SPECIALTY PHARMACY 708, 708–710 (2020).

[108] *See* Adam J. Fein, *CVS, Express Scripts, and the Evolution of the PBM BusinessModel*, DRUG CHANNELS (May 29, 2019), https://www.drugchannels.net/2019/05/cvs-expressscripts-and-evolution-of.html [https://perma.cc/J4FQ-M2ZM].

[109] *See id.*

[110] See Markian Hawryluk, *The Last Drugstore: Rural America is Losing its Pharmacies*, WASH. POST (Nov. 10, 2021, 7:00 AM), https://www.washingtonpost.com/business/2021/11/10/drugstore-shortage-rural-america/ [https://perma.cc/TY6Q-ZDQH].

[111] See Press Release, Am. *Pharmacists Ass'n, Pharmacy Coalition Praises Legislation to Relieve Patients and Pharmacies from Pharmacy DIR Fees* (May 27, 2021), https://pharmacist.com/APhA-Press-Releases/pharmacy-coalition-praises-legislation-to-relieve-patients-andpharmacies-from-pharmacy-dir-fees [https://perma.cc/JDJ4-ZYLA].

[112] *See* Linette Lopez, *What CVS Is Doing to Mom-And-Pop Pharmacies in the US Will Make Your Blood Boil*, BUS. INSIDER (Mar. 30, 2018, 4:59 AM), https://www.businessinsider.com/cvs-squeezing-us-mom-and-pop-pharmacies-out-of-business-2018-3 [https://perma.cc/U7RP-R7F9].

[113] *See Uncloaking Pharmacy Benefit Managers to Promote Market Competition*, BARCLAY DAMON (June 20, 2017), https://www.barclaydamon.com/blog/health-care/uncloakingpharmacy-benefit-managers-to-promote-market-competition [https://perma.cc/U3E4-YAXK].

[114] *See* True North Political Solutions, *White Paper: DIR Fees Simply Explained*, PHARMACY TIMES (Oct. 25, 2017), https://www.pharmacytimes.com/view/white-paper-dir-fees-simply-explained [https://perma.cc/JKC3-GPL4].

[115] 42 C.F.R. § 423.308 (2010).

[116] True North Political Solutions, *supra* note 114.

[117] *See id.*

DIR fees are not itemized and can be charged a year or more after medications are expensed—a practice that has since also been termed as "clawbacks".[118] There is no transparency on how DIR fees are calculated, yet they are extracted by the PBM from each pharmacy dispensing claim.[119] Pharmacies may not even know if a transaction is profitable for months after it transpired, depending on the DIR fee assessed to the pharmacy by the PBM.[120]

Independent pharmacy owners can be suddenly hit with unplanned expenses from these clawback fees, which are sometimes so high that the business is no longer profitable.[121] These predatory practices make it very difficult for independent pharmacies to remain operational.

According to the CMS fiscal year 2022 budget justification sent to Congress, pharmacy DIR fees under the Medicare program have increased by a staggering 91,500% between 2010 and 2019.[122] Independent pharmacies rarely have negotiating power to stop these fees.[123] They are at the mercy of the PBMs because they rely on in-network status from the insurers the PBM might be merged with. As PBMs make more profit off these fees, the rest of the supply chain is forced to charge higher prices to ensure they make a profit—hurting patients.[124]

Pharmacy DIR reform has strong bipartisan support in both the House and Senate, highlighted in the Pharmacy DIR Reform to Reduce Senior Drug Costs Act.[125] Additionally, in April 2020, 114 members of Congress signed a letter that I wrote to House and Senate leadership, requesting DIR fee reform be brought up for a vote.[126] Unfortunately, such a vote has not yet happened.

REBATES

PBMs processed over 90% of all pharmacy claims in 2016.[127] As the middlemen, PBMs are supposed to use their large purchasing power to negotiate for rebates off the manufacturer's drug list price and pass those savings on to patients.

Drug list prices are set by manufacturers.[128] They do not take into account any rebates or discounts to which PBMs and insurers agree. Manufacturers then offer rebates, best described as coupons, on their drugs to the PBMs and insurers in exchange for making their drugs available to patients.[129] These rebates are then, in theory, supposed to be passed down to the patients at the pharmacy counter or used to cover a patient's out-of-pocket insurance costs. Drug manufacturers willingly offer coupons on their products so patients get cheaper drugs.[130]

---

[118] *See id.*
[119] *See id.*
[120] *See id.*
[121] Laurie Toich, *DIR Fees and Independent Pharmacies: What is the Impact?*, PHARMACY TIMES (Feb. 13, 2017), https://www.pharmacytimes.com/view/dir-fees-and-independent-pharmacies-what-is-the-impact [https://perma.cc/RG6W-N36L].
[122] U.S. DEP'T HEALTH & HUM. SERVS. CTRS. FOR MEDICARE & MEDICAID SERVS., JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEE 242 (2022), https://www.cms.gov/files/document/fy2022-cms-congressional-justification-estimates-appropriations-committees.pdf [https://perma.cc/EEN3-53HF].
[123] Laurie Toich, *supra* note 121.
[124] *Pharmacy Benefit Managers and Their Role in Drug Spending*, *supra* note 52
[125] S. 1909, 117th Cong. (2021); see Gabrielle Ientile, *Pharmacy Associations Praise Bill Seeking to Reform DIR Fees*, DRUG TOPICS (June 2, 2021), https://www.drugtopics.com/view/pharmacy-associations-praise-bill-seeking-to-reform-dir-fees [https://perma.cc/2WTZ-G3Q9].
[126] Letter from Earl L. "Buddy" Carter, U.S. Representative, House of Representatives etal. to House & Senate Leadership (Apr. 27, 2020), https://buddycarter.house.gov/uploadedfiles/dir_letter_to_leadership.pdf [https://perma.cc/7N7C-RXHM].
[127] SUSAN K. URAHN, ALAN COUKELL, IAN REYNOLDS & ALISA CHESTER, PEW CHARITABLE TRUSTS, THE PRESCRIPTION DRUG LANDSCAPE, EXPLORED 40 (2019), https://www.pewtrusts.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored [https://perma.cc/Y55C-VHX2].
[128] *See How Are Prescription Drug Costs Really Determined?*, DRUG COST FACTS, https://www.drugcostfacts.org/prescription-drug-costs [https://perma.cc/WQA4-P8YS].
[129] *See id.*
[130] *See* Pragya Kakani, Michael Chernew & Amitabh Chandra, *Rebates in the Pharmaceutical Industry: Evidence from Medicines Sold in Retail Pharmacies in the U.S. 1* (Nat'l Bureau of Econ. Rsch., Working Paper No. 26846, 2020).

Total amount in annual fees PBMs charge pharmacies:

$9,100,000,000

Source: Drug Channels

"All of the time that we spend waiting for me to progress more so that insurance can tell me 'Actually maybe you should try the other drug' is going to cost me time. In neuromuscular diseases, time is muscle."

Kate Pecora
Rare Disease Advocate

Kate is not mincing words; the "lack of urgency" from insurance providers and PBMs isn't just costing her time and energy, it's costing her quality of life.

She spends hours every week fighting for basic treatment and coverage, time this young San Diego resident doesn't have. "I need a wheelchair because I can't walk," says Kate. "My insurance company came back and said that wheelchair access was not 'medically necessary' and there wasn't enough information to approve the claim." If a team of physical therapists, a medical equipment company, and a primary care physician aren't enough to convince a PBM or insurance company to cover a wheelchair, then, she says, there is clearly something wrong with our healthcare system. Up to this point, Kate has been able to maintain independent living, but is worried that delays and denials from prior authorizations may end up costing her that freedom.

PBMs leverage their power to get bigger rebates on drugs from manufacturers, putting even more money into their pockets.[131] Drug manufacturers have no choice in this matter. If they do not offer larger rebates to the PBM, the PBM can choose to not include its drugs in their list of covered medicines.[132] As PBMs demand larger rebates, manufacturers lose profits and are forced to increase costs to make up for the losses PBMs are pocketing.[133] Patients are on the losing end of this—paying increasingly higher prices for drugs.[134]

On May 4, 2021, the House Energy and Commerce Health Subcommittee, which I am seated on, held a hearing titled, "Negotiating a Better Deal: Legislation to Lower the Cost of Prescription Drugs."[135] Dr. Gaurav Gupta, founder of Ascendant BioCapital, testified to the committee that only 53% of what a patient pays for a drug at the counter makes it back to the drug manufacturer.[136] 47% gets taken by middlemen—largely PBMs.[137] PBMs are convoluting the rebate system, originally designed to decrease costs, in order to increase prices and take a larger portion of the cost increase for themselves.[138]

SPREAD PRICING

PBMs also utilize their power to pigeonhole independently owned pharmacies into predatory business contracts with a reimbursement structure

---

[131] *See* Frenz, *supra* note 68.

[132] *See Pharmacy Benefit Managers and Their Role in Drug Spending*, *supra* note 52.

[133] *See* Katheryn Houghton, *States Step Up Push to Regulate Pharmacy Drug Brokers*, KAISER HEALTH NEWS (June 30, 2021), https://khn.org/news/article/states-step-up-push-to-regulate-pharmacy-drug-brokers/ [https://perma.cc/WZB2-HEY3].

[134] *See* Ryan Oftebro, *Op-ed: Addressing Rising Drug Costs for Patients*, STATE OF REFORM (Mar. 4, 2022), https://stateofreform.com/news/washington/2022/03/op-ed-addressingrising-drug-costs-for-patients/ [https://perma.cc/6LQA-C8W6].

[135] *Negotiating a Better Deal: Legislation to Lower the Cost of Prescription Drugs: Hearing Before the Subcomm. on Health of the H. Comm. On Energy and Commerce*, 117th Cong. (2021).

[136] Prelim. Transcript, *Negotiating a Better Deal: Legislation to Lower the Cost of Prescription Drugs: Hearing Before the Subcomm. on Health of the H. Comm. On Energy and Commerce*, 117th Cong., at 120 (May 4, 2021).

[137] *See* Robert Langreth, David Ingold & Jackie Gu, *The Secret Drug Pricing System Middlemen Use to Rake in Millions*, BLOOMBERG (Sept. 11, 2018), https://www.bloomberg.com/graphics/2018-drug-spread-pricing/ [https://perma.cc/G99A-VATK].

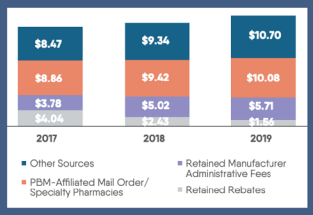
[138] *See* Frenz, *supra* note 68.

termed "spread pricing."[139] According to the National Community Pharmacists Association, "spread pricing is the PBM practice of charging payers like Medicaid more than they pay the pharmacy for a medication, and then the PBM keeps the 'spread' or difference, as profit."[140] For example, an independent pharmacy in Iowa serviced the local county jail and dispensed a generic bottle of antipsychotic pills for an inmate.[141] The PBM, CVS Caremark, billed the jail $198.22 for the medication but gave the pharmacy only $5.73.[142] CVS Caremark took $192.49 of profit on the generic medication, and the pharmacy reportedly lost money servicing the county jail for that year.[143]

PBMs use spread pricing tactics quite frequently to reimburse pharmacy claims below the cost of the dispensed drug. Pharmacy owners have little choice but to agree to these contracts, otherwise the PBM will not include them as an in-network pharmacy, likely putting the pharmacy out of business.[144]

Drug costs through Medicaid have increased, yet PBM reimbursements to pharmacies have decreased.[145] States have found that the practice of spread pricing meant Medicaid programs were billed more than what the actual pharmacies were paid for claims.[146] For example, in 2017, PBMs profited $1.3 billion of the $4.2 billion state Medicaid programs spent on drugs.[147]

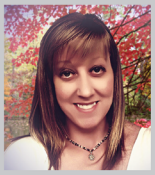
A few states have audited PBMs to uncover the profits they make from spread pricing contracts in Medicaid drug programs. Maryland found PBMs pocket $72 million annually from spread pricing.[148]



PBM Gross Profit ($B), 2017-2019

Source: PBM Accountability Project

"If there are medications out there that would help me get my independence back, then I should be able to have access to those."



Kami Obman
Artist

Kami has been through the wringer by the healthcare system. "Each time I thought I might be getting somewhere there's always been five steps back and its just been a very difficult road," she says. Kami understands better than most how wading through the sea of doctors appointments, insurance claims, prior authorizations, and more leads many patients with chronic physical illnesses to develop mental illnesses as well. "Emotionally, I have suffered. I have anxiety and that has been rampant," she says. "It's such a weight and burden to carry. It's a huge responsibility that takes up my entire life." While access to medication and treatment will not alleviate that entire burden, she knows that her health, and the health of thousands of patients just like her, would be massively improved if the system were designed around patients instead of PBMs.

[139] Trevor J. Royce, Sheetal Kircher & Rena M. Conti, *Pharmacy Benefit Manager Reform: Lessons From Ohio*, 322 J. AM. MED. ASS'N 299, 299 (2019).
[140] *Spread Pricing 101*, NAT'L CMTY PHARMACISTS ASS'N, https://ncpa.org/spread-pricing101 [https://perma.cc/2QTM-UGCN].
[141] *See* Langreth, et al., *supra* note 137.
[142] *Id.*
[143] *Id.*
[144] *Pharmacy Benefit Managers and Their Role in Drug Spending*, *supra* note 52.
[145] Rachel Garfield, Rachel Dolan & Elizabeth Williams, *Costs and Savings under Federal Policy Approaches to Address Medicaid Prescription Drug Spending*, KAISER FAM. FOUND. (June 22, 2021), https://www.kff.org/medicaid/issue-brief/costs-and-savings-underfederal-policy-approaches-to-address-medicaid-prescription-drug-spending/ [https://perma.cc/RQ47-3HX9].
[146] *See* Langreth, et al., *supra* note 137.
[147] *Id.*
[148] *See Spread Pricing 101*, *supra* note 140.

Michigan found PBMs overcharged their Medicaid program over $64 million, and Kentucky found PBMs pocketed $123.5 million in spread pricing annually.[149]

The Congressional Budget Office determined that a spread pricing ban in Medicaid programs would save federal taxpayers at least $1 billion over 10 years.[150] I introduced bipartisan legislation to stop this practice, H.R. 6101, the Drug Price Transparency in Medicaid Act of 2021.[151] This legislation would ban spread pricing tactics used by PBMs in Medicaid programs.[152] I have introduced this bill in previous Congresses as well,[153] but as of February 28, 2022 the legislation has still not passed Congress.

PATIENT STEERING

PBMs also use a practice called patient steering to steer patients away from independent pharmacies in favor of pharmacies or mail-order programs the PBM directly owns.[154]

To illustrate, consider a patient in rural Kansas walking into their local pharmacy that they have been a customer of for decades. After their pharmacist fills the prescription, they may get a phone call from the PBM telling them that their drug costs could be less expensive if the PBM filled the patient's prescription at a big box drug store, like CVS, or a mail-order service the PBM runs. Or maybe the PBM informs the patient that their local pharmacy is no longer in-network, forcing them to take an extended drive to a larger town where the medication can be filled by an in-network pharmacy, or a pharmacy that is merged with the PBM.

This is a patient steering and—make no mistake about it—it is harmful to patients.[155] Patient steering by PBMs requires patients to break preexisting relationships with pharmacists with whom they are comfortable.[156] A survey conducted by the National Community Pharmacists Association found 79% of independent pharmacists say their patients' prescriptions were transferred to a different pharmacy by a PBM without the patient's consent.[157]

Although the short-term gain of a less expensive drug for the patient sounds beneficial, the long-term consequences are worse. As PBMs steer patients into pharmacies they own, independent pharmacies lose business, and the healthcare delivery system becomes more integrated and anti-competitive, driving higher drug costs and presenting opportunities for PBMs to take more profits.[158] Consumers should have the freedom to choose, especially when it comes to their healthcare.

---

[149] *Id.*

[150] Garfield, et al., *supra* note 145.

[151] H.R. 6101, 117th Cong. (2021).

[152] *See id.*

[153] *NCPA Supports Bipartisan Bill to Ban PBM Spread Pricing Tactics; Pay Pharmacies Appropriately*, NAT'L CMTY. PHARMACISTS ASS'N (Dec. 1, 2021), https://ncpa.org/newsroom/news-releases/2021/12/01/ncpa-supports-bipartisan-bill-ban-pbm-spread-pricing-tactics-pay [https://perma.cc/DNB6-UA2A].

[154] *See* Letter from Ronna Hauser, Vice President, Pharmacy & Regul. Aff., Nat'l Comm. Pharmacists Ass'n, to Off. Sec'y, Fed. Trade Comm'n (Nov. 15, 2018), https://www.ftc.gov/system/files/documents/public_comments/2018/11/ftc-2018-0076-d-0018-162492.pdf [https://perma.cc/AR4W-JWBK].

[155] *See* CAL. PHARMACISTS ASS'N, SB 524 (SKINNER) – PBMS: PATIENT STEERING 1 (Aug. 2021), https://cpha.com/wp-content/uploads/2021/08/Patient-Steering-Fact-Sheet-_F.pdf [https://perma.cc/XTL2-UFXT].

[156] *See id.*

[157] Press Release, Nat'l Comm. Pharmacists Ass'n, Patient Steering a Massive Problem for Comm. Pharmacists, New Survey Shows (Sept. 17, 2020), https://ncpa.org/newsroom/newsreleases/2020/09/17/patient-steering-massive-problem-community-pharmacists-new-survey [https://perma.cc/H7JS-D8WW].

[158] Elizabeth Seeley & Surya Singh, *Competition, Consolidation, and Evolution in the Pharmacy Market*, COMMONWEALTH FUND (Aug. 12, 2021) https://www.commonwealthfund.org/publications/issue-briefs/2021/aug/competition-consolidation-evolution-pharmacy-market [https://perma.cc/32B4-JHRL].

IV. Potential Policy Solutions

Significant change addressing PBMs' predatory practices has proven to be difficult.

The Trump administration recognized the harmful impacts of PBMs, and, in February 2019, CMS issued a notice of proposed rulemaking to reduce out-of-pocket spending for beneficiaries at the pharmacy and other points-of-care.[159] This proposed rule would have forced PBMs to transfer rebates to the customer at the pharmacy counter, and DIR fees would have to be assessed at the point of sale instead of months after the medication is dispensed.[160]

This proposal would have ensured patients' out-of-pocket costs were reduced because the PBMs would no longer be able to take the drug manufacturer rebates for themselves—saving patients up to 30% of what they spend on drugs.[161] Assessing DIR fees at the point of sale would allow independently owned pharmacies to plan ahead for these fees and remodel their business to account for them.[162]

The Trump administration issued a final rule in November 2020, but the rule excluded any DIR fee reform and opted only to force rebates to patients at the point of sale.[163] The rule was set to take effect on January 1, 2022.[164] The PCMA sued the Trump administration, arguing the rule would lead to higher insurance premiums in Medicare Part D.[165] On January 30, 2021, the United States District Court for the District of Columbia issued an order postponing the rule's enactment until January 1, 2023.[166]

In a win for PBMs, the Biden administration further delayed the rule's implementation after a court order staying litigation on the rule until HHS is able to review it.[167] Congress then passed a legislative delay of the rule until 2026 as a "pay-for" to finance the infrastructure bill signed into law by President Biden on November 15, 2021.[168] The legislative delay was projected by the Congressional Budget Office to save the federal government $49 billion in premium increases if the rule took effect.[169]

As previously discussed, members of Congress have also introduced legislation to stop these PBM practices, notably the Pharmacy DIR Reform to Reduce Senior Drug Costs Act[170] and the Drug Price Transparency in Medicaid Act of 2021.[171]

---

[159] *See* Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-ofSale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, 84 Fed. Reg. 3240 (proposed Feb. 6, 2019) (to be codified at 42 C.F.R. pt. 1001), https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuseremoval-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals [https://perma.cc/8WKR-UNNG].

[160] *See id.*

[161] *See* Jeff Lagasse, *Updated: Trump-Era Rebate Rule for Medicare Part D on Hold Until 2023*, HEALTHCARE FIN. (Feb. 1, 2021), https://www.healthcarefinancenews.com/news/bidenadministration-puts-hold-trump-era-rebate-rule-medicare-part-d [https://perma.cc/SPJ5-K263].

[162] *See* T. Joseph Mattingly II & Ge Bai, *Reforming Pharmacy Direct and Indirect Remuneration in the Medicare Part D Program*, HEALTH AFFS. (July 19, 2021), https://www.healthaffairs.org/do/10.1377/forefront.20210714.70749/full/ [https://perma.cc/BBJ5-YW9W].

