



Cost-Sharing Roundtable: Improving Patient Access to Critical Therapies

Hosted by the PAN Foundation in collaboration with
The American Journal of Managed Care

Proceedings Report

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The Patient Access Network (PAN) Foundation

The Patient Access Network (PAN) Foundation is an independent, national 501 (c)(3) organization dedicated to helping federally and commercially insured people living with life-threatening, chronic, and rare diseases with the out-of-pocket costs for their prescribed medications. Partnering with generous donors, healthcare providers and pharmacies, PAN provides the underinsured population access to the healthcare treatments they need to best manage their conditions and focus on improving their quality of life. Since its founding in 2004, PAN has provided more than 500,000 underinsured patients with more than \$1 billion in financial assistance, through more than 50 disease-specific programs.

The American Journal of Managed Care

The American Journal of Managed Care (AJMC) is an independent, peer-reviewed forum for the dissemination of original research related to financing and delivering healthcare. *AJMC*'s mission is to publish research relevant to clinical decision makers and policymakers as they work to promote the efficient delivery of high-quality care. *AJMC* addresses a broad range of issues relevant to clinical decision making in a cost-constrained environment and examines the impact of clinical, management, and policy interventions and programs on healthcare and economic outcomes. *AJMC* circulates to nearly 49,000 clinical decision makers in managed care, including physicians, hospital directors, and medical/pharmacy/formulary directors at managed care organizations.

The *AJMC* family of publications also includes *The American Journal of Accountable Care*, *Evidence-Based Oncology*, and *Evidence-Based Diabetes Management*. In addition to the print platform, *AJMC* also hosts live meetings and conducts panel discussions that bring together payers, pharmacy benefit managers, providers, patients, and healthcare policy experts, to ensure a continuing dialogue among key stakeholders.

About This Report

This publication is a summary of the Roundtable's presentations and discussions. The opinions expressed in the summary are those of the individual Roundtable participants and are not necessarily the opinions of all workshop participants, PAN, or *AJMC*. PAN and *AJMC* staff did not participate in writing these proceedings. This document does not establish any conclusions or recommendations of PAN or *AJMC*; instead, it focuses on the issues and ideas presented by the speakers and Roundtable participants.

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Executive Summary

“More cost sharing is coming.” – JAMES ROBINSON

Hosted by the Patient Access Network (PAN) Foundation and *The American Journal of Managed Care (AJMC)*, the Cost-Sharing Roundtable contributed to the ongoing conversation about the growing burden of out-of-pocket (OOP) expenses in the United States. The Roundtable explored the many challenges that are imposed on patients and families by increased cost sharing, and it also explored potential solutions to these challenges. This report synthesizes the day long conference, which was held in Washington, DC on February 26, 2016.

Chapter 1 provides a summary of events that led to the planning of the Cost-Sharing Roundtable, as well as a historical framework for the current discussion. This chapter also describes the PAN Challenge, a call for research papers on cost sharing in both the Medicare and commercially insured populations.

Cost sharing is defined in **Chapter 2** and discussed in terms of the principles of both social insurance and moral hazard. These issues focus on the balance between promoting access and controlling costs, and how cost sharing impacts this balance. A key message in this chapter relates to the idea that in most cases, cost sharing is implemented in a “one size fits all” manner. This approach does not prioritize certain conditions over others, it does not incorporate the concept of “value,” and in many cases, it causes the greatest hardships for the most vulnerable populations.

Chapter 3 explores trends that have shaped the cost-sharing landscape, including how the Affordable Care Act (ACA) has shifted the public policy discussion from problems of uninsured Americans to new concerns about millions of Americans who are underinsured. Although one Roundtable speaker observed that some insurance

Attracting more than 150 registrants, the Cost-Sharing Roundtable began with introductions by PAN and AJMC leadership, followed by a presentation on the Kaiser Health Tracking polls, which discussed many of the negative effects of cost sharing on patients, as well as on their families and caregivers. Kaiser data were amplified by cost-sharing case studies from representatives of patient advocacy groups. Winners of the PAN Challenge call for papers presented their research on the effects of cost sharing on both Medicare and commercially-insured patients. After lunch, a presentation on financial toxicity characterized financial hardship as an additional adverse effect on health that is related to chronic disease. The Roundtable concluded with a panel discussion featuring individuals representing professional groups, academia, clinical practice, public policy, and the pharmaceutical industry.

is better than none, the ACA's reliance on cost sharing has resulted in substantial increases in out-of-pocket (OOP) expenses for millions of financially vulnerable patients. Roundtable participants argued that among Medicare beneficiaries, the Part D prescription drug benefit has not kept up with the rapid advances in drug development and the accompanying costs associated with new products. Among other pressures, the rising cost of new therapies has contributed to increased cost-sharing, particularly for patients with chronic and rare diseases.

Chapter 3 also examines the concept of value-based insurance design (VBID) and what steps need to be taken to incorporate value into the cost-sharing policy discussion. It also explores how the difficulties associated with navigating the language and structure of health insurance contribute to the challenges faced by patients and families in making the right decisions about coverage. The confusion associated with healthcare cost sharing and lack of understanding of health insurance benefits, including in-network/out-of-network cost differentials, is also discussed.