[163] 42 C.F.R. § 1001 (2020); *see* Press Release, U.S. Dep't of Health & Human Servs., HHS Finalizes Rule to Bring Drug Discounts Directly to Seniors at the Pharmacy Counter (Nov. 20, 2020), https://www.hhs.gov/about/news/2020/11/20/hhs-finalizes-rule-bring-drugdiscounts-directly-seniors-pharmacy-counter.html [https://perma.cc/LS3Q-PB48]

[164] Thomas Sullivan, *PBM Rebate Rule Effective Date Postponed*, POL'Y & MED., https://www.policymed.com/2021/02/pbm-rebate-rule-effective-date-postponed.html [https://perma.cc/V6BB-D5B5] (last updated Feb. 14, 2021).

[165] *See Pharm. Care Mgmt. Ass'n v. U.S. Dep't of Health & Human Servs.*, 21 Civ. 21-95 (JDB) (D.D.C. Mar. 15, 2021).

[166] *See* Order, *Pharm. Care Mgmt. Ass'n v. U.S. Dep't of Health & Human Servs.*, 21 Civ. 21-95 (JDB), at 1 (D.D.C. Jan. 30, 2021).

[167] *See* Order, *Pharm. Care Mgmt. Ass'n v. U.S. Dep't of Health & Human Servs.*, 21 Civ. 21-95 (JDB), at 1 (D.D.C. Mar. 15, 2021); see also Jacquie Lee & Ian Lopez, *HHS Delays Trump-Era Drug Rebate Rule to 2023 After Court Order*, BLOOMBERG (Mar. 18, 2021), https://news.bloomberglaw.com/pharma-and-life-sciences/biden-dela

[168] Infrastructure Investment and Jobs Act, Pub. L. No. 117-58, 135 Stat. 429 (2021).

[169] CONG. BUDGET OFF., INCORPORATING THE EFFECTS OF THE PROPOSED RULE ON SAFEHARBORS FOR PHARMACEUTICAL REBATES IN CBO'S BUDGET PROJECTIONS—SUPPLEMENTAL MATERIAL FOR UPDATED BUDGET PROJECTIONS: 2019 TO 2029 (2019), https://www.cbo.gov/system/files/2019-05/55151-SupplementalMaterial.pdf [https://perma.cc/Q54Q-587P].

[170] S. 1909, 117th Cong. (2021).

[171] H.R. 6101, 117th Cong. (2021).

Number of days it took to get authorization for her medication

$1,000 – $2,000

range of her monthly co-pays with insurance

"We're looking for superheroes to help us get the medicines that we need...that are available, accessible, and affordable without sacrificing the essential needs of daily living."

Charlene L.
Patient Advocate, Physician

Charlene defines her journey through the healthcare system as a "roller coaster ride" that she can't get off and does "not have any control over." Her frustrations stem from insurance companies treating her like a number instead of a person. To PBMs, step therapy is a cost-saving measure; but, for Charlene, it has "ripple effects" that impact not just her, but her friends and family, too. "All the medications that I had to try and fail the first time, they all had some kind of side effect," said Charlene. Those side effects can be catastrophic; Charlene believes the "fail-first" treatment system contributed to her cancer diagnosis. On top of the severe physical toll this system has taken on her and her health, she is still at times forced to choose between "bills, food, and medicine," due to the high cost of her prescriptions, an issue PBMs were supposed to address.

State action has also taken place to stop PBMs. On December 10, 2020, the Supreme Court ruled 8-0 in *Rutledge v. Pharmaceutical Care Management Association (PCMA)*[172] that an Arkansas law ("Act 900") does not preempt federal Employee Retirement Income Security Act of 1974 ("ERISA") laws.[173] Act 900 regulates reimbursements to pharmacies by PBMs for the cost of prescription drugs.[174] Under Act 900, PBMs are required to raise reimbursement rates for drugs if they are below the pharmacy's wholesale acquisition cost.[175] This would prohibit PBMs from reimbursing pharmacies less than what it cost for them to purchase the drug.[176]

The *Rutledge* case will likely service as a model for other states to enact laws aimed at stopping PBMs' practices. It was a big win for all pharmacists, and the ruling opens the door for states to take additional action against PBMs, not just stopping low reimbursement rates.

[172] 598 U.S. __ (2020).
[173] *See* Kimberly J. Donovan & Michele Noble, *Supreme Court Rules That Arkansas Act 900, Affecting the Prices That PBMs Pay to Pharmacies, Is Not Preempted Under ERISA*, NAT'L L. REV. (Dec. 11, 2020), https://www.natlawreview.com/article/supreme-court-rules-arkansas-act-900-affecting-prices-pbms-pay-to-pharmacies-not [https://perma.cc/DM85-TH22].
[174] PBM Reimbursement, ARK. PHARMACISTS ASS'N, https://www.arrx.org/reimbursement [https://perma.cc/D2X5-N6YF].
[175] *Id.*
[176] *Id.*

V. Conclusion

Members of Congress, and legislators across the country, have a tall order to fill. Lowering the cost of prescription drugs and addressing the role that PBMs play in setting those costs are not overly partisan issues. These are issues Democrats and Republicans all over the country and in Congress agree must be addressed. The PBM lobby is powerful and influential, but it is not untouchable. We know how to fix this mess. We know how to bring immediate relief to American's wallets. But we, collectively, must have the courage to fight back against PBMs and enact significant reforms to stop their predatory practices.

Number of days it took to get authorization for her medication

"Congress needs to understand that insurance companies...have more power to take lives and cause pain than the doctors that are actually trying to save lives or lessen pain."

Angela Deeds
Lynchburg, VA

Angela struggles not just affording medication for her gastroparesis, but accessing it. Despite having a specialist who knows her body and medical history better than anyone, she says "someone behind a computer," whom she has never met, has ultimate control over her care. She describes her fight for medication and treatment as a punishment, saying that "I'm being penalized for a condition I never wanted...I'm being punished for wanting a life, which according to the constitution, I'm allowed to have." Being only in her early 30s, Angela has her whole life ahead of her and wants the brick walls insurance companies and PBMs place in her path to disappear. She's tired of proving that she needs medication and is ready to get back to her life outside of being a patient.

Thank you to all the patients who took time out of their busy schedules to open up about the difficulties they've experienced at the hands of PBMs. This booklet is dedicated to you.

Congressman
BUDDY CARTER
Georgia's First District

PATIENT RIGHTS ADVOCATE.ORG

July 5, 2023

The Honorable Bob Good
Chair, Subcommittee on Health, Employment, Labor, and Pensions
461 Cannon House Office Building
Washington, DC 20515

The Honorable Mark DeSaulnier
Ranking Member, Subcommittee on Health, Employment, Labor, and Pensions
503 Cannon House Office Building
Washington, DC 20510

Dear Chair Good and Ranking Member DeSaulnier:

Thank you for recently hosting a hearing on Competition and Transparency: The Pathway Forward for a Stronger Health Care Market. This important conversation demonstrated your committee's strong and bipartisan support for price transparency as a solution to lower costs for employers and protect them and their employees from overcharges. The committee's position reflects the will of the American people, nearly 90% of whom support systemwide healthcare price transparency.

The need is urgent for all prices in healthcare to be readily available. One hundred million Americans are in medical debt. Many face bad credit ratings, garnished wages, liens on personal property, and personal bankruptcy, after being overcharged with no access or proof of the true, actual prices or competitive comparison. Employers and their employees face dramatic increases in their healthcare costs and premiums each year.

Actual, upfront prices for care and coverage will protect all American consumers – patients, employers, and unions, -- from overcharges, errors, and fraud, and provide remedy and recourse from discriminatory and predatory billing practices. Systemwide price transparency will unleash a competitive healthcare marketplace that will greatly lower the costs of healthcare and coverage that currently plague families, employers, and our country.

The Transparency in Coverage (TiC) rule requires many important disclosures, but plans and issuers should provide more useful information in more accessible forms to ensure that their members and their members' employers have access to the critical information they need to drive down the cost of their care and coverage. New legislation is needed to enhance disclosure requirements and to hold plans and issuers accountable to comply with the long delayed prescription drug price transparency provision in the TiC rule.

The need for legislation in this space is underscored by recent litigation brought by employers and unions against their insurers and third-party administrators (TPAs). For example, in the recent case Kraft Heinz Co. filed against its TPA, Aetna, the employer alleged that its TPA breached its fiduciary duties by refusing to hand over medical claims data. In a similar case, the Connecticut Bricklayers and Sheet Metal Workers Unions sued its plan administrators and consultants to gain access to similar claims and payment data. In contrast, the Osceola School District was able to save $21 million on healthcare over two years by moving to a price transparent healthcare model for its 6,500 employees.

Employers and their workers need clear laws enforced by federal agencies to ensure that they have access to their claims and payment data and similar information.

Key pillars of meaningful legislation to enable true, systemwide price transparency include:

1. Codification of the TiC rule to be applicable to all commercial coverage, especially the requirement for plans and issuers to post machine-readable files containing negotiated in-network prices, drug prices, and out-of-network prices;

2. Enhancements to drug price machine-readable files to ensure that the real prices of drugs are disclosed;

3. The following revisions to the "gag clause" prohibition of the Consolidated Appropriations Act, 2021:

a. Ensure that it applies to the appropriate parties, including TPAs serving group health plans;

b. Expand the prohibition to contract clauses that would prohibit or restrict the ability of a group health plans to audit their TPAs or insurers;

c. Broaden the data and information employers have access to about their own plans to include prices as well as reimbursement formulae; and

d. Express protections to allow employers and individuals to negotiate more favorable prices and to reap the financial benefits of such negotiations;

4. Accountability provisions that would preclude charging members amounts in excess of their expectations and require plans and issuers to attest to the accuracy of their disclosures;

5. Expanded applicability to Accountable Care Organizations that serve Medicare beneficiaries in the role of a payer and receive favorable reimbursement from the government; and

6. Specific penalties for plans, issuers, and TPAs that violate the gag clause prohibition by placing anti-competitive provisions in their contracts.

Legislation adhering to these critical pillars will enable the meaningful healthcare price transparency that Americans demand and the system needs to reverse the runaway medical costs burdening so many Americans.

Thank you for considering such legislation. We would be happy to meet with you to discuss and provide more details on these suggestions when appropriate.

Warmest Regards,

Cynthia A. Fisher
Founder and Chairman
PatientRightsAdvocate.org

Why We Stand Up for Transgender Children and Teens

Moira Szilagyi, MD, PhD, FAAP

August 10, 2022

As I reflect on the recent AAP Leadership Conference, where pediatricians from across the country gathered in person for the first time in three years, I feel a tremendous sense of pride. Pediatricians are guided by our values. We believe in the inherent worth of all children.... that each and every one deserves optimal health and the highest quality care. We stand on science

and keep children front and center. While we know everyone cares about children, especially their own children, the AAP cares about all children, each and every one. This includes children and youth who are transgender.

During the conference, pediatricians spoke up in support of a resolution on the need to expand education and training on gender-affirming care, and I was reminded of a patient encounter from when I was a freshly minted pediatrician.

I was seeing a 16-year-old girl, dressed in black from head to toe, who came in for a well visit. She was in foster care, the landing place for so many LGBTQ+ youth rejected by their biological families, especially when I was first starting my career. She was pretty noncommunicative. At the end of the visit, she said: "If you knew me, you would hate me."

A couple of additional visits followed over the course of several weeks, and she eventually disclosed that she was a lesbian. It was an opportunity for me to reassure her that I admired her, supported her and certainly did not hate her. Her mood changed instantly, and she opened up to me about the struggles she had endured and would face moving forward in a world that would not always be accepting.

The emotional and psychological trauma of rejection, whether by family, friends, society, or lawmakers, can leave scars that never heal. When we fail to accept people for who they are, we pass painful judgements on them and create so much unnecessary emotional and psychological pain.

The emotional and psychological trauma of rejection, whether by family, friends, society, or lawmakers, can leave scars that never heal. When we fail to accept people for who they are, we pass painful judgements on them and create so much unnecessary emotional and psychological pain.

I cannot tell you how many similar conversations I have had over the years with young LGBTQ+ patients. They are all, just like any teen, trying to find their way in life. Our duty to them as doctors is to support them on that journey--to help them become the best person they can be. This is the approach our gender-affirming care policy is grounded in.

There is strong consensus among the most prominent medical organizations worldwide that evidence-based, gender-affirming care for transgender children and adolescents is medically necessary and appropriate. It can even be lifesaving. The decision of whether and when to start gender-affirming treatment, which does not necessarily lead to hormone therapy or surgery, is personal and involves careful consideration by each patient and their family.

At this year's Leadership Conference, there was a second resolution on transgender youth, offered by five pediatricians who disagree with the Academy's approach to gender-affirming care. These pediatricians were unable to recruit a sponsor, which meant no one was willing to support their proposal. During our meeting, this resolution did not advance because it did not receive a second vote on the floor. Much like other formal democratic processes, the AAP Leadership Conference follows a set of standard parliamentary procedures to structure our discussions.

The conference serves to connect AAP state chapters, our national committees, councils and sections and the AAP Board of Directors, which is the policy-making body of the Academy. Part of this meeting involves debate and voting on resolutions, when AAP members have the opportunity to provide input on the Academy's efforts to address important child health issues. Other topics at the Leadership Conference ranged from expanding children's health insurance to reducing child poverty. The resolution process is important, because it keeps AAP leaders apprised of the issues and concerns of our members across the country.

However, we don't need a formal resolution to look at the evidence around the care of transgender young people. Evaluating the evidence behind our recommendations, which the unsponsored resolution called for, is a routine part of the Academy's policy-writing process. Critics of our gender-affirming care policy mischaracterize it as pushing medical or surgical treatments on youth; in fact, the policy calls for the opposite: a holistic, collaborative, compassionate approach to care with no end goal or agenda. The AAP Section on LGBTQ Health and Wellness, as well as other groups within AAP's membership, are engaged in numerous conversations about transgender care and we expect those discussions to continue. It is an important conversation, and one the AAP is eager to lead.

Gender-affirming care is a top issue of concern for pediatricians, and in fact, one of the **top ten resolutions** receiving the most support at the meeting was the one on expanding education and training for pediatricians on gender-affirming care. I was heartened to see this resolution pass with such broad support.

Yet outside of our organization, there is a dangerous movement taking place, led by extremists, targeting youth who are receiving gender-affirming care, and vilifying the

pediatricians providing their care. The result has been rampant disinformation about what this care is and real threats of violence against some of our members.

In some states, efforts are underway to restrict access to gender-affirming care and criminalize the pediatricians who provide it. This has already had a chilling effect on access to care in these communities, and other efforts across the country are focused on doing the same. The people who suffer the most from this discrimination are of course the children and teens just trying to live their lives as their true selves. Pediatricians will not stay silent as these lies are waged against our patients and our peers.

I am proud to lead the American Academy of Pediatrics, proud to stand alongside pediatricians providing gender-affirming care, and proud to support all children.

The views expressed in this article are those of the author, and not necessarily those of the American Academy of Pediatrics.

About the Author

Moira Szilagyi, MD, PhD, FAAP

Moira Szilagyi, MD, PhD, FAAP, is the 2022 president of the American Academy of Pediatrics.

AMERICAN COLLEGE of CARDIOLOGY.

ACC Underscores Safety of COVID-19 Vaccine

Oct 14, 2022

ACC News Story

With questions again being raised about the safety of COVID-19 vaccines, particularly in adolescent boys and young men receiving mRNA vaccines, the ACC is underscoring the benefits of COVID-19 vaccination, especially for patients with cardiovascular disease and related risk factors who remain among those at greatest risk from the virus.

The ACC has long supported vaccination as a vital protective measure against dangerous illness and for personal and community health. "There is no question that the benefits of COVID-19 vaccination generally outweigh the risks. While we do acknowledge that there is a very small risk of myocarditis after vaccination, particularly in adolescent boys and young men receiving mRNA vaccines, these instances are extremely rare, generally mild and treatable, and in most cases resolve quickly and without intervention," said **Eric Stecker, MD, FACC**, chair of ACC's Science and Quality Committee. "We should be clear that the risk of long COVID, heart damage and death are higher among unvaccinated COVID-19 patients, and we therefore encourage everyone, including young men, to receive a primary (two-shot) vaccination for COVID-19."

Stecker notes that it is reasonable for adolescent and young males to consult with a physician prior to receiving additional mRNA boosters, given the small but elevated risk of myocarditis in this group.

Throughout the pandemic the ACC has developed clinical guidance by critically evaluating the full spectrum of peer-reviewed, scientific evidence to make recommendations on a variety of topics, including vaccination benefits and risks. Most recently, the ***2022 ACC Expert Consensus Decision Pathway on Cardiovascular Sequelae of COVID-19 in Adults*** addressed myocarditis and other myocardial involvement, post-acute sequelae of SARS-CoV-2 Infection, and return to play. New **CardioSmart patient tools** include infographics on long COVID and return to play, as well as a post-COVID health history and symptom checklist and a fact sheet on common heart issues after COVID-19.

"The College welcomes continued scientific study of COVID-19, vaccination and related complications as this is a nuanced topic with continued health ramifications likely to be discovered for years to come," said Stecker. "We encourage people with questions or concerns about COVID-19 vaccination to talk to their clinician to determine the best course of action for their own health needs and concerns."

*For more COVID-19 clinical guidance, published research and expert perspectives, visit ACC's **COVID-19 Hub**.*

Clinical Topics: **COVID-19 Hub, Heart Failure and Cardiomyopathies, Prevention, Sports and Exercise Cardiology**

Keywords: *COVID-19, COVID-19 Vaccines, SARS-CoV-2, Cardiovascular Diseases, Myocarditis, Return to Sport, Vaccination, RNA, Messenger, Heart Injuries, Physicians, Risk Factors*

COMMITTEE ON
EDUCATION AND THE WORKFORCE
U.S. HOUSE OF REPRESENTATIVES
2176 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6100

June 6, 2023

The Honorable Virginia Foxx
Chair
Committee on Education and the Workforce
U.S. House of Representatives
Washington, DC 20515

Dear Chair Foxx:

We write to request that you schedule a hearing to examine the illegal employment of children in unsafe conditions, in violation of both the *Fair Labor Standards Act* (FLSA) and the *Occupational Safety and Health Act* (OSH Act). Proper oversight requires that Committee members have the opportunity to explore the scope of the problem and proposed legislation that has been referred to our Committee that would help address it.

"A self-supporting and self-respecting democracy can plead no justification for the existence of child labor," President Franklin Delano Roosevelt proclaimed in a 1937 message to Congress to support passage of FLSA.[1] Nevertheless, as we near the 85th anniversary of that landmark law later this month, the "existence of child labor" still looms large. High-profile exposés of companies illegally employing and overworking children in dangerous jobs[2] put a face on the

[1] *Message to Congress on Establishing Minimum Wages and Maximum Hours*, THE AMER. PRES. PROJ., https://www.presidency.ucsb.edu/documents/message-congress-establishing-minimum-wages-and-maximum-hours (last visited May 8, 2023).

[2] *A New Child Labor Crisis in America*, N.Y. TIMES (Mar. 9, 2023), https://www.nytimes.com/2023/03/09/podcasts/the-daily/migrant-child-labor-america.html; David J. Neal, *A Restaurant's Florida Franchisees Illegally Used Child Labor and Owed Workers $24,000*, MIAMI HERALD (Mar. 8, 2023), https://www.miamiherald.com/news/business/article272835475.html; *How Child Labor Violations Have Quadrupled Since 2015*, 1A: NPR (Mar. 6, 2023), https://www.npr.org/2023/03/06/1161486299/how-child-labor-violations-have-quadrupled-since-2015; Nandita Bose & Mica Rosenberg, *U.S. to Crack Down on Child Labor Amid Massive Uptick*, REUTERS (Feb. 27, 2023), https://www.reuters.com/business/us-crack-down-child-labor-amid-massive-uptick-2023-02-27/; Hannah Dreier, *Alone and Exploited, Migrant Children Work Brutal Jobs Across the U.S.*, N.Y. TIMES (Feb. 25, 2023), https://www.nytimes.com/2023/02/25/us/unaccompanied-migrant-child-

numbers available in the Wage and Hour Division's (WHD) own data, which show a near quadrupling of the number of children involved in child labor violations since 2015—and these are just the cases that have been detected.[3] This surge in child labor violations is happening while WHD has had steadily decreasing resources to invest in enforcement.[4]

Meanwhile, the National Institute for Occupational Safety and Health (NIOSH)—the agency charged with researching occupational risks to young workers—is likewise constrained by years of flat or diminished funding. In inflation-adjusted dollars, NIOSH has seen its budget cut every year since 2016.[5] With decreased funding, NIOSH has decreased capacity to monitor and report on the hazards children face at work. For example, NIOSH discontinued the Child Agriculture Injury Surveillance program, leaving policymakers with an "absence of timely, valid, and reliable injury data."[6]

Meaningful solutions are on the table. Reps. Hillary Scholten (D-MI) and Nancy Mace (R-SC) have introduced a bipartisan bill (H.R. 2388, *Justice for Exploited Children Act of 2023*) to increase civil monetary penalties for child labor violations. Rep. Dan Kildee (D-MI) has introduced a bill (H.R. 2956, *Combatting Child Labor Act*) to increase both civil monetary penalties and criminal sanctions. Additionally, we plan to introduce soon a comprehensive bill to toughen penalties for child labor violations and unsafe workplaces that harm children, expand research and expertise on these issues, update standards about occupations too hazardous for the employment of children, and track the statistics on the scope of child labor violations. Other legislative solutions may yet surface, especially if we have a proper hearing to discuss the problem.