Chapter 4 explores the complexity many patients and families face as they try to understand the implications of the strategies that health plans employ to implement cost sharing, such as deductibles, co-payments (co-pays), coinsurance, penalties for out-of-network care, step therapy and placement of certain drugs on specialty tiers. These cost-sharing strategies can present patients with high OOP costs, and the financial impact of these costs is often compounded by lost income due to illness. For some conditions, *all* therapies are on high tiers, a situation that can force patients to choose between a life-saving therapy and financial ruin for them and their families. In the health insurance marketplace, consumers frequently make decisions based on premiums without a full appreciation of the OOP burden they may incur if they become ill.

In **Chapter 5**, Kaiser Foundation data demonstrate the impact of cost sharing on Americans, including those with health insurance. The Kaiser data show that a high percentage of Americans have problems paying their medical bills, primarily due to cost sharing. The survey also demonstrates that Americans often cut back on basics such as food and utilities in order to pay medical bills, and that high OOP costs often make it impossible for patients to afford their treatment. Other data demonstrate that patients with chronic myeloid leukemia (CML) with high OOP costs are much slower to initiate lifesaving tyrosine kinase inhibitor (TKI) treatment than similar patients with lower OOP costs. Presentations detailing the effects of cost sharing on patients with cancer and multiple sclerosis (MS) illustrate how the health effects of these conditions, coupled with high OOP costs, result in a downward spiral from which patients and their families can't escape. This downward spiral—often leading to personal bankruptcy—has been termed “financial toxicity,” and is now widely recognized as a common result of unmanageable OOP costs.

Strategies aimed at mitigating the impact of cost sharing are described in **Chapter 6**. Kaiser data show that patients cut many types of expenses and try to be frugal in an effort to pay their medical bills. Unfortunately, the expenses that patients cut are frequently deleterious to their or their families' health, and attempts to negotiate prices or engage in other behaviors to manage expenses are rarely successful. There are, however, examples of successful efforts to curb the impact of cost sharing, including in-office dispensing of cancer medications. Patient advocacy groups are stepping up their efforts to lobby for policies that reduce cost sharing and pursue collaborative strategies with pharmaceutical companies and insurers. In addition to organizations such as PAN that help reduce the financial burden of cost sharing, pharmaceutical companies also offer patient assistance, and they are engaging in the cost-sharing conversation. Many of the organizations that presented at the Roundtable described patient assistance programs, hotlines, and other support programs. These programs have shifted their efforts from identifying resources for uninsured patients to connecting underinsured patients with appropriate support, helping them identify sources of financial aid, and navigate and optimize their health insurance coverage.

The final chapter discusses potential policy solutions to help mitigate the cost-sharing burden on people with chronic and rare diseases. These include reducing specialty-tier drug costs by increasing lower-tier drug costs, implementing strategies to more evenly distribute costs, and insulating Medicare Part D beneficiaries from high and variable cost sharing for specialty drugs.

This chapter also explores the potential utility of benefit redesign, including separation of deductibles for drugs and other medical expenses. Other suggestions included ensuring that at least one specialty drug in each therapeutic class is on a non-specialty tier, limiting monthly OOP costs to a defined minimum, implementing “reverse deductibles,” increasing prepaid care, and helping eliminate waste in the system. The trend toward VBID was suggested as a critical feature of system overhaul through an increased role for cost sharing that is based on clinical value and clinical nuance.

Despite the diversity of speakers, data sources, and topics, a number of themes emerged from the Roundtable, and these are summarized below.

What do we know?

- » The Affordable Care Act has shifted concerns away from problems associated with people who are uninsured to addressing the many challenges of people who are *underinsured*.
- » Americans—even those with health insurance—are worried about how to pay for needed healthcare treatments and services.

- » Cost sharing is a major driver of Americans' concerns about being able to afford healthcare and pay their medical bills.
- » Americans respond to cost-sharing burdens in many ways, including skipping doses of needed medications, delaying needed medical care, or opting out of care entirely. Americans also cut expenses for food, heat, and other necessities in order to pay their OOP medical expenses.
- » The overwhelming financial burdens related to OOP medical costs are a major cause of personal bankruptcy in the United States.
- » Many Americans have trouble understanding their health insurance benefits, including the link between their coverage and OOP expenses.
- » Patients' efforts to negotiate payment plans for needed health services, to shop for competitive pricing for their treatment, and other efforts to mitigate the impact of cost sharing are rarely successful.
- » Cost sharing is implemented in a "one size fits all" manner, it does not incorporate the concept of "value," and in many cases, it causes the greatest hardship for the most vulnerable populations.
- » Among Medicare beneficiaries, the Part D prescription drug benefit has not kept up with the rapid advances in drug development and the accompanying costs associated with new products. Among other pressures, the rising cost of new therapies has contributed to increased cost-sharing, particularly for patients with chronic and rare diseases.

What does the newest research show?

- » Among Medicare beneficiaries with chronic myeloid leukemia, those with high OOP costs had significantly lower fill rates and significantly longer time to initiation of life-saving therapy compared to their counterparts with minimal OOP costs due to receipt of low-income subsidies.
- » Redesign of health benefits at Covered California with respect to specialty drugs for the 2016 enrollment year—an effort led by advocacy organizations representing patients with HIV, multiple sclerosis, epilepsy, hepatitis C, and other chronic conditions—demonstrated that patients can be shielded from the heaviest cost-sharing burdens while keeping premiums affordable for the entire enrolled population, but that sustainable access to care requires reductions in the underlying cost of new clinical technologies.

What do advocacy organizations say and what are they doing to help?

- » It is challenging for patients and families to understand the financial implications of the many strategies that health plans employ to implement cost sharing. These strategies include deductibles, co-payments, coinsurance, penalties for out-of-network care, step therapy and placement of certain drugs on specialty tiers.
- » Accumulation of even modest OOP expenses can initiate a cascade of events that results in financial ruin for vulnerable populations, even when patients have health insurance coverage.
- » The financial impact of cost sharing is often compounded by lost income due to illness, and this contributes to a downward spiral from which patients often can't escape.
- » Effective treatment can be disrupted when patients transition to Medicare because certain medications are placed on specialty tiers and become out of reach due to high OOP costs.
- » Advocacy organizations have seen a dramatic shift from problems associated with lack of insurance to those involving underinsurance, and they have developed a variety of programs to support patients with overwhelming OOP expenses.
- » Advocacy organizations support their constituents by helping them to navigate the complex health insurance landscape, optimize the insurance they have, find more appropriate plans, and by connecting patients with external sources of support to cover OOP expenses.
- » Patient advocacy groups collaborate with pharmaceutical companies, health insurance plans, and medical organizations to identify sustainable solutions to meet the needs of their constituents.
- » Many advocacy organizations agree that problems with OOP costs can't be addressed with existing resources and programs.

What potential solutions were offered at the Roundtable?

- » Reducing specialty-tier drug costs by increasing lower-tier drug costs.
- » Implementing strategies to more evenly distribute costs, and insulating Medicare Part D beneficiaries from high and variable cost sharing for specialty drugs.
- » Enhancing efforts aimed at benefit redesign, including separation of deductibles for drugs and other medical expenses.
- » Ensuring that at least one specialty drug in each therapeutic class is on a non-specialty tier.

- » Limiting monthly OOP costs to a defined maximum.
- » Implementing “reverse deductibles.”
- » Increasing prepaid care.
- » Eliminating waste in the system.
- » Enhancing the focus on value-based insurance design through an increased role for cost sharing that is based on clinical value and clinical nuance.

What is the bottom line?

- » Roundtable participants acknowledged the importance of advocacy organizations and charitable assistance programs like PAN in supporting the needs of growing numbers of economically vulnerable patients with overwhelming OOP costs.
- » There was widespread agreement that these organizations and supports will not provide a viable, long-term solution to the cost-sharing problem.
- » To effectively address this complex issue, current efforts need to be supplemented by innovative, policy-based solutions that address cost sharing on a broader scale.

Advocacy organizations and charitable foundations are struggling to respond to the needs of growing numbers of economically vulnerable patients who are unable to access needed treatment due to cost-sharing. Increased reliance on the stopgap measures provided by these organizations is an indication that longer-term solutions are needed.

Introduction

“When an insured person has a healthcare cost problem, we tried to figure out what was really driving that. And they were most likely to tell us it was because of cost sharing. Surprise, surprise.” —MOLLYANN BRODIE

“Charges for my insulin exceeded \$1,200 a month: three times the amount of my house payment. I had to reduce the amount of insulin I took based on what I could afford; my health was negatively impacted as a result.”

—SURVEY RESPONDENT, KAISER/NEW YORK TIMES MEDICAL BILLS SURVEY, 2015

Why a Cost-Sharing Roundtable?

“Not getting groceries in some weeks to get by,” answered one respondent. “Can’t take the kids anywhere,” said a second. “Cold showers, can’t fix plumbing,” reported another. According to a 2015 Kaiser Family Foundation/*New York Times* Survey that focused on medical bills, these were among the tradeoffs that insured Americans aged 18-64 reported using to pay for their medical bills.

Results from a January 2016 Kaiser Health Tracking Poll indicated that 36% of respondents were very worried about having to pay for healthcare or health insurance, and 28% reported being very worried about being able to afford needed healthcare services. Among these respondents, concerns about the cost of insurance and healthcare ranked third and fourth, just below concerns about their income keeping up with prices and having adequate retirement savings.

The cost of healthcare is very much on Americans’ minds—even Americans who have health insurance.

As part of its tenth anniversary, the Patient Access Network (PAN) Foundation hosted a patient advocacy roundtable in fall 2014. The meeting provided a forum in which diverse organizations discussed the challenges of responding to growing numbers of patients who cannot afford OOP costs for needed medications and treatment. These challenges were shared across therapeutic areas, and there was strong

interest in continuing a dialogue on the topic of cost sharing. Ongoing, cross-organizational interest led to the Cost-Sharing Roundtable that is described in this report.