In short, the scourge of child labor that Congress sought to eliminate 85 years ago with the passage of FLSA is back, and it has returned at time when the agencies we expect to provide timely data and aggressive enforcement lack the resources they need. We ask that you schedule a hearing this month so that Committee members have the opportunity to hear about the nature

---

workers-exploitation.html; Terri Gerstein, *Child Labor Has Made a Comeback*, SLATE (Nov. 16, 2022), https://slate.com/business/2022/11/packers-sanitation-child-labor-department-hyundai-chipotle.html; *Child Labor Allegations at Alabama Hyundai Factory Lead to Class Action Lawsuit*, FOX 23 NEWS (Aug. 2, 2022), https://www.fox23.com/news/trending/child-labor-allegations-at-alabama-hyundai-factory-lead-to-class-action-lawsuit/article_96833571-664a-57ce-9413-f32a7018ec0b.html.

[3] *See* Wage & Hr. Div., *Child Labor*, U.S. DEP'T OF LAB., https://www.dol.gov/agencies/whd/data/charts/child-labor (last visited Mar. 13, 2023) (showing 1,012 children in child labor violations in FY15 compared to 3,876 in FY22).

[4] According to WHD data, the number of personnel hours spent on enforcement has decreased *every year since FY17*. *See* Wage & Hr. Div., *WHD: All Acts*, U.S. DEP'T OF LAB., https://www.dol.gov/agencies/whd/data/charts/all-acts (last visited Mar. 13, 2023).

[5] Adjusted to FY24 dollars, the most recent budget peak for NIOSH was FY16 ($446.1 million), and funding has steadily fallen through FY23 ($375.1 million).

[6] Barbara C. Lee & Marsha A. Salzwedel, *Safeguarding Youth from Agricultural Injury and Illness: The United States' Experience*, FRONTIERS PUB. HEALTH (Jan. 30, 2023), https://fjfsdata01prod.blob.core.windows.net/articles/files/1048576/pubmed-zip/.versions/1/.package-entries/fpubh-11-1048576/fpubh-11-1048576.pdf?sv=2018-03-28&sr=b&sig=cNjNVr1%2BGFqKPeOItn4O1wIB39G0gqRUb9yH%2BRj3QP4%3D&se=2023-05-19T16%3A06%3A02Z&sp=r&rscd=attachment%3B%20filename%2A%3DUTF-8%27%27fpubh-11-1048576.pdf.

and scope of the child labor problem confronting the country and the legislative solutions to address it.

Thank you for your prompt attention to this matter.

Sincerely,

ROBERT C. "BOBBY" SCOTT
Ranking Member

ALMA S. ADAMS, Ph.D.
Ranking Member
Subcommittee on Workforce Protections

U.S. Department of Justice
Civil Rights Division

Assistant Attorney General
950 Pennsylvania Ave, NW - RFK
Washington, DC 20530

March 31, 2022

Dear State Attorneys General:

The U.S. Department of Justice (the Department) is committed to ensuring that transgender youth, like all youth, are treated fairly and with dignity in accordance with federal law. This includes ensuring that such youth are not subjected to unlawful discrimination based on their gender identity, including when seeking gender-affirming care. We write to remind you of several important federal constitutional and statutory obligations that flow from these fundamental principles.

People who are transgender are frequently vulnerable to discrimination in many aspects of their lives, and are often victims of targeted threats, legal restrictions, and anti-transgender violence.[1] The Department and the federal government more generally have a strong interest in protecting the constitutional rights of individuals who are lesbian, gay, bisexual, transgender, queer, intersex, nonbinary, or otherwise gender-nonconforming,[2] and in ensuring compliance with federal civil rights statutes. The Department is also charged with the coordination and enforcement of federal laws that protect individuals from discrimination in a wide range of federally-funded programs and activities.[3]

Intentionally erecting discriminatory barriers to prevent individuals from receiving gender-affirming care implicates a number of federal legal guarantees. State laws and policies that prevent parents or guardians from following the advice of a healthcare professional regarding what may be medically necessary or otherwise appropriate care for transgender minors may infringe on rights protected by both the Equal Protection and the Due Process Clauses of the Fourteenth Amendment. The Equal Protection Clause requires heightened scrutiny of laws that discriminate on the basis of sex[4] and prohibits such discrimination absent an "exceedingly

[1] *See, e.g.*, Michelle M. Johns et al., Ctrs. for Disease Control and Prevention, *Transgender Identity and Experiences of Violence Victimization, Substance Use, Suicide Risk, and Sexual Risk Behaviors Among High School Students—19 States and Large Urban School Districts, 2017*, Morbidity and Mortality Weekly Report 68: 67-71 (2019), https://www.cdc.gov/mmwr/volumes/68/wr/mm6803a3.htm?s_cid=mm6803a3_w (finding that transgender youth reported higher levels of violence victimization compared to their cisgender peers).
[2] *See, e.g.*, Exec. Order No. 13,988, § 1, 86 Fed. Reg. 7023 (Jan. 20, 2021); Pamela S. Karlan, Principal Deputy Assistant Attorney General, Civ. Rts. Div., U.S. Dep't of Justice, Memorandum, *Application of Bostock v. Clayton County to Title IX of the Education Amendments of 1972* (Mar. 26, 2021), https://www.justice.gov/crt/page/file/1383026/download.
[3] Exec. Order No. 12,250, § 1-201, 45 Fed. Reg. 72,995 (Nov. 2, 1980).
[4] *See, e.g.*, *Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 610-13 (4th Cir. 2020), *as amended* (Aug. 28, 2020), *reh'g en banc denied*, 976 F.3d 399 (4th Cir. 2020), *cert. denied*, 2021 WL 2637992 (June 28, 2021); *Whitaker* v.

persuasive" justification.[5] Because a government cannot discriminate against a person for being transgender "without discriminating against that individual based on sex,"[6] state laws or policies that discriminate against transgender people must be "substantially related to a sufficiently important governmental interest."[7]

A law or policy need not specifically single out persons who are transgender to be subject to heightened scrutiny. When a state or recipient of federal funds criminalizes or even restricts a type of medical care predominantly sought by transgender persons, an intent to disfavor that class can "readily be presumed."[8] For instance, a ban on gender-affirming procedures, therapy, or medication may be a form of discrimination against transgender persons, which is impermissible unless it is "substantially related" to a sufficiently important governmental interest.[9] This burden of justification is "demanding."[10] Such a law or policy will not withstand heightened scrutiny when "the alleged objective" differs from the "actual purpose" underlying the classification.[11] In addition, the Due Process Clause protects the right of parents "to seek and follow medical advice" to safeguard the health of their children.[12] A state or local government must meet the heavy burden of justifying interference with that right since it is well established within the medical community that gender-affirming care for transgender youth is not only appropriate but often necessary for their physical and mental health.[13]

In addition to these constitutional guarantees, many federal statutes require recipients of federal financial assistance to comply with nondiscrimination requirements as a condition of receiving those funds. Relevant statutes include:

- **Section 1557 of the Affordable Care Act**[14] protects the civil rights of people—including transgender youth—seeking nondiscriminatory access to healthcare in a range of health

---

Kenosha Unified Sch. Dist. No. 1 Bd. of Educ., 858 F.3d 1034, 1051 (7th Cir. 2017), *cert. dismissed*, 138 S. Ct. 1260 (2018); *see also* Brief for the United States as Amicus Curiae Supporting Plaintiffs-Appellees, *Brandt v. Rutledge*, No. 21-2875 (8th Cir. Jan. 21, 2022); En Banc Brief for the United States as Amicus Curiae Supporting Plaintiff-Appellee, *Adams v. School Board of St. John's County*, No. 18-13592 (11th Cir. Nov. 26, 2021); Brief for the United States as Amicus Curiae Supporting Plaintiffs-Appellees, *Corbitt v. Taylor*, No. 21-10486 (11th Cir. Aug. 2, 2021).

[5] *United States v. Virginia*, 518 U.S. 515, 531 (1996) ("Parties who seek to defend gender-based government action must demonstrate an 'exceedingly persuasive justification' for that action.") (quoting *Mississippi Univ. for Women v. Hogan*, 458 U.S. 718, 724 (1982)).

[6] *Bostock v. Clayton Cnty.*, 140 S. Ct. 1731, 1741 (2020).

[7] *Grimm*, 972 F.3d at 608 (quoting *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 441 (1985) (internal quotations omitted)).

[8] *Bray v. Alexandria Women's Health Clinic*, 506 U.S. 263, 270 (1993) ("Some activities may be such an irrational object of disfavor that, if they are targeted, and if they also happen to be engaged in exclusively or predominantly by a particular class of people, an intent to disfavor that class can readily be presumed.").

[9] *Virginia*, 518 U.S. at 533.

[10] *Id.*

[11] *Miss. Univ.*, 458 U.S. at 730.

[12] *Parham v. J.R.*, 442 U.S. 584, 602 (1979).

[13] *See, e.g.*, *Brandt v. Rutledge*, 551 F. Supp. 3d 882, 891, 893 (E.D. Ark. 2021).

[14] 42 U.S.C. § 18116.

programs and activities.[15] Categorically refusing to provide treatment to a person based on their gender identity, for example, may constitute prohibited discrimination under Section 1557. As the U.S. Department of Health and Human Services has stated, restricting an individual's ability to receive medically necessary care, including gender-affirming care, from their health care providers solely on the basis of their sex assigned at birth or their gender identity may also violate Section 1557.[16]

- **Title IX of the Education Amendments of 1972**[17] prohibits sex discrimination, including sex-based harassment, by recipients of federal financial assistance that operate education programs and activities.[18] Policies and practices that deny, limit, or interfere with access to the recipient's education program or activity because students are transgender minors receiving gender-affirming care may constitute discrimination on the basis of sex in violation of Title IX.

- The **Omnibus Crime Control and Safe Streets Act of 1968**[19] prohibits sex discrimination in certain law enforcement programs and activities receiving federal financial assistance.[20] If a law enforcement agency takes a transgender minor who is receiving gender-affirming care into custody or arrests the child's parents on suspicion of child abuse because the parents permitted such medical care, that agency may be violating the statute's nondiscrimination provision.

- **Section 504 of the Rehabilitation Act of 1973**[21] protects people with disabilities, which can include individuals who experience gender dysphoria.[22] Restrictions that prevent, limit, or interfere with otherwise qualified individuals' access to care due to their gender

---

[15] *See, e.g.*, Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972, reprinted at 86 Fed. Reg. 27,984 (May 25, 2021).
[16] U.S. Dep't Health & Hum. Servs., *Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy* (Mar. 2, 2022), https://www.hhs.gov/sites/default/files/hhs-ocr-notice-and-guidance-gender-affirming-care.pdf.
[17] 20 U.S.C. § 1681, *et seq.*
[18] *See* Karlan, *supra* note 2; *see also Doe v. Snyder*, --- F.4th ---, 2022 WL 711420, at *9 (9th Cir. Mar. 10, 2022); *Grimm*, 972 F.3d at 619.
[19] 34 U.S.C. § 10101, *et seq.*
[20] *See* 34 U.S.C. § 10228(c)(1); *see also* Kristen Clarke, Assistant Attorney General, Civ. Rts. Div., U.S. Dep't of Justice, Memorandum, *Interpretation of Bostock v. Clayton County regarding the nondiscrimination provisions of the Safe Streets Act, the Juvenile Justice and Delinquency Prevention Act, the Victims of Crime Act, and the Violence Against Women Act* (Mar. 10, 2022), https://www.justice.gov/crt/page/file/1481776/download.
[21] 29 U.S.C. § 794. Additionally, Title II of the Americans with Disabilities Act extends disability civil rights protections with respect to all programs, services and activities of state and local governments, regardless of the receipt of federal financial assistance. *See* 42 U.S.C. § 12132.
[22] *See, e.g.*, *Doe v. Penn. Dep't of Corrections*, No. 1:20-cv-00023-SPB-RAL, 2021 WL 1583556, at *12 (W.D. Pa. Feb. 19, 2021), report and recommendation adopted in relevant part, 2021 WL 1115373 (W.D. Pa. March 24, 2021); *Lange v. Houston Cnty.*, 499 F. Supp. 3d 1258, 1270 (M.D. Ga. 2020); *Doe v. Mass. Dep't of Correction*, No. 1:17-cv-12255-RGS, 2018 WL 2994403 at *6 (D. Mass. June 14, 2018); *Blatt v. Cabela's Retail, Inc.*, No. 5:14-CV-04822, 2017 WL 2178123 (E.D. Pa. May 18, 2017).

dysphoria, gender dysphoria diagnosis, or perception of gender dysphoria may violate Section 504.

All persons should be free to access the services, programs, and activities supported by federal financial assistance without fear that they might face unlawful discrimination for doing so. Courts have held that many nondiscrimination statutes contain an implied cause of action for retaliation based on the general prohibition against intentional discrimination, and agencies have made this clear in regulations.[23] Thus, any retaliatory conduct may give rise to an independent legal claim under the protections described above.

* * *

Thank you for your continued commitment to improving the well-being of children and their families. The Department is always available to help ensure that state and local governments, many of which are recipients of federal financial assistance, meet their obligations under federal law. Please feel free to contact the Department's Civil Rights Division for assistance if you have further questions.

Sincerely,

Kristen Clarke
Assistant Attorney General
Civil Rights Division
U.S. Department of Justice

[23] *See, e.g.*, *Jackson v. Birmingham Bd. of Ed.*, 544 U.S. 167, 173 (2005) ("Retaliation against a person because that person has complained of sex discrimination is another form of intentional sex discrimination…"). Examples of agency regulations that prohibit retaliation include 24 C.F.R. § 1.7(e) (Dep't of Housing and Urban Development); 34 C.F.R. § 100.7(e) (Dep't of Education); 38 C.F.R. § 18.7(e) (Dep't of Veterans Affairs); and 45 C.F.R. § 80.7(e) (Dep't of Health and Human Services). Other relevant regulations can be found in the Civil Rights Division's Title VI Legal Manual. Civ. Rts. Div., U.S. Dep't of Justice, *Title VI Legal Manual*, Section VIII, https://www.justice.gov/crt/book/file/1364106/download.


September 2022
COMMITTEE ON EDUCATION & LABOR
NO RIGHT TO
DENY CARE:
THE IMPORTANCE OF PRESERVING PREVENTIVE CARE IN THE AFFORDABLE CARE ACT

TABLE OF CONTENTS

NO RIGHT TO DENY CARE

INTRODUCTION

The *Affordable Care Act* (ACA) expanded Medicaid for low-income Americans, protected access to coverage for people with preexisting conditions, and created Healthcare.gov and state-based exchanges where individuals can purchase quality, affordable coverage. Additionally, the ACA included another major reform that affected nearly everyone with private health insurance – the requirement for coverage of preventive care without any cost-sharing, such as deductibles or copays.[1] This requirement has not only helped the more than 14 million enrollees in coverage through the ACA exchanges,[2] but also the vast majority of the approximately 155 million Americans who have coverage through their job.[3]

A recent decision by a very conservative court, issued by a very conservative judge, jeopardizes the future of these critical reforms for millions of individual consumers, small business owners, workers, and their families. In the case *Braidwood v. Becerra*, the judge ruled that the Constitution does not allow a requirement for plans to cover certain preventive services.[4] The decision also found that the mandate to cover certain preventive service items, such as medication that can prevent HIV transmission, substantially burdens the religious exercise of one of the plaintiffs.[5] The ruling did not address every issue in the case, but the court indicated that it may also allow certain employers to limit coverage for other vital preventive services.[6]

This case is ongoing, and the decision will hopefully be overturned on appeal, but the stakes for American workers and families are high. Preventive service coverage has been enormously consequential in improving access to care for millions of Americans and it is critical that this protection be preserved.

---

[1] Public Health Service Act § 2713 (grandfathered health plans and those offering limited scope benefits such as stand-alone dental and vision plans are exempt from this requirement, however).
[2] Press Release, Biden-Harris Administration Announces 14.5 Million Americans Signed Up for Affordable Health Care During Historic Open Enrollment Period (Jan. 27, 2022), https://www.hhs.gov/about/news/2022/01/27/biden-harris-administration-announces-14-5-million-americans-signed-affordable-health-care-during-historic-open-enrollment-period.html.
[3] Employer Health Benefits: 2021 Annual Survey, Kaiser Family Foundation, available at https://files.kff.org/attachment/Report-Employer-Health-Benefits-2021-Annual-Survey.pdf.
[4] This case was formerly known as Kelley v. Becerra, but was later changed at the request of the plaintiffs. See Unopposed Motion to Amend Caption at 1, John Kelley, et al, v. Xavier Becerra, et al., No. 4:20-cv-00283-O (N.D. Texas, Aug. 10, 2022) ("The plaintiffs respectfully move to amend the caption so that Braidwood Management Incorporated is the first-listed plaintiff, and that the case be referred to as 'Braidwood Management Inc., et al. v. Xavier Becerra, et al.' going forward").
[5] Braidwood Management Inc., et al, v. Xavier Becerra, et al., No. 4:20-cv-00283-O (N.D. Texas, Sept. 7, 2022), available at https://storage.courtlistener.com/recap/gov.uscourts.txnd.330381/gov.uscourts.txnd.330381.92.0.pdf.
[6] In February 2021, the court dismissed plaintiffs' religious claims regarding the contraceptive mandate because the court had previously dealt with those claims by the same plaintiffs in a separate case, DeOtte v Azar. DeOtte v. Azar, 393 F. Supp. 3d. 490 (N.D. Tex. 2019). However, the court's decision in DeOtte was recently reversed by the Fifth Circuit. The plaintiffs now contend that their religious claims regarding the contraceptive mandate are no longer precluded by the DeOtte case and as a result, have asked the court to reconsider those claims. The court signaled that it will further deliberate on the plaintiffs' claims regarding the contraceptive mandate issue. With regards to plaintiffs' objections to other preventive services, the plaintiffs' amended complaint dropped religious objections to providing several other required preventive services, including the human papillomavirus (HPV) vaccine, screenings, and behavioral counseling for sexually transmitted diseases (STDs), and substance use.

NO RIGHT TO DENY CARE

LOSING ACCESS TO COMPREHENSIVE PREVENTIVE CARE COULD HARM MILLIONS OF PEOPLE AND INCREASE HEALTH CARE COSTS

Before the ACA was enacted in 2010, there was no federal requirement for private health plans to cover preventive services. Further, there were no limits on how much Americans might be forced to pay out-of-pocket to get preventive care. As a result, coverage for preventive services varied considerably across the country.[7] Some states required certain types of plans to cover certain preventive services, but the requirements were generally narrow and often did not cap out-of-pocket expenses.

Access to preventive care is essential to long-term health. Through preventive care, doctors and other health care providers can detect problems early when they are more treatable. Preventive services provide tremendous value by reducing the risk for developing a long-term, chronic disease. For example, preventive measures have led to a more than 75 percent reduction in new HIV infections each year since they peaked in 1984.[8] Research has shown that access to preventive care also reduces overall health care spending, as fewer people develop chronic conditions that require expensive treatment.[9]

THE AFFORDABLE CARE ACT ENSURES THAT WORKERS HAVE ACCESS TO PREVENTIVE CARE

The ACA included several reforms that improved the quality and affordability of health care coverage for millions of workers and their families. One of these reforms is a requirement for nearly all private health plans to cover a robust set of preventive services without patients having to pay anything out-of-pocket.[10] This requirement generally applies to all people, regardless of whether an individual gets their coverage through their employer or in the individual market – a combined total of about 170 million people.[11] Studies show that the requirement is one of the most popular parts of the ACA and the majority of Americans say that it is "very important" that it be preserved.[12]

---

[7] The Departments of Health and Human Services, Labor, and the Treasury issued interim final regulations in 2010 to implement the Affordable Care Act's preventive service coverage requirement. The preamble to the regulations includes an impact analysis that summarizes preventive service coverage available prior to the enactment of the Affordable Care Act. See, Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 41726, 41732 (July 19, 2010), available at https://www.federalregister.gov/documents/2010/07/19/2010-17242/interim-final-rules-for-group-health-plans-and-health-insurance-issuers-relating-to-coverage-of.