Hosted by PAN and *The American Journal of Managed Care (AJMC)*, the Cost-Sharing Roundtable was held on February 26, 2016, at the Henry J. Kaiser Family Foundation's Barbara Jordan Conference Center in Washington, DC. The event included focused discussions on the economic challenges associated with OOP costs faced by patients and their caregivers, as well as the identification of potential solutions to this growing problem. Roundtable attendees included representatives from patient advocacy organizations, professional groups, academia, clinical practice, individuals involved in public policy, and representatives from pharmaceutical companies and pharmacies.

The Roundtable kicked off with a welcome from Amy Niles, PAN Vice President of External Affairs; introductory remarks from Dan Klein, PAN President and CEO; and a welcome from Brian Haug, President, Managed Markets, Pharmacy and Rare Diseases, Michael J. Hennessy (MJH) Associates (publisher of *AJMC*).

Dan Klein noted that although cost sharing is a timely topic, balancing cost and access has been an issue for decades, as evidenced by the RAND Health Insurance Experiment that started in 1974.¹ Klein explained that what is new is the large and growing number of people who have difficulty accessing critical healthcare because of high OOP costs. After noting that more than 30 million Americans are uninsured, Klein

“I don't think anybody thinks that what PAN does is the best way to solve the problem or is ultimately sustainable over the long haul. So people hopefully look at PAN and say there's got to be a better way...PAN, and organizations like PAN, [which] pick up excess out-of-pocket costs...put pressure on other actors within the system to...figure out the right balance between cost sharing and premiums...and how to avoid shifting costs to the sickest people.” —DAN KLEIN



(l-r) Dan Klein, Susan Schneider, Emily Gibb, Matthew Eyles, Emmett Keeler, Mark Fendrick, and Clifford Goodman

¹ Results reported in Manning WG, Newhouse JP, Duan N, et al. Health Insurance and the Demand for Medical Care: Evidence from a Randomized Experiment. RAND Health Insurance Experiment Series. Santa Monica, CA: The RAND Corporation. 1988. <https://www.rand.org/content/dam/rand/pubs/reports/2005/R3476.pdf>. Accessed March 8, 2016.

explained, “Recent studies indicate that as many as one-third of people skip or cut doses of medications because of high costs, or delay seeking or obtaining medical care because of financial concerns.”

“Cost sharing at the time of the RAND Study was thought to be a reasonable and acceptable way to encourage informed healthcare consumerism,” Klein said. “Today, especially for the sickest patients, it, more often than not, is an insurmountable barrier to access, which is driving our concerns.”

Brian Haug offered introductory remarks on behalf of MJH Associates, which publishes *AJMC* as well as *Pharmacy Times* and *Rare Disease Report*. He said, “Collaborating around cost sharing with leading organizations...and...shar[ing] best practices...remove[s] barriers to ensure that patients get access to innovative treatments.”

It was in the spirit of collaboration and with the goal of identifying solutions that the February 26 Roundtable took place. The agenda, which can be found in **Appendix A**, featured case study presentations on the impact of cost sharing on patient populations including those with cancer, psoriasis, viral hepatitis, and multiple sclerosis (MS); a keynote address on the topic of “financial toxicity,” a panel discussion exploring strategies for mitigating cost-sharing burdens on patients; and presentations of the winning papers of the PAN Challenge. Requested in summer 2015 from patient advocacy organizations, the case studies addressed the impact of cost sharing, and described programmatic and policy solutions that the organizations have implemented to address cost-sharing issues.

The PAN Challenge

On June 9, 2015, PAN and *AJMC* announced the inaugural *PAN Challenge: Balancing Moral Hazard, Affordability and Access to Critical Therapies in the Age of Cost Sharing*. This call for papers was an effort to identify solutions for Americans with life-threatening, chronic and rare diseases who may not be able to access critical medications because they cannot afford the deductibles, co-pays, and coinsurance required by their health plans. The competition sought innovative and sustainable strategies for cost sharing that reduce inequality and promote access, affordability, and adherence to treatment.

PAN CHALLENGE WINNERS

Medicare patients

High Cost Sharing and Specialty Drug Initiation under Medicare Part D: A Case Study in Newly Diagnosed Chronic Myeloid Leukemia Patients

Jalpa A. Doshi, Pengxiang Li, Hairong Huo, Amy R. Pettit, Rishab Kumar, Brendan Weiss, and Scott Huntington

University of Pennsylvania

Commercially-insured patients

The Redesign of Consumer Cost Sharing for Specialty Drugs at the California Health Insurance Exchange

James Robinson, Anne Price, and Zachary Goldman

California Health Insurance Exchange

The PAN Challenge called for papers in two categories: (1) Medicare beneficiaries and (2) the commercially insured. The goal of the PAN Challenge was to stimulate a dialogue about how to ease the financial burden associated with cost sharing and to improve quality of life for millions of patients and their families.