[8] Smith, Dawn K., Kirk, Henry D., Weidle, Paul, J., The Evidence for Initial Intervention Strategies for Ending the HIV Epidemic in the U.S., American Journal of Preventive Medicine, 2021 S1-S5, available at https://www.ajpmonline.org/article/S0749-3797(21)00390-1/fulltext.

[9] Maciosek, Michael V., Coffield, Ashley B., Flottemesch, et al., Use of Preventive Services In U.S. Health Care Could Save Lives At Little Or No Cost. Health Affairs 2010, 29(9) 1656-1660, available at https://pubmed.ncbi.nlm.nih.gov/20820022/.

[10] Public Health Service Act section 2713 (grandfathered health plans and those offering limited scope benefits such as stand-alone dental and vision plans are exempt from this requirement, however).

[11] See Data Note: Changes in Enrollment in the Individual Health Insurance Market through Early 2019, Kaiser Family Foundation, available at https://www.kff.org/private-insurance/issue-brief/data-note-changes-in-enrollment-in-the-individual-health-insurance-market-through-early-2019/; see also Employer Health Benefits, supra note 3.

[12] Ashley Kirzinger, 5 Charts About Public Opinion on The Affordable Care Act, Kaiser Family Foundation (April 14, 2022), available at https://www.kff.org/health-reform/poll-finding/5-charts-about-public-opinion-on-the-affordable-care-act-and-the-supreme-court/.

NO RIGHT TO DENY CARE

Specifically, under the ACA, health plans and insurance companies must cover – without any cost-sharing – the following four categories of items and services:

- Evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force (USPSTF) with respect to the individual involved;[13]

- Immunizations for routine clinical use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) with respect to the individual involved;

- With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA); and

- With respect to women, preventive care and screenings provided for in comprehensive guidelines supported by HRSA, to the extent not included in certain recommendations of the USPSTF.

The range of items and services that that must be covered under these four categories is broad and includes, for example, cancer screenings, contraception, well-woman visits, pre-exposure prophylaxis (PrEP) for HIV prevention, routine vaccinations, screening for sexually transmitted diseases, breastfeeding services and supplies, tobacco cessation interventions, and many others. In just the first category of services that must be covered – those recommended by the USPSTF – there are 45 different types of preventive services.[14] Office visits to receive preventive care as well as services that are integral to receiving certain preventive services, such as specimen collection for recommended screenings, are generally also required to be covered.[15]

[13] The USPSTF published updated breast cancer screening recommendations in January 2016. However, section 223 of Division H of the Consolidated Appropriations Act, 2021 (Pub. L. 116-260) requires that for purposes of PHS Act section 2713, USPSTF recommendations relating to breast cancer screening, mammography, and prevention issued before 2009 remain in effect until January 1, 2023. In July 2021, the Departments of Health and Human Services, Labor, and the Treasury issued new guidance clarifying that most health plans must include PrEP coverage without cost-sharing based on the U.S Preventive Services Task Force's "Grade A" recommendation of June 2019. See, The Departments of Health and Human Services, Labor, and the Treasury, FAQs about Affordable Care Act Implementation Part 47 (July 19, 2021), https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-47.pdf.

[14] U.S. Preventive Service Task Force Published Recommendations, available at https://www.uspreventiveservicestaskforce.org/uspstf/topic_search_results?topic_status=P&grades%5B%5D=A&grades%5B%5D=B&searchterm=.

[15] See 29 CFR 2590.715-2713; see also FAQs About Affordable Care Act Implementation, Part 54, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf.

NO RIGHT TO DENY CARE

RECOMMENDATIONS FOR WHICH PREVENTIVE SERVICES MUST BE COVERED ARE DEVELOPED BY INDEPENDENT EXPERTS – NOT INSURANCE COMPANIES OR POLITICIANS

Although the preventive service coverage requirement is grounded in federal law and enforced by federal and state insurance regulators, the specific items and services that must be covered are recommended by experts in preventive medicine from several entities: the United States Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), and Health Resources and Services Administration (HRSA).

The USPSTF is an organization comprised of experts in disease prevention. Members are independent volunteers who seek to improve the health of people nationwide through evidence-based recommendations about preventive health services. The USPSTF has a rigorous process for the development of their recommendations that ensures they are not influenced by conflicts of interest. Additionally, stakeholders have an opportunity to submit comments on proposed recommendations before they are finalized.

ACIP is a Federal Advisory Committee established by law to offer advice to the Director of the CDC about disease prevention through the use of vaccines.[16] ACIP's members are experts in the fields of immunization practices and public health. Similar to the USPSTF, ACIP adheres to strict procedures to ensure transparency in the development of their recommendations. They hold meetings that are open to the public and they publish their framework for evaluating evidence before voting on each recommendation.

HRSA is one of nine Public Health Service agencies under the Department of Health and Human Services. Since 2016, HRSA has awarded contracts to the American College of Obstetricians and Gynecologists (ACOG) to convene a panel of medical professionals and other health experts to develop and update its preventive service recommendations.[17]

[16] ACIP Charter, Centers for Disease Control and Prevention, available at https://www.cdc.gov/vaccines/acip/committee/charter.html.
[17] Women's Preventive Service Guidelines, Health Resources and Services Administration, available at https://www.hrsa.gov/womens-guidelines.

NO RIGHT TO DENY CARE

COVERAGE FOR PREVENTIVE SERVICES HAS IMPROVED THE HEALTH OF MILLIONS OF AMERICANS

Since the ACA's preventive service coverage requirement took effect, numerous studies have sought to measure its impact on consumer access to preventive care. The studies generally all show that the law has been an enormous success: utilization rates for preventive care are up, racial and ethnic disparities in accessing preventive care are down, people are spending less out-of-pocket, and better health and economic outcomes are being achieved.[18]

Clinical guidelines suggest that a 58-year-old woman who is at risk for heart disease should receive a mammogram, a colon cancer screening, a Pap test, a diabetes test, a cholesterol test, and an annual flu shot. Under a typical insurance plan before the ACA was enacted, these tests could cost more than $300 out of her own pocket.[19] Now, under the ACA, she would not require any out-of-pocket spending. The law has similarly reduced costs for contraception, which used to be a major barrier women faced in accessing contraception. On average, women with private insurance who use oral contraceptives or intrauterine devices have been able to save about $250 a year since the ACA was enacted over ten years ago.[20]

The very coverage that the Braidwood case targeted—Truvada—is the first FDA-approved medication for HIV prevention and the only form of PrEP available for women. Without insurance, Truvada can cost between $1,600 and $2,000 per month, not including the cost of routine HIV testing and ancillary services that are required for continued prescriptions. One in five new HIV cases now affect women[21] and, when taken as recommended, PrEP reduces the risk of getting HIV by 99 percent, according to the CDC.[22] PrEP has also been used in combination with HIV medications to reduce the risk of mother-to-child HIV transmission during pregnancy, treat survivors of intimate partner violence and sexual assault, and protect people living with hemophilia and other immunocompromised people from HIV exposure.

[18] Access to Preventive Services Without Cost-sharing: Evidence from the Affordable Care Act, Department of Health and Human Services, Assistant Secretary for Planning and Evaluation (Jan. 11, 2022), available at https://aspe.hhs.gov/sites/default/files/documents/786fa55a84e7e383396193312 4a70dd2/preventive-services-ib-2022.pdf
[19] Background: The Affordable Care Act's New Rules on Preventive Care, Centers for Medicare and Medicaid Services (July 14, 2010), available at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/preventive-care-background#_ftnref6.
[20] Nora Becker, Daniel Polsky, Women Saw Large Decrease In Out-Of-Pocket Spending For Contraceptives After ACA Mandate Removed Cost Sharing, Health Affairs (July 2015), available at https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.0127.
[21] Centers for Disease Control and Prevention, Division of HIV Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, HIV and Women Fact Sheet, (August 8, 2022), https://www.cdc.gov/hiv/pdf/group/gender/women/cdc-hiv-women.pdf.
[22] Centers for Disease Control and Prevention, Division of HIV Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, PrEP Effectiveness, (June 6, 2022), https://www.cdc.gov/hiv/basics/prep/prep-effectiveness.html.

NO RIGHT TO DENY CARE

When the ACA preventive services coverage requirements first took effect, it was predicted that there would be both public health and economic benefits; not only would there be reduced transmission and earlier treatment of diseases, but some of the recommended preventive services would also result in savings due to lower health care costs overall and fewer workers and students missing work and school due to illness.[23] Shortly after the coverage requirement took effect, the Department of Health and Human Services estimated that it led to 54 million more Americans receiving preventive care without any out-of-pocket spending.[24] The Department also recently issued a comprehensive review of research examining the impact of the preventive service coverage requirement.[25] This review found that:

- Nearly 150 million people are estimated to have benefited from the law through increased screenings and improved health outcomes.

- Regarding cancer screenings, research suggests that increased access and lower costs have helped cancer survivors obtain the care they need. The greatest improvements have been for colorectal and cervical cancer screenings. Increased screening has resulted in an overall decrease in colorectal cancer incidence, and data show that newly insured immigrants, in particular, are being screened at higher rates than they were before the law took effect.

- The combination of the preventive service coverage requirement and the ACA's requirement that any dependent coverage be available up to age 26 has led to significantly more women receiving vaccinations for human papillomavirus (HPV), which prevents cervical cancer.

- More adults are receiving their annual recommended flu shots.

- The increase in access to contraception has been profound. Cost has historically been a major barrier to accessing contraception and PrEP, and better access is associated with reduced rates of poverty. By one estimate, in the first year after the preventive service coverage requirement took effect, women collectively saved approximately $1.4 billion on out-of-pocket expenses for contraception.

[23] Interim final regulations, supra note 7, at 41733.
[24] Fifty-Four Million Additional Americans Are Receiving Preventive Services Without Cost-Sharing Under The Affordable Care Act, Department of Health and Human Services, Assistant Secretary for Planning and Evaluation (Feb. 14, 2012), available at https://aspe.hhs.gov/reports/fifty-four-million-additional-americans-are-receiving-preventive-services-without-cost-sharing-under-0.
[25] Access to Preventive Services Without Cost-sharing: Evidence from the Affordable Care Act, supra note 19.


ED
&
LABOR
EDLABOR.HOUSE.GOV | @EDLABORCMTE

Children's hospitals are the latest target of anti-LGBTQ harassment

August 26, 2022 · 3:30 PM ET
Heard on All Things Considered

Shannon Bond

3-Minute Listen PLAYLIST Download Transcript

Boston Children's Hospital said it had received "threats of violence toward our clinicians and staff" after false claims were made online that the hospital provides genital surgeries to minors.

Lane Turner/The Boston Globe via Getty Images

Hospitals and doctors around the country are facing harassment and even death threats over the medical care they offer to transgender kids. In many cases, they have been the subject of posts by a Twitter account called Libs of TikTok, as well as stories in conservative media outlets casting gender-affirming care as child abuse and mutilation.

Which raises the question: where should social networks draw the line with accounts promoting narratives that spark harassment campaigns on their platforms and beyond?

NATIONAL

Accusations of 'grooming' are the latest political attack — with homophobic origins

Children's National Hospital in Washington, D.C. became the most recent target this week when Libs of TikTok posted an audio recording in which hospital staff appeared to say that gender-affirming hysterectomies had been performed on minors. The hospital said that claim was incorrect and that none of the people recorded deliver care to patients.

"The information in the recording is not accurate. We do not and have never performed gender-affirming hysterectomies for anyone under the age of 18," Children's National said in a statement to NPR. "The operator speaking provided wrong information."

The statement continued: "Since the spreading of misinformation on Twitter, we have been the target of a large volume of hostile and threatening phone calls and emails."

Childrens' hospitals in Boston, Seattle, Chicago, and Portland, Oregon, have also been targeted. Last week, Boston Children's Hospital warned it was receiving "a large volume of hostile internet activity, phone calls, and harassing emails including threats of violence toward our clinicians and staff" after false claims it performs genital surgeries on minors.

The U.S. Justice Department even weighed in, with the U.S. Attorney for Massachusetts calling the attacks "disturbing."

False claims, out-of-context videos

These false narratives about pediatric gender-affirming care are rooted in fundamental "misperceptions," said Dr. Angela Kade Goepferd, a pediatrician and director of the Gender Health Program at Children's Minnesota.

"People have misperceptions that we're doing surgery on young kids. People have misperceptions that we are changing kids from boys into girls at a very young age," they said.

They said care for transgender kids is wide-ranging, from efforts to help children socially transition to puberty-blocking medications, and is undertaken with the input

of pediatric psychologists, clinical social workers, hormone experts and endocrinologists, as well as families. Gender-affirming surgeries are not a routine part of pediatric gender care, they said, and Children's Minnesota does not perform any such surgeries.

Some of the claims about Children's National, Boston Children's and other hospitals were pushed by the Libs of TikTok account, which regularly reposts videos and social media posts from LGBTQ people, teachers, schools and other institutions. The clips are sometimes taken out of context and framed to fuel outrage or ridicule of LGBTQ and anti-racist causes, in what the account owner has described as "exposés" of "the crazies."

For example, a short clip about gender-affirming hysterectomies from a video originally posted by Boston Children's that Libs of TikTok reposted makes no mention of patients' ages. But Libs of TikTok tweeted alongside the clip the false claim that the hospital offers the surgery "for young girls."

Libs of TikTok, run by a Brooklyn woman named Chaya Raichik, has 1.3 million followers on its biggest platform, Twitter. It's gained prominence and influence in right-wing circles over the last year as conservatives increasingly try to use anti-LGBTQ sentiment to gain support.

NPR reached out to Raichik for this story. She initially responded and agreed to an interview, but did not respond to a follow-up message. Raichik frequently condemns criticism of her online activities as efforts to "cancel and silence" her. She has said that she has also been targeted with death threats.

Platforms struggle with harassment networks

Twitter and Facebook prohibit bullying and harassment, coordinated mass attacks, and incitement to violence. Both companies ban the use of the word "groomer" as a smear against LGBTQ people under their rules against hate speech.

The platforms have taken down some of the threats against the hospitals. But it's less clear how much accountability the companies can or will put on accounts that draw attention to the targets that end up getting harassed.

Twitter has previously temporarily suspended Libs of TikTok for breaking its rules. The company declined to comment on the account. Following Boston Children's Hospital's reported threats, Libs of TikTok said it had been permanently suspended by Facebook for violating the platform's community standards. But that was quickly reversed, and the account returned to posting on Facebook, saying the social network said that was an error. Facebook declined to comment on the suspension.

Libs of TikTok appears to have evaded outright bans by coming right up to the edge of the platforms' rules but not breaking them. The account does not explicitly encourage followers to threaten anyone, and typically uses its target's own words, sometimes stripped of context, to imply wrongdoing.

But while its individual posts may stick to the letter of the platforms' rules, their cumulative effect is what worries researchers like Joan Donovan, who studies online extremism, media manipulation and disinformation at Harvard's Shorenstein Center on Media, Politics and Public Policy.

"We've reached this phase in social media where people know what to do when an account like Libs of TikTok calls out another account or a person or institution," she said. Call-outs can spark harassment campaigns known as "brigading," where commenters pile on a common target.

In the case of the children's hospitals, "the threats have moved from insulting people or targeted accounts online into more direct threats," Donovan said. "The online threat escalates very quickly into offline violence when we start to see these patterns of attack."

For social networks to deal with what Donovan calls "networked incitement," she says effectively tracking those threats means looking beyond single posts on specific platforms.

"The precipitating comments may not be that incendiary, but if that creates a pattern of attack that is recognizable, which it is with an account like Libs of TikTok, then these companies are well within their jurisdiction to warn and then ban the account."

Right-wing groups target LGBTQ events, education and healthcare

Pediatricians and children's hospitals are just the latest targets of right-wing outrage, in a new iteration of decades-old smears of gay, lesbian and transgender people as pedophiles or "groomers."

"The Libs of TikTok account has been a major actor in driving a lot of the harassment campaigns that we've seen over the past year," said Ari Drennen, LGBTQ program director at Media Matters for America, the liberal advocacy group.

NATIONAL

Far right groups shift focus to LBGTQ events. Their hateful aim hasn't changed

In some cases, events and figures publicized by Libs of TikTok have been targeted offline by far-right extremists known for brawling.

On a single day this summer, for example, men with ties to the white nationalist group Patriot Front were arrested outside a Pride event in Coeur D'Alene, Idaho, and alleged members of the far-right Proud Boys crashed a drag queen story hour at a library in San Lorenzo, Calif. Libs of TikTok had tweeted about both events, although there's no conclusive link between the posts and the extremist groups' activities.

As the *Washington Post* reported in April, the account's subjects and posts are regularly featured and promoted by other conservative influencers and media figures, including podcaster Joe Rogan. Raichik has appeared on Tucker Carlson's prime time Fox News show.

The escalating stigmatization of transgender medical care has doctors worried.

"This is a developmentally appropriate, team-based approach that allows kids time to figure out their identities," said Dr. Goepferd of Children's Minnesota.

Threats to hospitals ripple out, affecting not only hospital staff but also patients and families seeking all kinds of care, as well as longer-term research needed in the field. "I worry that this type of false narrative would make research institutions or funders nervous to fund more research into finding out what is the best possible care we could be providing right now," Goepferd said.

"The fact that somewhere the message has gotten through that it's okay to attack physicians, pediatricians, children's hospitals in this way is just a really disturbing

societal trend," they said.

Editor's Note: *Facebook parent Meta pays NPR to license NPR content.*

Editor's Note

Aug. 26, 2022

This story has been updated to clarify that Dr. Angela Kade Goepferd said gender-affirming surgeries are not a routine part of pediatric gender care, and that Children's Minnesota does not perform any gender-affirming surgeries.

More Stories From NPR

POLITICS

DeSantis campaign shares apparent AI-generated fake images of Trump and Fauci

TECHNOLOGY

YouTube will no longer take down false claims about U.S. elections

TECHNOLOGY

Fake viral images of an explosion at the Pentagon were probably created by AI

TECHNOLOGY

People are trying to claim real videos are deepfakes. The courts are not amused

HEALTH

As the pandemic winds down, anti-vaccine activists are building a legal network

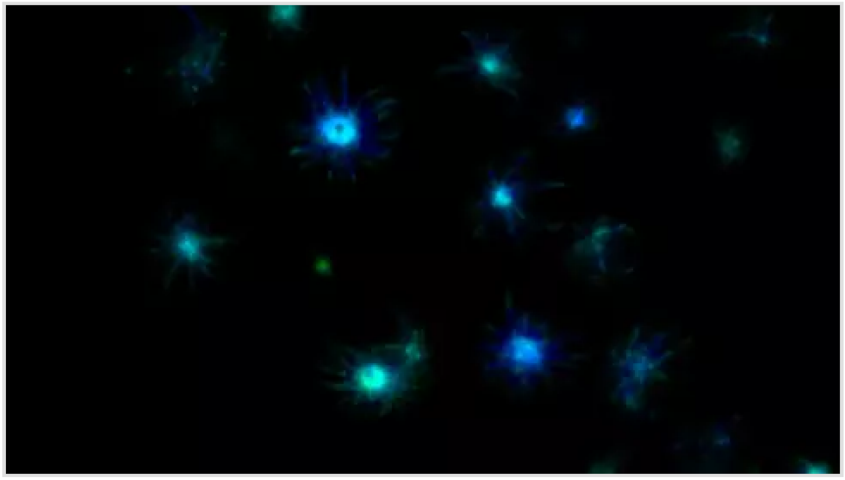
TECHNOLOGY

AI-generated deepfakes are moving fast. Policymakers can't keep up

Popular on NPR.org

BUSINESS

A 3-hour phone call that brought her to tears: Imposter scams cost Americans billions



RESEARCH NEWS

Huntington's spreads like 'fire in the brain.' Scientists say they've found the spark

CLIMATE

Defense arguments are set to open in a landmark climate case brought by Montana youth

CLIMATE

In some fights over solar, it's environmentalist vs. environmentalist

POLITICS

For many migrants being bused from New York City to other towns, hostility awaits

CLIMATE

A new satellite could help clean up the air in America's most polluted neighborhoods

NPR Editors' Picks

NATIONAL

'Tiny sub, big ocean': Why the Titanic submersible search is so challenging

GAMING

He once had motor skill challenges. Now he's the world's fastest Rubik's cube solver

ELECTIONS

Republican primary spending projected to approach or surpass $1 billion

WORLD

From Beijing to London, Blinken pushes for Ukraine peace deal and recovery

NATIONAL

Some states are restricting abortion. Others are spending millions to fund it

NATIONAL SECURITY

"Profound differences" remain between U.S. and China, Secretary Blinken tells NPR

Untangling Disinformation

READ & LISTEN

Home

News

Culture

Music

Podcasts & Shows

CONNECT

Newsletters

Facebook

Instagram

Press

Public Editor

Corrections

Contact & Help

ABOUT NPR

Overview

Diversity

NPR Network

GET INVOLVED

Support Public Radio

Sponsor NPR

NPR Careers

SEX & GENDER

What the Science on Gender-Affirming Care for Transgender Kids Really Shows

Laws that ban gender-affirming treatment ignore the wealth of research demonstrating its benefits for trans people's health

By Heather Boerner on May 12, 2022

As attacks against transgender kids increase in the U.S., Minnesotans hold a rally at the state's capitol in Saint Paul in March 2022 to support trans kids in Minnesota and Texas and around the country. Credit: Michael Siluk/UCG/Universal Images Group via Getty Images

Editor's Note (3/30/23): This article from May 2022 is being republished to highlight the ways that ongoing anti-trans legislation is harmful and unscientific.