Papers were required to address the following questions:

- » How does federal policy regarding healthcare cost sharing (e.g., deductibles, co-pays, coinsurance, and OOP limits) affect the ability of individuals with chronic and rare diseases to have affordable access to critical therapies?
- » What policy solutions are likely to improve access to critical therapies for individuals with chronic and rare diseases?

Individuals and teams of individuals who were U.S. residents; at least 18 years of age; and sponsored by a university, college or health system were invited to register for the PAN Challenge and submit an abstract by October 30, 2015. An expert panel reviewed the abstracts and invited semifinalists to submit 2,500-5,000 word papers by December 31, 2015. One winning paper from each category was announced (see above), and both winning papers were published in a supplement of the *AJMC*. A \$10,000 prize was given for each winning paper, and runners up received \$5,000. The runner-up in the Medicare category was Dr. Jeah Jung, Department of Health Policy and Administration, College of Health and Human Development, Penn State University, for a paper entitled, *Early Impacts of Closing the Donut Hole in Medicare Part D on Specialty Cancer Drug Use*. The runner up in the commercially insured category was Yi-Syuan Huang, an MS Healthcare Decision and Analysis candidate in the School of Pharmacy, University of Southern California, for her paper, *A Comparison of Willingness to Pay Among Commercially Insured Population for Biosimilars*.

What is Cost Sharing?

“Cost sharing obviously creates severe access barriers. But cost sharing is the one thing that the employers and the insurers and individuals are seizing on to moderate the premium.” — JAMES ROBINSON

Cost sharing refers to expenses that are not covered by health insurance and must be paid by patients. These OOP costs can include deductibles, coinsurance and co-pays.

In their winning PAN Challenge paper, James Robinson, PhD, MPH, Director of the Berkeley Center for Health Technology School of Public Health, University of California, Berkeley, and his colleagues explained, “Payment for the services reimbursed by health insurance is divided between the insurance premium, which is paid by all enrollees regardless of health status, and the cost-sharing provisions, which are disproportionately borne by the sickest enrollees who utilize the most care.”

Robinson described cost sharing as a necessary evil that has gone too far out of balance. He explained that the extent to which insurance protects patients from the cost of their own choices is mitigated to varying degrees by cost sharing (see **TABLE 1**).

“The basic fact of human nature is we spend other people’s money more easily than we spend our own,” Robinson said. “And if it’s insured, we’ll use more of it than if it’s not insured.”

He illustrated cost sharing with a familiar example, “Cost sharing encourages price shopping. The reason why people use generic drugs, 88% of prescriptions are generic rather than brand? Because of cost sharing. That’s the only reason. Otherwise our drug bill would be that much higher.”

T A B L E 1		
TOO MUCH Principles of social insurance	TOO LITTLE Principles of moral hazard	IMPLICATIONS
<ul style="list-style-type: none"> » Consumers respond to cost sharing by reducing use of appropriate as well as inappropriate services » Cost sharing often is higher for non-discretionary services (e.g., specialty drugs) than for discretionary services » Cost sharing often is higher for more expensive (specialty) drugs than for cheaper drugs » Cost sharing reduces the redistribution of income from the predictably healthy to the predictably ill 	<ul style="list-style-type: none"> » We spend others' money more easily than our own » Cost sharing encourages price shopping (generic v. brand drugs, ASC v. HOPD, local hospital v. COE) » As physicians are moving to "value-based payment" that encourages conservative use of resources, insurance design should motivate patients to cooperate rather than resist conservative use » Healthy people favor low premiums and high cost sharing, and will prefer no insurance to comprehensive expensive plans (adverse selection) 	<ul style="list-style-type: none"> » Cost sharing creates severe access barriers » But reductions lead to higher premiums, lower enrollment and adverse selection » Redesign must be careful to stay within actuarial values » Value-based design implies increases in cost sharing for some services, reductions for others » In the long term, access to care requires that care be less expensive

ASC, ambulatory surgery center; HOPD, hospital outpatient department; COE, Center of Excellence

In the 1970s, the RAND Health Insurance Experiment examined medical spending behavior among people whose cost sharing ranged from almost 100% to zero. Roundtable panelist Emmett Keeler, PhD, Senior Mathematician, RAND; Professor, UCLA and Pardee RAND Graduate School, was one of the authors of this seminal study. Keeler explained that two major findings of the RAND experiment were that (1) cost sharing reduced medical expenditures, and (2) health outcomes were not affected by cost sharing.

Keeler recalled reactions to these findings, "That was a big unpleasant surprise for the doctors, and kind of a puzzle because we all know that there are certain conditions where medical care should actually help!"

Keeler said that the RAND experiment was a catalyst for the expansion of cost sharing that occurred in the 1980s after the study's findings

COST-SHARING BURDEN

Disproportionate effect

Cost sharing in non-health exchange (ACA) insurance is not usually income-adjusted, increasing burden on low-income or very sick patients

Worse outcomes

High cost sharing prevents many patients from adhering to prescribed drug regimens, adverse effects on patient health

Fails to consider clinical value

Applied across the board, cost sharing "does not send a signal to physicians to prescribe using evidence-based criteria and to innovators to develop truly innovative new drugs." —ROBINSON ET AL

were published. In the ensuing decades, however, he felt that cost-sharing burdens have increased to a degree that reduces access to needed treatment.