For the first 40 years of their life, Texas resident Kelly Fleming spent a portion of most years in a deep depression. As an adult, Fleming—who uses they/them pronouns and who asked to use a pseudonym to protect their safety—would shave their face in the shower with the lights off so neither they nor their wife would have to confront the reality of their body.

What Fleming was experiencing, although they did not know it at the time, was gender dysphoria: the acute and chronic distress of living in a body that does not reflect one's gender and the desire to have bodily characteristics of that gender. While in therapy, Fleming discovered research linking access to gender-affirming hormone therapy with reduced depression in transgender people. They started a very low dose of estradiol, and the depression episodes became shorter, less frequent and less intense. Now they look at their body with joy.

So when Fleming sees what authorities in Texas, Alabama, Florida and other states are doing to bar transgender teens and children from receiving gender-affirming medical care, it infuriates them. And they are worried for their children, ages 12 and 14, both of whom are agender—a identity on the transgender spectrum that is neither masculine nor feminine.

"I'm just so excited to see them being able to present themselves in a way that makes them happy," Fleming says. "They are living their best life regardless of what others think, and that's a privilege that I did not get to have as a younger person."

LAWS BASED ON "COMPLETELY WRONG" INFORMATION

Currently more than a dozen state legislatures or administrations are considering—or have already passed—laws banning health care for transgender young people. On April 20 the Florida Department of Health issued guidance to withhold such gender-affirming care. This includes social gender transitioning—acknowledging that a young person is trans, using their correct pronouns and name, and supporting their desire to live publicly as the gender of their experience rather than their sex assigned at birth. This comes nearly two months after Texas Governor Greg Abbott issued an order for the Texas Department of Family and Protective Services to investigate for child abuse parents who allow their transgender preteens and teenagers to receive medical care. Alabama recently passed SB 184, which would make it a felony to provide gender-affirming medical care to transgender minors. In Alabama, a "minor" is defined as anyone 19 or younger.

If such laws go ahead, 58,200 teens in the U.S. could lose access to or never receive gender-affirming care, according to the Williams Institute at the University of California, Los Angeles. A decade of research shows such treatment reduces depression, suicidality and other

devastating consequences of trans preteens and teens being forced to undergo puberty in the sex they were assigned at birth).

The bills are based on "information that's completely wrong," says Michelle Forcier, a pediatrician and professor of pediatrics at Brown University. Forcier literally helped write the book on how to provide evidence-based gender care to young people. She is also an assistant dean of admissions at the Warren Alpert Medical School of Brown University. Those laws "are absolutely, absolutely incorrect" about the science of gender-affirming care for young people, she says. "[Inaccurate information] is there to create drama. It's there to make people take a side."

The truth is that data from more than a dozen studies of more than 30,000 transgender and gender-diverse young people consistently show that access to gender-affirming care is associated with better mental health outcomes—and that lack of access to such care is associated with higher rates of suicidality, depression and self-harming behavior. (Gender diversity refers to the extent to which a person's gendered behaviors, appearance and identities are culturally incongruent with the sex they were assigned at birth. Gender-diverse people can identify along the transgender spectrum, but not all do.) Major medical organizations, including the American Academy of Pediatrics (AAP), the American Academy of Child and Adolescent Psychiatry, the Endocrine Society, the American Medical Association, the American Psychological Association and the American Psychiatric Association, have published policy statements and guidelines on how to provide age-appropriate gender-affirming care. All of those medical societies find such care to be evidence-based and medically necessary.

AAP and Endocrine Society guidelines call for developmentally appropriate care, and that means no puberty blockers or hormones until young people are already undergoing puberty for their sex assigned at birth. For one thing, "there are no hormonal differences among prepubertal children," says Joshua Safer, executive director of the Mount Sinai Center for Transgender Medicine and Surgery in New York City and co-author of the Endocrine Society's guidelines. Those guidelines provide the option of gonadotropin-releasing hormone analogues (GnRHas), which block the release of sex hormones, once young people are already into the second of five puberty stages—marked by breast budding and pubic hair. These are offered only if a teen is not ready to make decisions about puberty. Access to gender-affirming hormones and potential access to gender-affirming surgery is available at age 16—and then, in the case of transmasculine youth, only mastectomy, also known as top surgery. The Endocrine Society does not recommend genital surgery for minors.

Before puberty, gender-affirming care is about supporting the *process* of gender development rather than directing children through a specific course of gender transition or maintenance of cisgender presentation, says Jason Rafferty, co-author of AAP's policy statement on gender-affirming care and a pediatrician and psychiatrist at Hasbro Children's Hospital in Rhode Island. "The current research suggests that, rather than predicting or preventing who a child might become, it's better to value them for who they are now—even at a young age," Rafferty says.

A SAFE ENVIRONMENT TO EXPLORE GENDER

A 2021 systematic review of 44 peer-reviewed studies found that parent connectedness, measured by a six-question scale asking about such things as how safe young people feel confiding in their guardians or how cared for they feel in the family, is associated with greater resilience among teens and young adults who are transgender or gender-diverse. Rafferty says he sees his role with regard to prepubertal children as offering a safe environment for the child to explore their gender and for parents to ask questions. "The gender-affirming approach is not some railroad of people to hormones and surgery," Safer says. "It is talking and watching and being conservative."

Only once children are older, and if the incongruence between the sex assigned to them at birth and their experienced gender has persisted, does discussion of medical transition occur. First a gender therapist has to diagnose the young person with gender dysphoria.

After a gender dysphoria diagnosis—and only if earlier conversations suggest that hormones are indicated—guidelines call for discussion of fertility, puberty suppression and hormones. Puberty-suppressing medications have been used for decades for cisgender children who start puberty early, but they are not meant to be used indefinitely. The Endocrine Society

guidelines recommend a maximum of two years on GnRHa therapy to allow more time for children to form their gender identity before undergoing puberty for their sex assigned at birth, the effects of which are irreversible.

"[Puberty blockers] are part of the process of 'do no harm,'" Forcier says, referencing a popular phrase that describes the Hippocratic Oath, which many physicians recite a version of before they begin to practice.

Hormone blocker treatment may have side effects. A 2015 longitudinal observational cohort study of 34 transgender young people found that, by the time the participants were 22 years old, trans women experienced a decrease in bone mineral density. A 2020 study of puberty suppression in gender-diverse and transgender young people found that those who started puberty blockers in early puberty had lower bone mineral density *before* the start of treatment than the public at large. This suggests, the authors wrote, that GnRHa use may not be the cause of low bone mineral density for these young people. Instead they found that lack of exercise was a primary factor in low bone-mineral density, especially among transgender girls.

Other side effects of GnRHa therapy include weight gain, hot flashes and mood swings. But studies have found that these side effects—and puberty delay itself—are reversible, Safer says.

Gender-affirming hormone therapy often involves taking an androgen blocker (a chemical that blocks the release of testosterone and other androgenic hormones) and estrogen in transfeminine teens, and testosterone supplementation in transmasculine teens. Such hormones may be associated with some physiological changes for adult transgender people. For instance, transfeminine people taking estrogen see their so-called "good" cholesterol increase. By contrast, transmasculine people taking testosterone see their good cholesterol decrease. Some studies have hinted at effects on bone mineral density, but these are complicated and also depend on personal, family history, exercise, and many other factors in addition to hormones."

And while some critics point to decade-old study and older studies suggesting very few young people persist in transgender identity into late adolescence and adulthood, Forcier says the data are "misleading and not accurate." A recent review detailed methodological problems with some of these studies. New research in 17,151 people who had ever socially transitioned found that 86.9 percent persisted in their gender identity. Of the 2,242 people who reported that they reverted to living as the gender associated with the sex they were assigned at birth, just 15.9 percent said they did so because of internal factors such as questioning their experienced gender but also because of fear, mental health issues and suicide attempts. The rest reported the cause was social, economic and familial stigma and discrimination. A third

reported that they ceased living openly as a trans person because doing so was "just too hard for me."

THE HARMS OF DENYING CARE

Data suggest the effects of denying that care are worse than whatever side effects result from delaying sex-assigned-at-birth puberty. And medical society guidelines conclude that the benefits of gender-affirming care outweigh the risks. Without gender-affirming hormone therapy, cisgender hormones take over, forcing body changes that can be permanent and distressing.

A 2020 study of 300 gender-incongruent young people found that mental distress—including self-harm, suicidal thoughts and depression—increased as the children were made to proceed with puberty according to their assigned sex. By the time 184 older teens (with a median age of 16) reached the stage in which transgender boys began their periods and grew breasts and transgender girls' voice dropped and facial hair began to appear, 46 percent had been diagnosed with depression, 40 percent had self-harmed, 52 percent had considered suicide, and 17 percent had attempted it—rates significantly higher than those of gender-incongruent children who were a median of 13.9 years old or of cisgender kids their own age.

Conversely, access to gender-affirming hormones in adolescence appears to have a protective effect. In one study, researchers followed 104 teens and young adults for a year and asked them about their depression, anxiety and suicidality at the time they started receiving hormones or puberty blockers and again at the three-month, six-month and one-year mark. At the beginning of the study, which was published in *JAMA Network Open* in February 2022, more than half of the respondents reported moderate to severe depression, half reported moderate to severe anxiety, and 43.3 percent reported thoughts of self-harm or suicide in the past two weeks.

But when the researchers analyzed the results based on the kind of gender-affirming care the teens had received, they found that those who had access to puberty blockers or gender-affirming hormones were 60 percent less likely to experience moderate to severe depression. And those with access to the medical treatments were 73 percent less likely to contemplate self-harm or suicide.

"Delays in prescribing puberty blockers and hormones may in fact worsen mental health symptoms for trans youth," says Diana Tordoff, an epidemiology graduate student at the University of Washington and co-author of the study.

That effect may be lifelong. A 2022 study of more than 21,000 transgender adults showed that just 41 percent of adults who wanted hormone therapy received it, and just 2.3 percent had access to it in adolescence. When researchers looked at rates of suicidal thinking over the past year in these same adults, they found that access to hormone therapy in early adolescence was associated with a 60 percent reduction in suicidality in the past year and that access in late adolescence was associated with a 50 percent reduction.

For Fleming's kids in Texas, gender-affirming hormones are not currently part of the discussion; not all trans people desire hormones or surgery to feel affirmed in their gender. But Fleming is already looking at jobs in other states to protect their children's access to such care, should they change their mind. "Getting your body closer to the gender [you] identify with—that is what helps the dysphoria," Fleming says. "And not giving people the opportunity to do that, making it harder for them to do that, is what has made the suicide rate among transgender people so high. We just—trans people are just trying to survive."

IF YOU NEED HELP If you or someone you know is struggling or having thoughts of suicide, help is available. Call the National Suicide Prevention Lifeline at 1-800-273-8255 (TALK), use the online Lifeline Chat or contact the Crisis Text Line by texting TALK to 741741.

ABOUT THE AUTHOR(S)

Heather Boerner is a health care and science journalist based in Pittsburgh. Her work has appeared in the *Daily Beast*, the *Washington Post*, the *Atlantic*, and NPR. Follow her on Twitter @HeatherBoerner

THE TENNESSEAN

CONTRIBUTORS | Opinion *This piece expresses the views of its author(s), separate from those of this publication.*

Hospitals for teens with gender dysphoria shouldn't be political battlegrounds | Opinion

I have questions about what age appropriate healthcare looks like for young people with gender dysphoria, but politicians should not be the ones making these decisions for teens and their parents.

Anna Caudill Guest Columnist

Published 2:12 p.m. CT Oct. 31, 2022 | Updated 2:13 p.m. CT Oct. 31, 2022

Key Points

Anna Caudill is executive director of Post Adoption Learning Services, a member of the Council of Parent Attorneys and Advocates, and mother to two children with disabilities.

When our church community helped us adopt two disabled young boys, I had no idea how hard parenting would be.

I was unprepared for the crushing helpless feeling every time a doctor said one of them needed surgery. I told adoption advocate Mary Beth Chapman more than once that if we could see around the bend in the road, we'd be afraid to go on.

More than once, our Sunday School class prayed us through, reminding me that we were never alone but seen and loved. The rare vacation was always within a half hour of a strong children's hospital, just in case. We joked that the Ronald McDonald House was our summer home.

We persevered, in no small part thanks to the dedicated child life specialists, pediatric nurses, and physicians of children's hospitals. Because of them, my children are not afraid when they head into a hospital for annual ultrasounds or lab work. My sons trust that when they enter a children's hospital, they are safe.

That's why I cannot understand why any elected official would ever try to put Vanderbilt University Medical Center patients or physicians in danger.

Hear more Tennessee Voices:*Get the weekly opinion newsletter for insightful and thought provoking columns.*

'Intentional campaign of disinformation' harms children

Several Tennessee officials recently joined forces regarding claims that VUMC's does genital reassignment surgeries on young children without parental consent, a claim the hospital says is untrue. Before Vanderbilt confirmed to legislators that they have treated an average of five patients a year since 2018, none younger than 16 and none involving genital alteration, U.S. Sen. Marsha Blackburn joined Tennessee's GOP leadership to echo these claims.

Setting aside how many patients that is, their ages, or how Vanderbilt could guarantee payment for surgeries performed on minors without parental consent — there is the very real issue of the danger these lies can cause.

A similar campaign was focused against Boston Children's Hospital recently. After weeks of the same kind of lies as the ones that have been brought against Vanderbilt, a Massachusetts woman called in a bomb threat, resulting in a lockdown of that clinic along with the entire Children's Hospital campus.

Within days, the American Academy of Pediatrics, American Medical Association, and Children's Hospital Association—Vanderbilt Children's is a member — sent a joint statement begging the Department of Justice for protection from "coordinated attacks...rooted in an intentional campaign of disinformation...resulting in a rapid escalation of threats, harassment, and disruption of care."

Sign up for Latino Tennessee Voices newsletter:*Read compelling stories for and with the Latino community in Tennessee.*

A hospital lockdown is terrifying

The helpless feeling of watching my child in pain is nothing compared to a hospital lockdown. In 2012, the summer my then 7-year-old lay in traction for 46 days following a grueling pelvic reconstruction, a woman became violent in the dead of night. At 2 in the morning I was jolted awake by the lockdown announcement, and police rushed past our room.

I drew the shades. My son slept on, his legs held straight by weights hanging from the bed's edge. I'd topped each of the pins holding his pelvis together with a tiny eraser in the shape of a Disney character so they wouldn't seem so scary to him. More police filed past. I wedged a

chair against the door and tried to gauge whether I could disconnect the hospital bed and squeeze it into the patient bathroom. Would it buy a few more minutes of life? Would it matter? Had we gone through six weeks of hell, with a daily care regimen that sent my baby screaming, to die like this?

Gov. Bill Lee, Senator Blackburn and state Sen. Jack Johnson, and Rep. William Lamberth know what happened to Boston Children's Hospital. They're experienced enough to know there were children terrified in their hospital rooms that day, chemo that was postponed and ambulances that were diverted elsewhere. They know this is no responsible way to represent Tennesseans or the children who come from all over the world for care at one of America's top ten pediatric hospitals.

Politicians shouldn't make health care decisions for parents

There is nothing helpful, moral, or remotely Christian about knowingly endangering over 100,000 children's lives this year to debate the healthcare choices of five patients. What is the end goal of disrupting the relationship between disabled and sick children and healthcare providers?

Children's hospitals are not a political battleground.

Even though I have questions about what age appropriate healthcare looks like for young people with gender dysphoria, I know without a doubt that politicians should not be the ones making these life altering decisions for teens and their parents.

I also know children who don't have gender dysphoria but do have other conditions requiring gender-affirming treatment.

And as a Christian and a mother to two boys whose lives depend on safe hospitals, I know we can and should have these conversations without resorting to lies and terrorizing children and doctors.

I expect my elected officials to keep children safe from domestic terror threats, not to provoke them for the sake of winning a midterm election.

Anna Caudill is executive director of Post Adoption Learning Services, a member of the Council of Parent Attorneys and Advocates, and mother to two children with disabilities. She

was named a 2013 Angel in Adoption by the Congressional Coalition on Adoption.

COMMITTEE ON
EDUCATION AND THE WORKFORCE
U.S. HOUSE OF REPRESENTATIVES
2176 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6100

July 19, 2023

Christine Monahan
Assistant Research Professor
Georgetown University
500 First Street NW
Washington, DC 20001

Dear Professor Monahan:

Thank you again for testifying at the June 21 Subcommittee on Health, Employment, Labor, and Pensions hearing on "Competition and Transparency: The Pathway Forward for a Stronger Health Care Market."

Enclosed are additional questions submitted by Subcommittee members following the hearing. Please provide written responses no later than August 9,2023, for inclusion in the hearing record. Responses should be sent to Michael Davis of the Committee staff who can be contacted at Michael.Davis@mail.house.gov or (202) 225-7101.

We appreciate your contribution to the work of the Subcommittee.

Sincerely,

Bob Good
Chairman
Subcommittee on Health, Employment, Labor, and Pensions

Enclosure

Questions for the Record for
CHRISTINE MONAHAN

Committee on Education and the Workforce
Subcommittee on Health, Employment, Labor, and Pensions
"Competition and Transparency: The Pathway Forward for a Stronger Health Care Market"
Wednesday, June 21, 2023
10:15 a.m.

Rep. Rick Allen (R-GA)

1. Ms. Monahan, the Transparency in Coverage rule requires insurers to provide a great deal of pricing information in machine-readable files. This has led to insurers posting massive data files that are impossible to comprehend, which completely defeats the purpose and intent of the legislation. What are ways the Transparency in Coverage reporting requirements could be improved or streamlined to make pricing data more accessible for employers and patients?

Rep. Mark DeSaulnier (D-CA)

1. The *Consolidated Appropriations Act, 2021* prohibited contract provisions that prevent plan fiduciaries from accessing quality and cost information (so-called "gag clauses"). However, there are increasing reports that vendors such as third-party administrators are throwing up roadblocks that prevent access to this information.
    a. What barriers do plan fiduciaries face in accessing the data described in the CAA?
    b. What is your assessment of the effectiveness of the requirement that plans attest that their contracts do not contain these provisions?
    c. What would the implications be of treating data as a plan asset under ERISA?
    d. Would it be useful for the Department of Labor to issue guidance on situations in which plan data is considered a plan asset? Is legislation needed?
    e. How would you recommend Congress improve this provision?

2. One issue that frequently comes up is whether service providers, including pharmacy benefit managers (PBMs) and third-party administrators (TPAs), have conflicts of interest when they administer group health plans. These companies often successfully argue that they are not acting as fiduciaries with respect to the health plans they contract with.
    a. Would identifying functions performed by entities like TPAs and PBMs in which they are acting as fiduciaries change their business practices?
    b. What are some considerations that we should weigh when looking at this issue?
    c. Would it be possible for the Department of Labor to issue guidance clarifying functions of TPAs and PBMs that are fiduciary in nature or is legislation needed?

3. The *Consolidated Appropriations Act, 2021* amended ERISA to require that plan fiduciaries must be provided with detailed disclosures of direct and indirect compensation earned by service providers that contract with the plan. The statute specifically states that covered service providers include pharmacy benefit managers and third-party administrators, among many others.
    a. Why is this information necessary to ensure that compensation paid to vendors is reasonable?
    b. To what extent are entities described in this provision currently providing fiduciaries with the disclosures needed to ensure the reasonableness of their contracts?
    c. What improvements would you recommend that would strengthen the disclosures that vendors must provide?

4. Health care costs in the United States are the highest in the world, accounting for more than one sixth of our gross domestic product. Individuals covered under private health plans, including employer-sponsored plans, are billed by providers at rates that are usually multiple times what Medicare, Medicaid, and other public programs pay for the same services.
    a. Why is it so difficult for employers to reduce how much they pay for health care?
    b. How would payment reforms, such as improving hospital outpatient billing practices, help lower costs for consumers and for businesses?
    c. Is there an argument that under ERISA plan fiduciaries have an obligation to seek lower costs and, if so, how could this help reduce health care spending?

GEORGETOWN UNIVERSITY
McCourt School of Public Policy

CENTER ON HEALTH INSURANCE REFORMS

WRITTEN RESPONSES TO QUESTIONS FOR THE RECORD FOR
CHRISTINE H. MONAHAN, J.D.
ASSISTANT RESEARCH PROFESSOR
CENTER ON HEALTH INSURANCE REFORMS
MCCOURT SCHOOL OF PUBLIC POLICY
GEORGETOWN UNIVERSITY

FOLLOWING THE U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON EDUCATION AND THE WORKFORCE SUBCOMMITTEE ON HEALTH, EMPLOYMENT, LABOR, AND PENSIONS

HEARING ON

"COMPETITION AND TRANSPARENCY: THE PATHWAY FORWARD FOR A STRONGER HEALTH CARE MARKET"

WEDNESDAY, JUNE 21, 2023

Rep. Rick Allen (R-GA)

1. *Ms. Monahan, the Transparency in Coverage rule requires insurers to provide a great deal of pricing information in machine-readable files. This has led to insurers posting massive data files that are impossible to comprehend, which completely defeats the purpose and intent of the legislation. What are ways the Transparency in Coverage reporting requirements could be improved or streamlined to make pricing data more accessible for employers and patients?*

There are several ways the Transparency in Coverage (TiC) reporting requirements can be improved or streamlined to make pricing data more accessible for employers and patients. Below are a set of recommendations developed by leading experts in the area, including my colleagues Sabrina Corlette and Karen Davenport of the Center on Health Insurance Reforms at Georgetown University's McCourt School of Public Policy:[1]

- Reduce data redundancy by:
  - Requiring the use of relational databases or file structures, to identify where there are the same (or very similar) negotiated rates or limiting the posted files to unique network arrangements and associated fee schedules, providing users with the ability to crosswalk to the employer identification numbers (EIN) to which the network arrangement applies
    - Alternatively, consider creating a file structure that allows insurers to post one rate for a service or provider if different plans (self-insured, large-group fully insured, individual, etc) share the same rate.
  - Requiring a flag in the in-network file to denote providers with 20 or more services performed in the last year (a similar threshold is required for the out-of-network files)
  - Reducing frequency of reporting from monthly to quarterly or even biannually. This has the advantage of both giving users more time to analyze the data and reducing the compliance burden on issuers
- Improve accessibility by:
  - Requiring a clear library index (or "augmented index file") and standardized labeling of files so that users can see what provider/service codes are in each file
  - Maintaining a repository of issuers in compliance with the rule and include links to their data sources; issuers not in compliance should also be publicly identified
  - Imposing a file size limit to ensure that files are not unreasonably large. While ultimately each plan or issuer would still need to publish the same volume of data, requiring them to post a greater number of smaller files will enable users with standard computing capacity to download and use the data

[1] Further information is available online at *Transparency in Coverage: Recommendations* for Improving Access to and Usability of Health Plan Price Data*, https://georgetown.app.box.com/s/1ezsggz1c7smsaexkr8rght15sokgusl.

    - Requiring issuers to use the same file type across all users, to enable the use of a single, standard, and open-source code to access the information
- Improve usability by:
    - Requiring clearer and standardized labels (file names) on each file (i.e., standard labels for network type, the services included, service area, etc.)
    - Require standardized conventions for and inclusion of providers' National Provider Identifiers (NPIs)
- Improve data quality by:
    - Reviewing a random sampling of files to assess data quality during each posting period. Issuers with poor data quality should be required to take corrective action
    - Providing a public-facing portal and reporting template for users to submit potential violations of the TiC posting requirements and flag potential data quality problems
    - Convene and maintaining a standing group of technical experts to advise the Centers for Medicare & Medicaid Services (CMS) on ways to improve accessibility and data quality, with the goal of ensuring that the agency is continually striving to ensure that the published data meets the needs of researchers, regulators, and purchasers

Congress may also want to consider requiring the Department of Health and Human Services (HHS) to produce an annual report that leverages the newly available price data to provide legislators and other stakeholders with critical information about the drivers of health system costs.

Rep. Mark DeSaulnier (D-CA)

1. *The* Consolidated Appropriations Act, 2021 *prohibited contract provisions that prevent plan fiduciaries from accessing quality and cost information (so-called "gag clauses"). However, there are increasing reports that vendors such as third-party administrators are throwing up roadblocks that prevent access to this information.*
    a. *What barriers do plan fiduciaries face in accessing the data described in the CAA?*

Ongoing litigation and reports from stakeholders indicate that plan fiduciaries continue to face significant barriers in accessing the data described in the *Consolidated Appropriations Act, 2021* (CAA). These barriers include the continued existence of contract provisions that limit plan sponsors' access to claims data, months or years of delays after data is requested, and significant gaps in the data when it is finally shared.

For example, a recent *Bloomberg* article by John Tozzi reported that the company Kraft Heinz has alleged that it "requested its claims data in November 2021. What Aetna provided, more than a year later, left out hundreds of data fields, including information that would link a medical

claim to a specific payment in order for the company to see if it was billed correctly." [2] Another company, Owens-Minor, has alleged that a unit of Elevance "blocked the company's attempt to get its health plan data with 'a year-long trail of emails and other correspondence, littered with defendant's excuses, arbitrary conditions, and illusory promises.'"[3] Tozzi reports that an "Elevance representative said the insurer wouldn't release billing information that would allow Owens & Minor to compare how much providers charged versus how much was paid for the services, according to the complaint. Elevance said in a legal filing that its contracts with providers are confidential."[4] More generally, Karen van Caulil, chief executive officer of the Florida Alliance for Healthcare Value, explained to Tozzi that employers have faced a "nightmare of delays" getting data claims data from their health plans.[5]

b. What is your assessment of the effectiveness of the requirement that plans attest that their contracts do not contain these provisions?

Meaningful enforcement mechanisms are critical to ensuring compliance with the CAA's provisions. While attestation can play a role in enforcement, I have heard concerns from stakeholders regarding current federal guidance that allows third-party administrators (TPAs), pharmacy benefit managers (PBMs), and other service providers to attest to compliance with the gag clause prohibition on behalf of the plan.[6] Gag clauses generally serve the interests of service providers and, under current law, service providers do not necessarily face liability if gag clauses remain in their contracts. As service providers themselves have emphasized, the responsibility for compliance falls solely on the plan.[7] Thus, service providers have little incentive to closely scrutinize their contracts to ensure all gag clauses have been removed and also may take a narrow view of what constitutes a gag clause. At the same time, employers may be encouraged to rely on their service providers' attestations—including explicitly so by the brokers and consultants they hire—particularly if the employer lacks independent expertise to identify and successfully negotiate for the removal of any gag clauses. This effectively has the fox guarding the hen house. For many of the same reasons, the Purchaser Business Group on Health has

---

[2] John Tozzi, *Health Insurers Don't Want You to Know Where Your Money Is Going*, BLOOMBERG (Aug. 2, 2023), https://www.bloomberg.com/news/features/2023-08-02/what-health-insurance-companies-won-t-reveal-about-your-medical-bills.
[3] *Id.*
[4] *Id.*
[5] *Id.*
[6] FAQS ABOUT AFFORDABLE CARE ACT AND CONSOLIDATED APPROPRIATIONS ACT, 2021 IMPLEMENTATION PART 57 (Feb. 23, 2023), https://www.cms.gov/files/document/aca-part-57.pdf.
[7] *See, e.g.*, Memorandum of Law in Support of Defendants' Motion to Dismiss Plaintiffs' Complaint at 25, Trs. of Int'l Union of Bricklayers & Allied Craftworkers Local 1 Conn. Health Fund v. Elevance, No. 3:22-cv-01541-VLB (D. Conn. Mar. 10, 2023) (arguing that the plan sponsors can seek to renegotiate their contracts to meet "***their*** obligations" if they so desire, but the gag clause prohibition does not impose any duties on the third-party administrator (emphasis in original)).

explained that employers and purchasers may "have no other option but to consider submitting a false attestation or none at all."[8]

c. What would the implications be of treating data as a plan asset under ERISA?

My impression is that treating data as a plan asset under ERISA would generally be welcomed by employers who are struggling to get and use this data today. On top of the issues accessing their data described above, even when service providers like TPAs share data with plan sponsors they may impose significant limitations on how the plan sponsor may use that data. This includes language prohibiting plan sponsors from using claims data to negotiate deeper discounts for services or advance transparency of health care quality and costs. Presumably if data were treated as a plan asset, such limitations would not apply to a plan sponsor's use of plan data.

At the same time, treating data as a plan asset also raises significant privacy concerns, including the extent to which plan member's personal health information is protected from improper access or use. Experts in privacy law and potentially affected stakeholders should be consulted on these topics.

d. Would it be useful for the Department of Labor to issue guidance on situations in which plan data is considered a plan asset? Is legislation needed?

The Department of Labor (DOL) would be well-suited to research this issue further, including the potential privacy concerns I noted above. DOL can then provide recommendations on how best to move forward, including the most appropriate legal mechanism for implementing any reforms.

e. How would you recommend Congress improve this provision?

The gag clause provision can be significantly improved by strengthening compliance and enforcement, such as the provisions currently proposed in H.R. 4527, the *Health Data Access, Transparency, and Affordability Act*. Key reforms include ensuring responsible plan fiduciaries can audit plan data without their vendors imposing unreasonable restrictions, holding service providers liable for violations of the law, and voiding any unlawful gag clauses, including contract terms that unduly delay a plan fiduciary's access to plan data.

[8] Darren Fogarty, *What Employers Need to Know About Removing Gag Clauses from Health Care Contracts*, PURCHASER BUS. GRP. ON HEALTH (Aug. 1, 2023), https://www.pbgh.org/what-employers-need-to-know-about-removing-gag-clauses-from-health-care-contracts/.

2. *One issue that frequently comes up is whether service providers, including pharmacy benefit managers (PBMs) and third-party administrators (TPAs), have conflicts of interest when they administer group health plans. These companies often successfully argue that they are not acting as fiduciaries with respect to the health plans they contract with.*
   a. *Would identifying functions performed by entities like TPAs and PBMs in which they are acting as fiduciaries change their business practices?*
   b. *What are some considerations that we should weigh when looking at this issue?*
   c. *Would it be possible for the Department of Labor to issue guidance clarifying functions of TPAs and PBMs that are fiduciary in nature or is legislation needed?*

I offer a single response to the above questions. Service providers like PBMs and TPAs have been able to successfully argue to courts they do not function as fiduciaries under ERISA in many circumstances because they are not exercising any discretion when administering the plan and they do not exercise authority or control with respect to the management and disposition of plan assets.[9] For example, courts have distinguished the act of "determining the amount of plan assets to be paid," from "controlling the actual payment – i.e., the disposition – of those assets."[10] Additionally, these entities also argue and courts often accept that they are not fiduciaries when performing activities like negotiating formularies, networks, and reimbursement rates or even recovering and settling potential overpayments because they are acting without regard to an individual health plan but rather their broader books of business and independent interests.[11] Whether these conclusions are the best or only reading of existing law may be debated, but they are certainly common and are likely to continue to dominate court decisions absent legislative change.

Under this framework, simply naming TPAs and PBMs as fiduciaries in legislation may be inadequate. Plan sponsors are the archetypal fiduciary, but this does not mean they are acting as fiduciaries with respect to every activity they perform. For example, employers generally act as "settlors," rather than fiduciaries, when establishing a health plan and thus can exercise business judgment with respect to decisions like whether to offer coverage at all, what type of coverage to

---

[9] *See* 29 U.S.C. § 1002(21)(A) (defining fiduciaries); *Pegram v. Herdrich*, 530 U.S. 211 (2000) (discussing scope of fiduciary functions); *Mass. Laborers' Health & Welfare Fund v. Blue Cross Blue Shield of Mass.*, 2022 U.S. Dist. LEXIS 58083, *26–27 (D. Mass. 2022) (discussing cases involving whether TPAs and PBMs are functional fiduciaries); *Report to the Honorable Thomas E. Perez, U.S. Sec'y of Lab: PBM Compensation and Fee Disclosure* 12–13, ADVISORY COUNCIL ON EMP. WELFARE & PENSION BENEFIT PLANS (Nov. 2014) (summarizing case law on fiduciary status of PBMs).

[10] *Mass. Laborers' Health & Welfare Fund v. Blue Cross Blue Shield of Mass.*, 66 F.4th 326 (1st Cir. 2023).

[11] *See, e.g.*, *id.* at 322–23.

offer and to which employees, how much to contribute financially to that coverage.[12] If only labeled in legislation as fiduciaries, TPAs and PBMs are likely to agree they are fiduciaries when conducting activities courts have traditionally held to be fiduciary functions, but maintain that they are still not fiduciaries when performing activities that courts have said do not constitute fiduciary functions under existing case law. Like employers, they could simply wear "two hats."[13]

Consistently extending ERISA's fiduciary duties to common TPA and PBM activities like negotiating prescription drug formularies and provider networks, and setting reimbursement rates thus will likely require more specific changes in the law. Part of this would involve identifying the broad functions that policymakers believe should come with fiduciary duties—that is, what are the functions where these entities should be acting "solely in the interest of the participants and beneficiaries," for the "exclusive purpose" of "providing benefits to participants and their beneficiaries"?[14] These may be functions that significantly affect the cost or availability of care and where, due to market failures, PBMs and TPAs currently lack adequate incentives to negotiate better deals for employer plans and/or derive significant profits at the expense of employer plans and their participants and members. But policymakers also will likely need to consider and specify in law how ERISA's fiduciary duties should apply when PBMs and TPAs are negotiating contracts and deals that apply across multiple plans with different terms, rather than one specific plan. This would represent a departure from current precedent.[15] These reforms collectively would likely affect many common PBM and TPA business practices where profits dominate decision-making, but I defer to other experts and stakeholders to advise on these impacts.

---

[12] *See* Dana Muir & Norman Stein, *Two Hats, One Head, No Heart: The Anatomy of the ERISA Settlor/Fiduciary Distinction*, 93 N.C. L. REV. 459, 478–84 (2015) (discussing the Supreme Court's settlor/fiduciary doctrine).

[13] *Id.* at 463.

[14] 29 U.S.C. § 1104(a)(1).

[15] *Peterson v. UnitedHealth Group, Inc.*, 913 F.3d 769, 776 (8th Cir. 2019) ("While administrators like United may happen to be fiduciaries of multiple plans, nevertheless 'each plan is a separate entity' and a fiduciary's duties run separately to each plan." (quoting *Standard Ins. Co. v. Saklad*, 127 F.3d 1179, 1181 (9th Cir. 1997)).

3. *The* Consolidated Appropriations Act, 2021 *amended ERISA to require that plan fiduciaries must be provided with detailed disclosures of direct and indirect compensation earned by service providers that contract with the plan. The statute specifically states that covered service providers include pharmacy benefit managers and third-party administrators, among many others.*
   a. *Why is this information necessary to ensure that compensation paid to vendors is reasonable?*

Employers, as plan sponsors, have a duty to ensure the compensation they pay service providers is reasonable for the services provided.[16] In 2007, DOL recognized that plan fiduciaries—whether for pension or health plans—cannot comply with their legal duties when they do not have access to relevant information, stating: "To meet these obligations, it is vital that fiduciaries have enough information to make informed assessments and decisions about the services, the costs and the providers."[17] DOL thus proposed regulations that would require service providers to disclose their compensation and conflicts of interest to pension and health plans.[18] The Department, however, finalized the proposal for pension plans only, explaining that commenters effectively argued that it should develop a comprehensive disclosure framework specific to health plans rather than applying the same standards to both pension and health plans.[19] This never occurred and disclosures were not specifically required for health plans until Congress intervened and established new rules under the CAA.

It is my understanding that action was not taken before the CAA was enacted because both federal officials and employers tended to assume that health plan service providers—or at least the benefits consultants charged with vetting other plan service providers—were looking out for employer plans' best interests without close inquiry. Unfortunately, it has become clear that the employer-sponsored insurance market is rife with excessive and wasteful spending to which employers have largely been in the dark. This includes hidden fees and overpayments to TPAs and PBMs,[20] and massive commissions for employer benefit consultants and brokers

---

[16] 29 U.S.C. § §1104(a)(1), 1108(b)(2); U.S. DEP'T OF LABOR, INFORMATION LETTER 02-19-1998, https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/information-letters/02-19-1998.

[17] Reasonable Contract or Arrangement Under Section 408(b)(2)—Fee Disclosure, 72 Fed. Reg. 70,988, 70,995 (Dec. 13. 2007).

[18] *Id.* at 70,989.

[19] Reasonable Contract or Arrangement Under Section 408(b)(2)—Fee Disclosure, 75 Fed. Reg. 41,600, 41,603 (July 16, 2010).

[20] Bob Herman, *Fed up with Exorbitant Health Costs, Employers and Workers Are Taking Insurers to Court*, STAT NEWS (June 12, 2023), https://www.statnews.com/2023/06/12/employers-sue-health-insurers; Christine Monahan, *Questionable Conduct: Allegations Against Insurers Acting as Third-Party Administrators*, CHIRBLOG (Mar. 24, 2023), https://chirblog.org/questionable-conduct-allegations-insurers-acting-third-party-administrators/; *Pharmacy Benefit Tactics Drive up Drug Prices, Limit Access, Contribute to Health Risks*, PURCHASER BUS. GRP. ON HEALTH (Dec. 2022),

recommending and arranging contracts on behalf of employers.[21] Critically, employers have relied on their benefit consultants and brokers to offer impartial advice, not appreciating that, as Bob Herman recently reported for *Stat News*, that "[s]ome consulting firms often are getting paid more—a lot more—by the PBMs and health insurance carriers that they are supposed to scrutinize than by companies they are supposed to be looking out for."[22] Absent disclosure requirements, for example, an employer may be unaware that their broker receives significantly more money from a TPA or PBM if the employer renews their contract and thus may not alert them to more cost effective alternatives they employer otherwise may have chosen.

b. To what extent are entities described in this provision currently providing fiduciaries with the disclosures needed to ensure the reasonableness of their contracts?

Herman's reporting raises questions about the extent of compliance and clarity of disclosures, particularly with respect to indirect compensation,[23] but I do not have more specific information to share in response to this question.

c. What improvements would you recommend that would strengthen the disclosures that vendors must provide?

One concern I have heard from stakeholders is that service providers will just include complex formulas or percentages that broadly describe how compensations would be calculated, without disclosing specific compensation amounts. I can also understand why some vendors may argue that this flexibility is necessary, particularly to the extent their contracts for direct and indirect compensation from third-parties take several variables into account. One approach to resolving these competing concerns may be to additionally require that vendors disclose the total amount of direct and indirect compensation they received after the plan year has ended. This could be included at the same time disclosures regarding anticipated compensation are made, along with an explanation of any changes in the terms of their compensation contracts to the extent such

---

https://www.pbgh.org/wp-content/uploads/2022/12/Pharmacy-Benefit-Tactics-Drive-Up-Drug-Prices-Limit-Access-Contribute-to-Health-Risks.pdf; Erin E. Trish et al., *PBMs Are Inflating the Cost of Generic Drugs. They Must Be Reined in.*, STAT NEWS (June 30, 2022), https://www.statnews.com/2022/06/30/pbms-inflating-cost-generic-drugs/.

[21] Bob Herman, '*It's Beyond Unethical': Opaque Conflicts of Interest Permeate Prescription Drug Benefits*, Stat (June 20, 2023), https://www.statnews.com/2023/06/20/pbms-consulting-firms-investigation/; *EP379: How Much Money, Really, Are Employee Benefit Consultants and/or Brokers Making from Plan Sponsors? With AJ Loiacono*, RELENTLESS HEALTH VALUE (Sept. 15, 2022), https://relentlesshealthvalue.com/episode/ep379; Marshall Allen, *Behind the Scenes, Health Insurers Use Cash and Gifts to Sway Which Benefits Employers Choose*, PROPUBLICA (Feb. 20, 2019), https://www.propublica.org/article/health-insurance-brokers-cost-commissions-bonuses.

[22] Herman, *supra* note 21.

[23] *Id.*

changes are expected to meaningfully impact the amount of compensation to come in the following year.

To shed further light on these types of compensation streams, policymakers may want to consider adopting parallel provisions that require PBMs and TPAs to publicly disclose the direct and indirect compensation they pay to plan vendors like brokers and benefit consultants. Policymakers also may want to explore establishing whistleblower protections for workers of service providers that do not disclose or inadequately disclose direct or indirect compensation, so they can safely report these failures to either the client or DOL without fear of retribution.