In their winning PAN Challenge paper, Robinson and colleagues described how annual deductibles in the thousands of dollars and high-percentage patient contributions to healthcare costs effectively create barriers to care among people with commercial insurance. Their report also discussed how substantial cost sharing for specialty drugs—especially when all medications for certain diseases are placed on specialty tiers—limits patients’ ability to reduce OOP expenses by using a cheaper brand. A number of speakers pointed out this problem for both the commercially insured and among those with Medicare.

Dr. Mark Fendrick, a primary care physician who directs the Center for Value-Based Insurance Design at the University of Michigan, reiterated that when cost sharing goes up, people not only stop buying the things they shouldn’t be buying—the goal of cost sharing—but they also stop buying the things they need. He also emphasized cost sharing’s lack of prioritization.

“With very few exceptions in the United States, health plans have one-size-fits-all cost sharing,” said Fendrick. “This means you pay the doctor the same for a cardiologist after a heart attack or a dermatologist for acne. You pay the same for every drug within the tier of the formulary, whether it be lifesaving drugs for diabetes, HIV, cancer, or depression, or generic drugs that make your toenail fungus go away or your hair grow back.”

A common theme throughout the Roundtable was that cost sharing is a financial burden on many patients, especially those who rely on prescription medications to treat chronic diseases. Reflecting on the tradeoff between insurance premiums and cost sharing, Robinson said, “The challenge in reforming health insurance benefits is to limit cost sharing while keeping the overall premiums affordable.”

Trends that Shape the Cost-Sharing Landscape

“... having issues based on cost-sharing...is sadly almost a privilege. Many, many people are just outright denied based on a lot of non-medical criteria, denied treatment just as utilization management cost-containment strategies.” —CHRISTINE RODRIGUEZ

The Roundtable provided an opportunity for discussion of factors that have shaped the cost-sharing landscape. Although designed to support uninsured Americans, the ACA resulted in a shift from millions of Americans who were previously *uninsured* to millions being *underinsured*. Paradoxically, the Medicare Part D prescription drug benefit—originally designed to help Medicare beneficiaries pay for outpatient prescription drugs—has led to high cost sharing, especially for new and specialty drugs. Many of the Part D cost-sharing features were adopted by commercial insurers, thereby increasing the impact across the board. Finally, scientific advances that have led to accelerated drug development and approval, coupled with the availability of record numbers of new specialty drugs, have resulted in increased demand for access to new medications.

The Affordable Care Act

Until the 2010 passage of the ACA, which provides insurance coverage to people who had previously been uninsured, the major issue on the health insurance landscape was the simple lack of coverage for millions of Americans. In the post-ACA era, the most pressing issue is lack of *enough* coverage. There was general agreement that the ACA contributed in a meaningful way to the current OOP landscape through its reliance on cost sharing. However, Emmett Keeler placed this shift in perspective. “In the tradeoff between underinsurance and no insurance, I’m definitely on the side of underinsurance,” he said. “And to the extent that almost everybody can get some kind of insurance, I think the US is in a better place.”

Under the ACA, insurance is categorized by actuarial value—cost to the insurer—into four “metal” tiers (**Tables 2 and 3**) that reflect the relationship between type of policy and degree of cost sharing. In Platinum plans, the premiums are the highest and cost sharing lowest; bronze plans have lower premiums but higher cost sharing.

There are significant cost-sharing implications associated with the level of health plan patients choose. For example, a healthy person may choose a lower-level plan with modest premiums, but these plans may not provide adequate coverage if this person gets sick because these plans expose patients to high OOP costs. On the other hand, higher-level plans with lower deductibles, co-pays, and coinsurance have higher monthly premiums, which are paid OOP.

T A B L E 2 . Cost sharing by ACA plan category²

CATEGORY	INSURANCE PAYS	PATIENT PAYS
Platinum	90%	10%
Gold	80%	20%
Silver	70%	30%
Bronze	60%	40%
Catastrophic	<60%	>40%

T A B L E 3 . Example Bronze and Silver plans: California³

SERVICE	COST SHARING (BRONZE)	COST SHARING (SILVER)
Deductible	\$5,000	\$2,000
PCP Office Visit	\$60 (3 per year)	\$45
SCP Office Visit	\$70	\$65
Urgent Care Visit	\$120	\$90
ER Visit	\$300	\$250
Lab Test	30%	\$45
X-ray	30%	\$65
Generic Drug	\$25	\$25
Brand Drug	\$50	\$50
Max OOP: Individual	\$6,350	\$6,350
Max OOP: Family	\$12,700	\$12,700

²How to pick a health insurance plan: The 'metal' categories: Bronze, Silver, Gold & Platinum. <https://www.health care.gov/choose-a-plan/plans-categories/>. Accessed March 10, 2016.

³Robinson J, Price A, Goldman Z. PAN Challenge paper. Source: Covered California Plan Options Participant Guide.