4. *Health care costs in the United States are the highest in the world, accounting for more than one sixth of our gross domestic product. Individuals covered under private health plans, including employer-sponsored plans, are billed by providers at rates that are usually multiple times what Medicare, Medicaid, and other public programs pay for the same services.*
   a. *Why is it so difficult for employers to reduce how much they pay for health care?*

Employers face several barriers to reducing health care costs. Historically, employers' exposure to rising health care costs have been moderated by the federal tax exclusion for employer-paid health insurance premiums.[24] Employers also have been able to shift costs to their employees by increasing their premium contributions, reducing the generosity of benefits, or limiting wage increases to offset the rising cost of health care services.[25] A lack of transparency regarding health care prices and costs also has long limited employers' interest and ability to reduce how much they pay for health care. As my colleagues Sabrina Corlette and Maanasa Kona have written, "most employers have little to no access to data on the prices they are paying, the relationship of prices to the actual costs of delivering care, or whether or not the prices being charged are correlated with higher quality or better patient outcomes. This can lead to what the U.S. Congressional Budget Office calls a 'lack of sensitivity' to high prices."[26]

Even when motivated and armed with information about health care prices and costs—which is becoming increasingly available thanks to recent executive and congressional action although more can still be done—employers face significant barriers to reducing costs because of the lack

[24] *See, e.g.*, CONG. BUDGET OFF., REDUCE TAX SUBSIDIES FOR EMPLOYMENT-BASED HEALTH INSURANCE (2022), https://www.cbo.gov/budget-options/58627.
[25] *See* Maanasa Kona & Sabrina Corlette, *The Erosion of Employer-Sponsored Health Insurance and Potential Policy Responses*, CHIRBLOG (Dec. 5, 2022), https://chirblog.org/erosion-employer-sponsored-health-insurance-potential-policy-responses/.
[26] Sabrina Corlette & Maanasa Kona, *Can Employer-Sponsored Insurance Be Saved? A Review of Policy Options: Price Transparency*, CHIRBLOG (July 6, 2023), https://chirblog.org/can-employer-sponsored-insurance-be-saved-a-review-of-policy-options-price-transparency/ (linking to CONG. BUDGET OFF., POLICY APPROACHES TO REDUCE WHAT COMMERCIAL INSURERS PAY FOR HOSPITALS' AND PHYSICIANS' SERVICES (2022), https://www.cbo.gov/system/files/2022-09/58222-medical-prices.pdf).

of competition and misaligned incentives in the health care marketplace. There is widespread agreement that the primary cause of rising health care costs is rising prices for health care, particularly hospital care, which has been driven by consolidation in health care provider markets.[27] And, while the insurance market is significantly consolidated itself, the major insurers that employers hire to act as TPAs often lack significant incentive to negotiate competitive reimbursement rates under the current system.[28] Individual employers and even groups of employers struggle to gain meaningful price concessions given these forces.[29]

b. How would payment reforms, such as improving hospital outpatient billing practices, help lower costs for consumers and for businesses?

Payment reforms, including regulating hospital outpatient billing practices, can help lower costs for consumers and for business, although the impact will vary depending on the nature of the reform. Specifically in the context of outpatient billing practices, the reform that would have the largest effect on total costs would be to prohibit hospitals from charging facility fees for outpatient services that can be safely and effectively delivered outside of a hospital setting and capping the remaining professional payment. The impact this would have would depend on where the payment level is set and the scope of services covered by the reform. For example, a payment level that is set based on the median for all rates an insurer pays for a given service in a geographic region will have much less of an effect than a payment level that is set at the median reimbursement rate an insurer pays independent practices for a given service in a geographic region. Similarly, a policy that is limited to prohibiting such fees in off-campus settings will have a much smaller effect than one that includes specified services delivered in on-campus settings as well.

---

[27] *See* Maanasa Kona & Sabrina Corlette, *Can Employer-Sponsored Insurance Be Saved? A Review of Policy Options: Limiting Provider Consolidation and Anti-Competitive Behavior*, CHIRBLOG (Mar. 8, 2023), https://chirblog.org/can-employer-sponsored-insurance-saved-review-policy-options-limiting-provider-consolidation-anti-competitive-behavior/; Aaron Glickman & Janet Weiner, *Health Care Cost Driers and Options for Cost Control* 6, PENN LDI (Apr. 2020), https://ldi.upenn.edu/wp-content/uploads/2021/06/LDI-Issue-Brief-2020-Vol.-23-No.-4_12.pdf; Gerard F. Anderson et al., *It's Still The Prices, Stupid: Why The US Spends So Much On Health Care, And A Tribute To Uwe Reinhardt*, 38 HEALTH AFFS. 87 (Jan. 2019), https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.05144.

[28] *See, e.g.*, CONG. BUDGET OFF., *supra* note 26 at 11; *Inside Big Health Insurers' Side Hustle*, TRADEOFFS (Sept. 23, 2021), https://tradeoffs.org/2021/09/23/inside-big-health-insurers-side-hustle/; Bob Herman, *Seven Health Insurance CEOs Raked in a Record $283 Million Last Year*, STAT NEWS (May 12, 2022), https://www.statnews.com/2022/05/12/health-insurance-ceos-raked-in-record-pay-during-covid/; Sarah Kliff & Josh Katz, *Hospitals and Insurers Didn't Want You to See These Prices. Here's Why.*, N.Y. TIMES (Aug. 22, 2021), https://www.nytimes.com/interactive/2021/08/22/upshot/hospital-prices.html.

[29] Corlette & Kona, *supra* note 25.

Restricting outpatient facility fee billing without a cap on payments would likely meaningfully reduce consumer out-of-pocket cost exposure and thus improve affordability for many consumers. Consumers are particularly affected by outpatient facility fee billing due to current trends in health insurance benefit design, including the growing size and prevalence of deductibles and separate cost-sharing obligations for hospital and physician charges. Nonetheless, hospitals with market power would likely be able to make up for lost revenue by increasing other charges. Thus, the effect on total spending and premiums would likely be small, particularly over the longer-term.

Bringing more transparency to health care billing, including requiring off-campus settings owned by or affiliated with hospitals to acquire and bill with unique provider identifiers, could generate savings either for consumers with respect to out-of-pocket costs or on total spending only to the extent private insurers leverage this information. The reform nonetheless has value even when private insurers lack the market power and/or incentive to rein in spending because it will provide valuable information to policymakers and regulators regarding the current scope and effects of outpatient facility fee billing and consolidation more broadly. Officials, in turn, can use this information to develop targeted policy reforms or more effectively enforce existing regulations.

For sources and further discussion of these issues, please see Linda Blumberg & Christine H. Monahan, *Facility Fees 101: What is all the Fuss About?*, Health Affairs (Aug. 4, 2023), https://www.healthaffairs.org/content/forefront/facility-fees-101-all-fuss and Christine H. Monahan, Karen Davenport, and Rachel Swindle, *Protecting Patients from Unexpected Outpatient Facility Fees: States on the Precipice of Broader Reform*, Georgetown Center on Health Insurance Reforms & West Health (July 2023), https://georgetown.app.box.com/file/1259606468349?v=statefacilityfeereport.

For a discussion of other payment reform options, please see Linda J. Blumberg, Sabrina Corlette, & Jack Hoadley, *Can Employer-Sponsored Insurance Be Saved? A Review of Policy Options: Price Regulation*, CHIRblog, (Jan. 18, 2023), https://chirblog.org/can-esi-be-saved-review-of-policy-options-price-regulation/.

c. Is there an argument that under ERISA plan fiduciaries have an obligation to seek lower costs and, if so, how could this help reduce health care spending?

Yes, there is an argument that ERISA plan fiduciaries have an obligation to seek lower costs. One important fiduciary function is the choice of service providers—from brokers and benefit consultants, to TPAs and PBMs, to hospitals and physicians providing health care to participants.[30] Because service providers' receipt of plan assets in exchange for services presents

[30] *See, e.g.*, *Whitfield v. Cohen*, 682 F. Supp. 188, 195 (S.D.N.Y. 1988) (choosing a service provider is a fiduciary act requiring the responsible fiduciary to prudently investigate the credentials of the service provider and its ability to serve the plan); *Perez v. Chimes D.C.*,

risks of conflicts, plans can contract with service providers only to the extent their services "are necessary for the establishment or operation of the plan" and they are paid "no more than reasonable compensation."[31] Fiduciaries also must monitor service providers, including regularly evaluating "whether to continue using the current service providers or look for replacements," reviewing their performance, and checking the fees they charge.[32]

There are strong arguments that existing spending by employer-sponsored plans is not reasonable and has been inadequately monitored by plan fiduciaries. This applies equally to excessive fees and other payments made to TPAs, PBMs, brokers, and benefit consultants who help set up and administer the plans, which I've discussed above, and to hospital reimbursement rates that often are far above levels that would enable hospitals to "break even."[33]

Nonetheless, determining what is reasonable presents challenges. It is not the case that fiduciaries simply must pick the lowest bidder when evaluating service providers, as DOL has advised that, "[t]he responsible plan fiduciary must engage in an objective process designed to elicit information necessary to assess the qualifications of the provider, the quality of services offered, and the reasonableness of the fees charged in light of the services provided."[34] What's more, as I previously described, individual employers face significant market barriers to securing lower costs. It remains to be determined what steps plan fiduciaries must take to ensure they are acting prudently and their spending is reasonable. How far they choose to go in an effort to avoid litigation, or how far courts or DOL demand they go if presented this question, will affect the extent of cost savings that may be secured. So too will actions by policymakers. For example, reforms that limit abusive outpatient billing and other anticompetitive practices could enable plan fiduciaries to negotiate better deals and thus move the bar on how much cost savings employers can reasonably achieve.

2016 U.S. Dist. LEXIS 126982, *13–29 (D. Md. Sept. 19, 2016) (same); *Solis v. Webb*, 931 F. Supp. 2d 936, 953 (N.D. Cal. 2012) ("Implicit within the duty to select and retain fiduciaries is a duty to monitor their performance."); U.S. DEP'T OF LAB., *supra* note 16 (discussing health care providers as service providers).

[31] 29 U.S.C. § 1108(b)(2)(A).

[32] ERISA Fiduciary Advisor, U.S. Dep't of Lab., https://webapps.dol.gov/elaws/ebsa/fiduciary/q4f.htm#:~:text=Monitoring%20a%20service%20provider,providers%20or%20look%20for%20replacements.

[33] *See* Christopher Whaley, *Prices Paid to Hospitals By Private Health Plans: Findings from Round 4 of an Employer-Led Transparency Initiative*, RAND (2022), https://www.rand.org/content/dam/rand/pubs/research_reports/RRA1100/RRA1144-1/RAND_RRA1144-1.pdf; *Understanding NASHP's Hospital Cost Tool: Commercial Breakeven*, NAT'L ACAD. FOR STATE HEALTH POL'Y (Mar. 28, 2022), https://nashp.org/commercial-breakeven/

[34] U.S. DEP'T OF LAB., *supra* note 16.

COMMITTEE ON
EDUCATION AND THE WORKFORCE
U.S. HOUSE OF REPRESENTATIVES
2176 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6100

July 19, 2023

Gloria Sachdev
President and CEO
Employers' Forum of Indiana
3352 Walnut Creek Drive North
Carmel, IN 46032

Dear Dr. Sachdev:

Thank you again for testifying at the June 21 Subcommittee on Health, Employment, Labor, and Pensions hearing on "Competition and Transparency: The Pathway Forward for a Stronger Health Care Market."

Enclosed are additional questions submitted by a Subcommittee member following the hearing. Please provide written responses no later than August 9, 2023, for inclusion in the hearing record. Responses should be sent to Michael Davis of the Committee staff who can be contacted at Michael.Davis@mail.house.gov or (202) 225-7101.

We appreciate your contribution to the work of the Subcommittee.

Sincerely,

Bob Good

Bob Good
Chairman
Subcommittee on Health, Employment, Labor, and Pensions

Enclosure

Questions for the Record for
GLORIA SACHDEV

Committee on Education and the Workforce
Subcommittee on Health, Employment, Labor, and Pensions
"Competition and Transparency: The Pathway Forward for a Stronger Health Care Market"
Wednesday, June 21, 2023
10:15 a.m.

Rep. Mark DeSaulnier (D-CA)

1. The *Consolidated Appropriations Act, 2021* prohibited certain contract terms, known as gag clauses, that limit access to cost and quality data. Despite this prohibition, many employers report that they continue to face onerous requirements imposed by their third-party administrators (TPAs) and other service providers that prevent accessing data.
    a. What are some of the barriers that prevent compliance with the CAA's gag clause requirements?
    b. If a plan fiduciary wants to audit the data, do TPAs and other service providers choose who conducts the audit? Are the fees imposed reasonable?
    c. What are your recommendations for improving this provision?

2. In your testimony you discuss the issue of who owns data that is generated in the course of administering an employer-sponsored group health plan. This information is very important and has the potential to be used for the benefit of the plan participants to lower costs and improve quality.
    a. Do you agree that the data is not the property of the TPA or other service providers? If it does not belong to the TPA, should it be treated as a plan asset under ERISA?
    b. Should the Department of Labor help plans determine when and how this data should be treated as a plan asset?
    c. Is legislation necessary to clarify this matter?

3. In 2020, the Departments of Health and Human Services, Labor, and the Treasury issued final rules under the ACA regarding Transparency in Coverage. These rules have been a step forward for both consumers, who now have access to cost-sharing information, and for researchers, employers, and policymakers, who now have access to detailed information regarding health care costs. But challenges remain, and I am curious to learn more about the employer perspective on this issue.
    a. What has been the experience of employers in navigating the data? Has it been useful or does more work need to be done to ensure it is useable?
    b. How can CMS include provider quality transparency as part of the data?
    c. If this Committee considers legislation to codify the regulation, what suggestions would you have for additional changes that should be made?

   d. Should health plans be required to submit this information to HHS, DOL, and Treasury? How would this help facilitate establishment of a federal database and perhaps a national All-Payer Claims Database?

4. Under ERISA, fiduciaries have important responsibilities with respect to the plan, including a duty to act prudently and solely in the interest of plan participants and beneficiaries. However, in many cases entities such as third-party administrators and pharmacy benefit managers argue that they are not fiduciaries and are not subject to these obligations.
   a. How would adhering to a fiduciary standard change the practices of third-party administrators and pharmacy benefit managers?
   b. Would it be useful for federal policymakers – either through legislation or regulatory action – to specify which functions performed by third-party administrators, pharmacy benefit managers, and others entail fiduciary duties under ERISA?

5. The *Consolidated Appropriations Act, 2021* amended Section 408(b)(2) of ERISA to provide that contracts or arrangements between plan fiduciaries and service providers must include disclosures of direct and indirect compensation earned by service providers. The statute specifically specifies that contracts for the design and implementation of pharmacy benefit management services and third-party administrative services are subject to this requirement.
   a. Is it your understanding that service providers such as third-party administrators and pharmacy benefit managers are providing these disclosures to employers?
   b. If employers are not provided this information, how are they able to determine if the compensation their vendors are receiving is reasonable?

COMMITTEE ON
EDUCATION AND THE WORKFORCE
U.S. HOUSE OF REPRESENTATIVES
2176 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6100

July 19, 2023

Gloria Sachdev
President and CEO
Employers' Forum of Indiana
3352 Walnut Creek Drive North
Carmel, IN 46032

Dear Dr. Sachdev:

Thank you again for testifying at the June 21 Subcommittee on Health, Employment, Labor, and Pensions hearing on "Competition and Transparency: The Pathway Forward for a Stronger Health Care Market."

Enclosed are additional questions submitted by a Subcommittee member following the hearing. Please provide written responses no later than August 9, 2023, for inclusion in the hearing record. Responses should be sent to Michael Davis of the Committee staff who can be contacted at Michael.Davis@mail.house.gov or (202) 225-7101.

We appreciate your contribution to the work of the Subcommittee.

Sincerely,

Bob Good
Chairman
Subcommittee on Health, Employment, Labor, and Pensions

Enclosure

Questions for the Record for
GLORIA SACHDEV

President and CEO, Employers' Forum of Indiana

Submitted August 9, 2023

Committee on Education and the Workforce Subcommittee on Health, Employment, Labor, and Pensions
"Competition and Transparency: The Pathway Forward for a Stronger Health Care Market"
Wednesday, June 21, 2023 at10:15 a.m.

Thank you for the opportunity to share additional thoughts on this important topic. The comments in this document represent my own views and not that of Employers' Forum of Indiana members or their organizations.

Questions for Rep. Mark DeSaulnier (D-CA)

1. The *Consolidated Appropriations Act, 2021* prohibited certain contract terms, known as gag clauses, that limit access to cost and quality data. Despite this prohibition, many employers report that they continue to face onerous requirements imposed by their third- party administrators (TPAs) and other service providers that prevent accessing data.

   a. **What are some of the barriers that prevent compliance with the CAA's gag clause requirements?**

      i. This recent article highlights several barriers: https://www.ibj.com/articles/lawsuits-show-emerging-rift-between-employers-health-insurers.
      ii. While some TPAs provide data requested, others outright refuse to give self-funded employers requested data. This has resulted in employers across the country beginning to take legal action.
      iii. Often the data requested is not provided in a timely manner, i.e. 12-18 months after it is requested.
      iv. An example discussed in the article above, which I have personally been involved with, is "Unite Here Health, a union plan that covers 200,000 service workers and their families, tried to compel its insurer Blue Cross Blue Shield of Illinois to share its claims data with Rand for a prominent study of hospital prices, but the insurer refused, according to Ivana Krajcinovic, a vice president of the union health plan. A spokesman for the insurer, Dave Van de Walle, said in an email that participation in the Rand survey "is voluntary, and BCBSIL has opted out." BCBSIL should not have the purview to "opt out" when their self-funded employer client is demanding that employers' claims should be sent to Rand Corp for participation in a national price transparency study…or for any other means the employer wishes to use their own data.

   b. **If a plan fiduciary wants to audit the data, do TPAs and other service providers choose who conducts the audit? Are the fees imposed reasonable?**

      i. Many of the largest employers can hire an auditor of their choosing without any

TPA/service provider fees added on.

ii. However, often TPAs and PBMs insist on having veto rights over plan sponsor-selected auditors or require them to choose from a list of "approved auditors". Fees vary, and it unclear to me if these fees are reasonable.

iii. The following TPA and PBM contract provisions are also common:
   a) Frequency of audit is restricted, i.e. once every 3 years
   b) Look back period is restricted, i.e. only 18 months of claims data can be audited
   c) Audit sample size is restricted, i.e. 250-300 claims, and the TPA must agree on how the claim sample is selected
   d) Limitation of time frame in which an audit can occur
   e) General reference to limitations per "audit guidelines and policies"
   f) Requiring pre-approval of auditor selection
   g) Requiring review of the draft audit report and meeting with the auditors before the information is presented to the plan.
   h) Requiring that results of any audit cannot be extrapolated across the entire population of claims.

c. What are your recommendations for improving this provision?

i. Clarify that employers OWN ALL aspects of their data (charges, prices paid, employer contribution, employee contribution, utilization, quality, etc.)

ii. The term "Service Providers" could be clarified to include TPAs, carriers, insurance companies, PBMs, brokers/benefit consultants, data warehouses, and any organization that has employer data. This is important as service providers may subcontract data warehouse services to a third party or a subsidiary they own in their vertical business.

iii. Prohibit any type of audit restriction and audit fees. Require that plan sponsor and employers have a duty to select an auditor of their choice as they are the ones held as the fiduciary.

iv. Require discloser of all service advisors' (define advisors as noted in #1) indirect compensation (i.e. vacations and pro football tickets) and direct financial compensation.

v. If service providers are unwilling to follow the law set forth in Consolidated Appropriations Act, 2021 Section 201, there must be meaningful repercussions to financially incentivize the service providers to comply. The penalties need to be strong enough to force compliance, and without requiring employer group health plans to use the courts to access their data. Small employers do not have the resources to take large service provider companies to court.

vi. As lawsuits are expensive and especially cost-prohibitive for small employers, require service providers to pay for all employers' legal expenses.

vii. Note a specific time frame, i.e. 14 business days, in which TPAs, PBMs and all other service providers must provide employer-requested data. Providing a response (which could be as simple as "we are working on it" is not a substitution for providing the requested data.

viii. Assure that the gag clause prohibition applies to ALL agreements, no matter what the agreements are titled.

ix. Develop a process for employers to report bad actors to the federal government to facilitate accountability.

x. Employers should be allowed to share any and all aspects of the data they own with any third party for analysis without an additional fee for sending an electronic file(s). Self-funded employers currently pay a negotiated administration fee to TPAs and PBMs and within this administration fee should be unlimited data requests. Exhorbitent hidden fees are unacceptable.

xi. An opportunity for clarification is the look back period for employer attestation. The rule currently goes back to 2020 and it is unclear if employers need to attest for a former vendor partner or just current vendor partners.

2. In your testimony you discuss the issue of who owns data that is generated in the course of administering an employer-sponsored group health plan. This information is very important and has the potential to be used for the benefit of the plan participants to lower costs and improve quality.

   a. **Do you agree that the data is not the property of the TPA or other service providers? If it does not belong to the TPA, should it be treated as a plan asset under ERISA?**

      i. Yes, I agree that the data is not the property of the TPA or other service providers. The plan owns the data. Employers may rely on partners to house the data, sort through the data, and keep the data secure, but it should be made clear that employers maintain ownership rights.
      ii. Self-insured plan sponsors own and manage substantial financial risk of their covered population. They also have a fiduciary requirement to pay reasonable costs, thus they need unfettered access to their own data to support evidence-based purchasing decisions.
      iii. I need additional information on how "plan asset" is defined in this context and subsequent implications.

   b. **Should the Department of Labor help plans determine when and how this data should be treated as a plan asset?**

      i. Yes, this may help. Creating a DOL FAQ that states all data used in determining dollar transactions from plan assets becomes a plan asset may be helpful. For an employer plan sponsor to ascertain if their TPA is engaging in spread pricing, not overpaying a provider bill, etc., employers must be able to have their independent auditor have access to the 837 electronic claim files which go from provider to TPA noting charges, AND the 835 electronic files which are from the TPA to the provider with details on adjustments and the amount to be paid.

   c. **Is legislation necessary to clarify this matter?**

      i. Yes, making it clear that there is one data owner, the plan sponsor, is critically important.

3. In 2020, the Departments of Health and Human Services, Labor, and the Treasury issued final rules under the ACA regarding Transparency in Coverage. These rules have been a step forward for both consumers, who now have access to cost-sharing information, and for researchers, employers, and policymakers, who now have access to detailed information regarding health care costs. But challenges remain, and I am curious to learn more about the employer perspective on this issue.

   a. **What has been the experience of employers in navigating the data? Has it been useful or does more work need to be done to ensure it is useable?**

      i. The information has the potential to be highly valuable to employers to help them align payment with the value of services provided and determine which TPA has negotiated the best rate per provider per procedure....and which providers are accepting the best payment rate per procedure.
      ii. Accessibility and usability for employers has been challenging because of the large size of MRF data files and the complexity in sorting out valuable information. Thus,

more work needs to be done here. For example, it is challenging to determine how to ascertain net hospital system payment because each health system has numerous NPIs and/or Tax ID numbers and these are not linked to a health system ID number.

b. **How can CMS include provider quality transparency as part of the data?**

i. All purchasers of healthcare want to know where the best quality at the best price is. CMS could simply require hospitals to add their hospital CMS Hospital Compare quality star ratings to the MRFs. This may also incentivize hospitals to review and improve their quality over time.

ii. Background: CMS publishes a valuable data file, Hospital Compare, which is a free, public-facing data file that is updated quarterly. CMS Hospital Compare's quality data is organized into five domains, namely mortality, safety of care, readmissions, patient experience, timely and effective care. These five domains then roll up into an Overall Hospital Compare Star Rating. Both the Overall Star Rating and Patient Survey Star Rating are posted on CMS's website. For both of these metrics, 5-stars represents hospitals with the best quality and 1-star represents hospitals with the worst quality.

iii. A new opportunity is for CMS to pursue reporting of hospital quality by how purchasers shop for care. People/employers do not shop for care by readmission rate, mortality, etc., although researchers and policy makers may find this of value. Rather, they shop by what healthcare service are needed, i.e. oncology care, cardiovascular care, GI services, imaging services, etc. CMS maintains a MDC Clinical Category data dictionary, so this data dictionary could be used to develop a new quality measure set by organizing CMS claims data by clinical category.

iv. In addition, CMS may wish to consider creating an incentive for commercial data to be analyzed alongside CMS claims data using the Clinical Category format. Large commercial data warehouses currently exist and could conduct such an analysis.

c. **If this Committee considers legislation to codify the regulation, what suggestions would you have for additional changes that should be made?**

i. I strongly suggest consideration be given to creating a Summary MRF for the everyday employer/consumer to use. While the larger MRFs have useful information, access is limited to organizations with huge data storage capability. Every employer, consumer, policy maker, and researcher should have access to a MRF subset without having to pay a third party vendor. This Summary MRF should be in MS Excel as most people have this program on their personal computers. Excel has a file size limit and thus a defined subset of procedures, i.e. 300-500 procedures will need to be considered. The Summary MRF could include the date of the last update, rate (reflected as a dollar amount) for the plan name, network type, funding type (fully insured versus self-insured), service description, service MS-DRG diagnostic code, service CPT billing code, provider name, provider NPI, and the Place of Service code.

ii. While having separate NPIs is helpful to know WHERE a particular service is provided, each NPI and Tax ID, as relevant, should be mapped to a health system ID number. An advantage of requiring a health system ID number to MRFs is that it permits monitoring of hospital mergers and acquisitions on a monthly basis, allows comparison of price and quality of for-profit providers versus non-profit providers, allows state and federal monitoring of prices provided off-campus versus on-campus hospital services for monitoring of site neutral payments, etc.

iii. Ownership of NPI's and Tax ID's of all providers should be available in a file to monitor for horizontal and vertical integration and how this impacts pricing. Multiple

ownership lines need to be made available as several organizations may co-own a provider.

d. **Should health plans be required to submit this information to HHS, DOL, and Treasury? How would this help facilitate establishment of a federal database and perhaps a national All-Payer Claims Database?**

i. I do not know which federal organization would be best to submit health plan data to, but do believe when a health plan posts their data on their own website, they should send a copy to be placed in a federal database. This level of transparency will allow easier access for employers, researchers, and policy makers to conduct wide and deep analysis longitudinally for purchasing and regulatory monitoring purposes.

4. Under ERISA, fiduciaries have important responsibilities with respect to the plan, including a duty to act prudently and solely in the interest of plan participants and beneficiaries. However, in many cases entities such as third-party administrators and pharmacy benefit managers argue that they are not fiduciaries and are not subject to these obligations.

a. **How would adhering to a fiduciary standard change the practices of third-party administrators and pharmacy benefit managers?**

i. Holding TPAs and PBMs to a fiduciary standard would be a game changer as they would then have to perform their responsibilities in the best interest of their plan client, ensuring only reasonable, appropriate plan costs were paid from plan assets. Thus, would enhance aligning employer/employee payment with the value of services provided.
ii. In numerous industries, a person/organization hired to provide a service is required to act as fiduciary to their client, i.e. attorneys, real estate agents, financial investment advisors, etc. These people/organizations can still make a profit while doing what is in the best interest of their client. It is not enough for service providers to disclose the compensation that they get from various vendors. They should also be required to provide advice that is in the best interest of their clients, not themselves.

b. **Would it be useful for federal policymakers – either through legislation or regulatory action – to specify which functions performed by third-party administrators, pharmacy benefit managers, and others entail fiduciary duties under ERISA?**

i. It may be helpful to outline functions in regulatory guidance.
ii. I hesitate recommending legislation as functions will likely change over time with greater transparency, improved technology, etc.

5. The *Consolidated Appropriations Act, 2021* amended Section 408(b)(2) of ERISA to provide that contracts or arrangements between plan fiduciaries and service providers must include disclosures of direct and indirect compensation earned by service providers. The statute specifically specifies that contracts for the design and implementation of pharmacy benefit management services and third-party administrative services are subject to this requirement.

a. **Is it your understanding that service providers such as third-party administrators and pharmacy benefit managers are providing these disclosures to employers?**

i. To my knowledge, it is variable. Some TPAs and PBMs are complying and are some are side-stepping by disclosing fees designated as "commissions" or "fees in exchange" for placing an employer on an account but are not including "book of business bonuses" paid to brokers/benefit consultants for meeting certain revenue goals at end-of-quarter or year-end.
ii. Clearly defining "indirect" would be helpful to include bonus trips and other non-cash perks in exchange for meeting referral targets.
iii. Some PBMs and TPAs are informing their clients that they will manage the required disclosures directly but are not sharing the submitted disclosures with the plan sponsors.

b. **If employers are not provided this information, how are they able to determine if the compensation their vendors are receiving is reasonable?**

i. If they are not provided with the disclosure information, they cannot determine reasonable compensation. Making it worse is that the undisclosed compensation by TPAs and PBMs is ultimately passed on to employers and working families, further increasing their healthcare expenditures.

COMMITTEE ON
EDUCATION AND THE WORKFORCE
U.S. HOUSE OF REPRESENTATIVES
2176 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6100

July 19, 2023

JC Scott
President and CEO
Pharmaceutical Care Management Association
325 Seventh St. NW
Washington, DC 20004

Dear Mr. Scott:

Thank you again for testifying at the June 21 Subcommittee on Health, Employment, Labor, and Pensions hearing on "Competition and Transparency: The Pathway Forward for a Stronger Health Care Market."

Enclosed are additional questions submitted by a Subcommittee member following the hearing. Please provide written responses no later than August 9, 2023, for inclusion in the hearing record. Responses should be sent to Michael Davis of the Committee staff who can be contacted at Michael.Davis@mail.house.gov or (202) 225-7101.

We appreciate your contribution to the work of the Subcommittee.

Sincerely,

Bob Good
Chairman
Subcommittee on Health, Employment, Labor, and Pensions

Enclosure

Questions for the Record for
JC SCOTT

Committee on Education and the Workforce
Subcommittee on Health, Employment, Labor, and Pensions
"Competition and Transparency: The Pathway Forward for a Stronger Health Care Market"
Wednesday, June 21, 2023
10:15 a.m.

Rep. Mark DeSaulnier (D-CA)

1. During the hearing you stated that you believe your companies are in compliance with the requirements of Section 408(b)(2) of ERISA. As you are aware, this requirement provides that covered service providers disclose their direct and indirect compensation to plan fiduciaries. This includes the "development or implementation of . . . pharmacy benefit management services."
    a. Please confirm that your member companies provide these disclosures to their clients.
    b. Please describe in detail what compensation is being provided through these disclosures:
        i. Do pharmacy benefit managers disclose whether they are acting as a fiduciary with respect to the plan? In what situations, if any, do pharmacy benefit managers agree that they are acting as a fiduciary?
        ii. How is information presented? Is compensation expressed in a dollar amount or only as a formula? If expressed as a dollar amount, is sufficient detail provided to ensure that the plan fiduciary understands costs with respect to their plan? Is compensation described with specificity or only aggregate amounts?
        iii. What steps are taken to ensure information is understandable to plan fiduciaries?

2. Under Section 408(b)(2) of ERISA, "indirect compensation" is defined as "compensation received from any source other than the covered plan, the plan sponsor, the covered service provider, or an affiliate." Do you believe that this definition includes remuneration that pharmacy benefit managers receive in the form of rebates from drug manufacturers? If not, please explain why rebates are not "compensation received from any source other than the covered plan, the plan sponsor, the covered service provider, or an affiliate."

To: **Committee on Education and the Workforce Subcommittee on Health, Employment, Labor, and Pensions**

Re: **"Competition and Transparency: The Pathway Forward for a Stronger Health Care Market" (June 21, 2023, 10:15 a.m.)**

Responses from J.C. Scott, CEO of the Pharmaceutical Care Management Associations (PCMA) to Questions for the Record from Rep. Mark DeSaulnier (D-CA)

---

1. During the hearing you stated that you believe your companies are in compliance with the requirements of Section 408(b)(2) of ERISA. As you are aware, this requirement provides that covered service providers disclose their direct and indirect compensation to plan fiduciaries. This includes the "development or implementation of . . . pharmacy benefit management services."

   [PCMA Response]

   It is PCMA's understanding that its member companies do, when negotiating the terms of and providing PBM services to ERISA-covered group health plans, take reasonable and good faith efforts to comply with all applicable legal requirements. This includes providing appropriate disclosure of direct and indirect compensation to ERISA fiduciaries so they may ensure their plans are not paying more than reasonable compensation as required under Section 408(b)(2)(A) of ERISA.

   The disclosure requirements referenced in the Subcommittee's statement above, which were promulgated via provisions in the Consolidated Appropriations Act of 2021 (CAA), are not required by *all* of an ERISA-covered plan's service providers, but instead, only those that qualify as "*covered* service providers." The statutory language then defines that term as targeting brokers and benefit consultants—i.e., those providing "[b]rokerage services . . . with respect to selection of . . . pharmacy benefit management services" and "[c]onsulting . . . related to the development or implementation of . . . pharmacy benefit management services." 29 USC § 1108(b)(2)(B)(ii)(bb).

   As a trade association representing a host of member company PBMs of different sizes and business models, PCMA is unable to comment on the specific compliance positions taken by any one of its members. In light of the above, PCMA's member companies may be taking varying positions on whether or not they are considered covered service providers under Section 408(b)(2)(B). PCMA is unable to provide definitive comments on an interpretation of the scope and nature of the disclosure rules set forth in Section 408(b)(2)(B).

   Nevertheless, as service providers to ERISA plans and thus parties in interest, PBMs customarily make appropriate disclosures to ensure their clients have the information necessary to confirm that no more than reasonable compensation be paid for their services as required by Section 408(b)(2)(A). Likewise, PBMs may provide such information to facilitate plan sponsors' ability to comply with their obligations (to the extent

applicable) to report service provider fees and other compensation on Schedule C to Form 5500 on an annual basis.

a. Please confirm that your member companies provide these disclosures to their clients.

[PCMA Response] PCMA's response to Item 1 above is incorporated herein by reference.

b. Please describe in detail what compensation is being provided through these disclosures:

[PCMA Response] PCMA's response to Item 1 above is incorporated into the following responses by reference. Further, in regard to the responses below, as a trade association, PCMA is unable to comment on the specific terms and disclosures agreed upon and made by its member companies to their respective customers under their applicable contracts.

i. Do pharmacy benefit managers disclose whether they are acting as a fiduciary with respect to the plan? In what situations, if any, do pharmacy benefit managers agree that they are acting as a fiduciary?

[PCMA Response] Specifically with respect to ERISA, PBMs are generally not considered (under statute or federal case law) fiduciaries on behalf of their ERISA-covered plan customers with respect to most of the services they provide. Nonetheless, PCMA understands that PBMs may sometimes agree to serve as fiduciaries on behalf of applicable plans in certain limited circumstances pursuant to negotiated customer contracts (e.g., in regard to claims appeals).

ii. How is information presented? Is compensation expressed in a dollar amount or only as a formula? If expressed as a dollar amount, is sufficient detail provided to ensure that the plan fiduciary understands costs with respect to their plan? Is compensation described with specificity or only aggregate amounts?

[PCMA Response] Member companies ordinarily participate in extended negotiations with ERISA-covered plan customers and their advisors, which include detailed discussions and disclosures relating to the services provided, and fees charged or retained under such arrangements. The information furnished by its member companies to ERISA plan fiduciaries is customarily provided in a format and on a cadence mutually agreed to between the parties, which may be updated at any time throughout the term of the arrangement.

iii. What steps are taken to ensure information is understandable to plan fiduciaries?

[PCMA Response] The information furnished by its member companies to ERISA plan fiduciaries is customarily provided in a format and on a

cadence mutually agreed to between the parties, which may be updated at any time throughout the term of the arrangement.

2. Under Section 408(b)(2) of ERISA, "indirect compensation" is defined as "compensation received from any source other than the covered plan, the plan sponsor, the covered service provider, or an affiliate." Do you believe that this definition includes remuneration that pharmacy benefit managers receive in the form of rebates from drug manufacturers? If not, please explain why rebates are not "compensation received from any source other than the covered plan, the plan sponsor, the covered service provider, or an affiliate."

[PCMA Response] PCMA's response to Item 1 above is incorporated herein by reference. As noted above, PBMs often disclose information on various forms of compensation, including indirect compensation, sufficient to allow the applicable ERISA fiduciaries to confirm that the compensation paid to the PBM is reasonable for purposes of Section 408(b)(2)(A). Whether such information includes rebates as a form of "indirect compensation" may depend on varying factual circumstances, including the structure of the arrangement between the PBM and plan and the underlying negotiated contractual terms. Given the fact-dependent nature of the inquiry, PCMA does not have a definitive interpretation regarding whether manufacturer rebates are a form of "indirect compensation" under Section 408(b)(2) of ERISA.

July 19, 2023

Sophia Tripoli
Senior Director of Health Policy
Families USA
210 16th Street SE
Washington, DC 20003

Dear Ms. Tripoli:

Thank you again for testifying at the June 21 Subcommittee on Health, Employment, Labor, and Pensions hearing on "Competition and Transparency: The Pathway Forward for a Stronger Health Care Market."

Enclosed is an additional question submitted by a Subcommittee member following the hearing. Please provide a written response no later than August 9, 2023, for inclusion in the hearing record. Your response should be sent to Michael Davis of the Committee staff who can be contacted at Michael.Davis@mail.house.gov or (202) 225-7101.

We appreciate your contribution to the work of the Subcommittee.

Sincerely,

Bob Good

Bob Good
Chairman
Subcommittee on Health, Employment, Labor, and Pensions

Enclosure

Questions for the Record for
SOPHIA TRIPOLI

Committee on Education and the Workforce
Subcommittee on Health, Employment, Labor, and Pensions
"Competition and Transparency: The Pathway Forward for a Stronger Health Care Market"
Wednesday, June 21, 2023
10:15 a.m.

Rep. Rick Allen (R-GA)

1. Ms. Tripoli, your written testimony discusses the problems that employers and states have had with pharmacy benefit managers and the amount of hidden profit they receive from their services. Do you think increasing transparency for the rebate system, spread pricing, and renumeration would address these hidden profit issues? Why or why not?

FAMILIESUSA
THE VOICE FOR HEALTH CARE CONSUMERS

Responses to Question for the Record for Sophia Tripoli, Senior Director of Policy, Families USA

Committee on Education and the Workforce Subcommittee on Health, Employment, Labor, and Pensions "Competition and Transparency: The Pathway Forward for a Stronger Health Care Market" Wednesday, June 21, 2023 10:15 a.m.

Thank you to Chairman Good and Ranking Member DeSaulnier for the opportunity to testify before the Committee on the important topic of the rising cost of health care and the role of health industry consolidation and pricing abuses. After the hearing, members of the Committee submitted questions for the record, which I've answered below.

If any committee members or staff would like to discuss these issues further, please contact Jane Sheehan, Director of Federal Relations at Families USA (JSheehan@familiesusa.org). It is an honor to support the committee's critical work to expand and improve access to high quality, affordable health care. Please don't hesitate to be in touch if there is anything more we can do to be of service to that shared mission.

Rep. Rick Allen (R-GA)

1. ***Ms. Tripoli, your written testimony discusses the problems that employers and states have had with pharmacy benefit managers and the amount of hidden profit they receive from their services. Do you think increasing transparency for the rebate system, spread pricing, and renumeration would address these hidden profit issues? Why or why not?***

Yes, greater transparency would begin to address these hidden profit issues. As third-party administrators designed to serve as intermediaries between health insurance providers and drug manufacturers, the key function of a pharmacy benefit manager (PBM) is to negotiate drug price concessions from pharmacies and drug manufacturers to lower prescription drug costs for health plans and employers.[i] However, there is far too much opaqueness in the functioning of PBMs and certain business practices that are good for PBMs are bad for consumers. It's this lack of transparency that allows for PBMs to pocket high rebates and continue abusive practices like spread pricing, where PBMs charge a different amount of reimbursement than they pay to pharmacies for generic drugs, in order to fly under the radar.[ii]

PBMs should be required to report comprehensive and accurate data - including but not limited to revenue, price, and utilization data - resulting from their negotiations with drug manufacturers and contracts with insurers, as well as to participate in fully transparent contracting practices. Requiring that plans and employers (the clients of PBMs) receive key

information including negotiated prices, gross PBM profits, cost-effectiveness of the PBM's drug lists, and spending patterns, would help to reduce drug benefit costs by increasing competition between PBMs, and would empower the clients of PBMs to negotiate better contract terms.[iii,iv] Greater transparency into the business practices that PBMs use in their contracts is a critical first step to ensuring PBMs' financial incentives are not driving up drug costs for America's families. However, to truly address this problem, there should also be increased oversight and regulation of vertical and horizontal PBM concentration, and requirements that 100% of rebates are passed through to the consumer. Additionally, Congress should pursue reforms that take on the systemic abuses from big drug companies who are ultimately responsible for skyrocketing drug prices and unaffordable prescription drugs.

---

[i] *Pharmacy Benefit Managers,* The Center for Insurance and Policy Research, NAIC, April 2022, https://content.naic.org/cipr-topics/pharmacy-benefit-managers

[ii] *Pharmacy Benefit Managers and Their Role in Drug Spending,* The Commonwealth Fund, Apr. 2019, https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending

[iii] Miller, M., *Response to FTC RFI: Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers,* Arnold Ventures, May 2022, https://craftmediabucket.s3.amazonaws.com/uploads/AV-FTC-PBM-Comment-Letter.pdf

[iv] Bai, G., Socal, M., et al, *Policy Options to Help Self-Insured Employers Improve PBM Contracting Efficiency, Health Affairs*, May 2019, https://www.healthaffairs.org/do/10.1377/forefront.20190529.43197/full/

[Whereupon at 12:08 p.m., the Subcommittee was adjourned.]

○