Mollyann Brodie, PhD, Executive Director, Public Opinion and Survey Research, Kaiser Family Foundation, pointed out that although growth in premiums may have slowed in recent years, wage stagnation, coupled with general financial and economic anxiety, is a significant source of concern for many Americans when it comes to paying for healthcare. She noted that a majority of insured adults aged 18–64 have concerns about increasing costs for healthcare or health insurance, with more than half viewing healthcare costs as their greatest financial burden, and almost half having put off needed care because of costs.

Cost Sharing in Medicare

According to Matthew Eyles, Executive Vice President, Policy & Regulatory Affairs, America's Health Insurance Plans (AHIP), cost sharing began to become problematic with the passage of the Medicare Modernization Act of 2003. This legislation established the prescription drug benefit known as Medicare Part D, which took effect in 2006.

“The pharmaceutical market was so fundamentally different in 2003 than it is today, and treatments themselves have changed,” Eyles said. “Treatments that were brand new and foreign to the system were the exception rather than the old, small-molecule blockbuster benefit design under which Part D was created.”

Medicare Part D Prescription Drug Benefit: How it Works

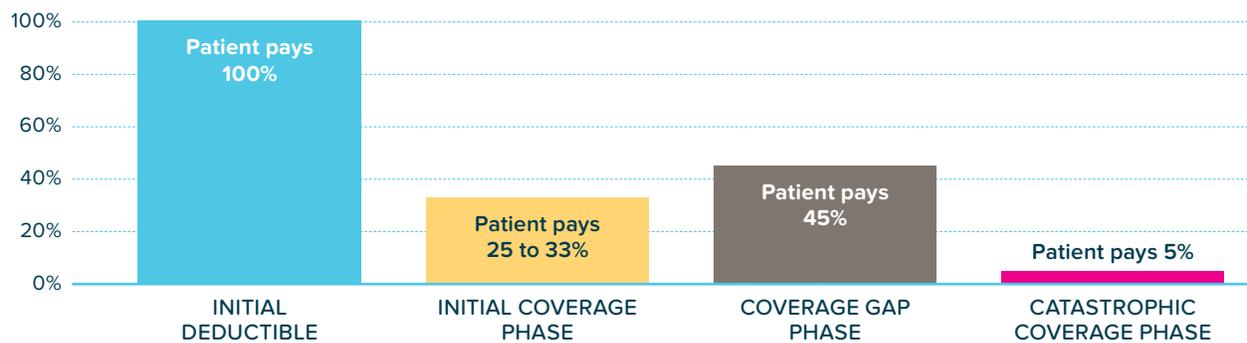
For many patients and their families, the policy debate concerning drug coverage under Medicare Part D is hampered by the complexity of the benefit design. In her winning PAN Challenge paper, Jalpa Doshi, PhD, Associate Professor of Medicine; Director, Economic Evaluations Unit, Center for Evidence-Based Practice, Director, Value-Based Insurance Design Initiatives, University of Pennsylvania, Center for Health Incentives and Behavioral Economics, acknowledged this complexity and used it to illustrate challenges with access.

“The relationship between high out-of-pocket costs and specialty drug treatment access is particularly relevant for Medicare Part D's prescription drug benefit,” Doshi said. “Part D plans may place any drug that exceeds a designated cost threshold (\$600/month from 2011–2015) on a specialty tier.”

Doshi described how the Medicare cost-sharing cycle is a “roller coaster ride” for enrollees. She explained this roller coaster for a hypothetical calendar year (**Figure 1**). On January 1, beneficiaries pay 100% of costs until their initial deductible is met (the maximum deductible in 2015 was \$320). Next, they enter the Initial Coverage Phase, in which they face specialty tier-level coinsurance payments of 25% or 33%.

Once patients hit the initial coverage limit when their total drug spending meets almost \$3,000 (in 2015), they then enter the Coverage Gap Phase, also called the “donut hole.” Prior to 2011, patients used to have to pay 100% of their drug costs during this phase, but this went down to 45% with passage of the ACA.

FIGURE 1 . Specialty drug cost sharing under Medicare Part D standard drug benefit



After spending a total of \$4,700 (2015), patients enter the Catastrophic Coverage Phase, during which they pay 5%. Although it sounds affordable, Doshi pointed out that the 5% coinsurance can be significant, ranging from \$350 to \$500 each month.

She emphasized, “...there are no out-of-pocket maximums [during the Catastrophic Coverage Phase] so the patient continues to pay 5% coinsurance on expensive specialty drugs until the end of the calendar year, and then on January 1 of the next year, the coverage cycle resets and they start this roller coaster ride again.”

Leah McCormick Howard, JD, Vice President, Government Relations and Advocacy, National Psoriasis Foundation, explained that when patients are doing well on a therapy and then cannot afford it any longer when they shift to Medicare, they may need to switch to older, less effective treatments. She explained, “What’s scary is the drop off when patients transition over to Medicare.... Patients who have been stable for 10 or 15 years on a biologic cannot afford the coinsurance in Medicare, and so they’re turning back to either very old oral systemics or going onto topical [agents].”

Costs of Drug Development

The high cost of drug development is a crucial aspect of the cost-sharing landscape, and this topic was touched upon briefly in the Roundtable. Emily Gibb, Director, Public Policy & Patient Assistance, GlaxoSmithKline, offered perspective on drug development costs by sharing that GlaxoSmithKline’s specialty drug spending is expected to grow from \$87 billion in 2015 to over \$400 billion by 2020, a fourfold increase. After a pharmaceutical company invests as much as \$1 billion to develop a new small-molecule brand-name drug, when patent protections expire, generic manufacturers quickly develop generic equivalents at a fraction of the cost to patients.⁴

⁴Ryan C. The new frontier of pharmaceuticals: Biosimilars. American Action Forum. September 10, 2015. http://www.americanactionforum.org/research/the-new-frontier-of-pharmaceuticals-biosimilars/#_ednref6. Accessed March 19, 2016.

“We have seen price constriction in some of the older legacy areas like respiratory, where you have four or five comparable products on the market,” said Gibb. “This is something we really need to watch going forward, because how interchangeability gets defined for biologics and for new innovations will skew whether things can actually be comparable, and therefore, whether the economics will drive down the price.”

Biologics are a class of specialty drug that have much longer development time and double the R&D and production costs than small-molecule drugs.⁵ Often the most effective treatments for certain diseases, biologics can cost more than 20 times the price of small-molecule drugs.⁶ Therefore, in addition to being diagnosed with a chronic condition, patients may quickly realize that their only effective treatment option can cost in the tens of thousands of dollars per year.⁷ Although only 2% of Americans use biologics, they make up 40% of US prescription drug spending.⁷

“Biologics offer a particularly devastating example of these cost-based access issues [because] more and more plans... place biologics into a drug formulary category requiring higher co-payments or coinsurance,” said McCormick Howard. Unlike small-molecule drugs, biologics cannot be exactly replicated and thus have no generic equivalent.

“As a representative of the health plan community,” said Matthew Eyles, “I would be remiss if I didn’t say it’s really about the underlying cost of care and the cost of these products.” Gibb added, “The reimbursement structures have to catch up in order for us to bring innovative products to patients.”

Value

The notion of value, and how it contributes to the complexity of cost sharing was discussed by a number of Roundtable speakers. Mark Fendrick pointed out that cost sharing does not factor in treatment value, only treatment cost. Emily Gibb added, “There are no universal definitions of value. Until we can sort through some of these challenges around value and what a pharmaceutical product brings in that space and in...value-based contracting arrangements with providers and plans, we will be somewhat limited.”

⁵ Lamberti MJ, Getz K. Profiles of New Approaches to Improving the Efficiency and Performance of Pharmaceutical Drug Development. A Tufts Center for the Study of Drug Development White Paper. May 2015. http://csdd.tufts.edu/files/uploads/CSSD_PhRMAWhitePaperNEWEST.pdf. Accessed March 19, 2016.

⁶ Emerton DA. Profitability in the biosimilars market: Can you translate scientific excellence into a healthy commercial return? *BioProcess Int.* 2013; 11 (6 suppl): 6-14,23.

⁷ Glover L. Why are biologic drugs so costly? *US News & World Report.* February 6, 2015. <http://health.usnews.com/health-news/health-wellness/articles/2015/02/06/why-are-biologic-drugs-so-costly>. Accessed March 19, 2016.

Discriminatory Design

Conditions with particularly high OOP costs can result in discrimination against groups that are disproportionately affected by these conditions. Christine Rodriguez, MPH, Senior Policy Manager, National Viral Hepatitis Roundtable, noted that although hepatitis C is the most common blood borne infection in the United States, it disproportionately impacts baby boomers, communities of color, and people who inject drugs. She then posed the question of whether the nondiscrimination regulations in the ACA may be violated by this practice, especially with regard to communities of color. Rodriguez stressed that for hepatitis C, high cost sharing leads to poor adherence to treatment. In turn, low adherence can lead to increased morbidity and preventable drug resistance, as well as the costs associated with these unfavorable outcomes.

Health Insurance Literacy

The difficulty many patients and their families face in navigating the complex and confusing rules and taxonomy of health insurance was another theme that ran through the Roundtable. Common problems include choosing a plan that is a bad fit (higher cost sharing than the patient can handle), not realizing that a doctor is out-of-network, and not realizing that a medication isn't covered, or that it is not adequately covered by the insurance plan. Emily Gibb said that the GlaxoSmithKline Reimbursement Resource Center was able to find alternative insurance plans with more need-appropriate coverage for around 40% of patients. "We have a challenge of health literacy, where people...can't see which plan would be best for their particular healthcare needs," she said.

Complexity and Confusion

“The fact that you have to go through this roller coaster of initial deductible, initial coverage with co-pay, donut hole, catastrophic coverage, and then phased co-pay, and then maybe start all over again next year, how do patients deal with that?” —CLIFFORD GOODMAN

Cost Sharing: Sources and Definitions

The many factors that contribute to cost sharing can be confusing to consumers, a point that was raised often during the Roundtable. Speakers agreed that the trends described in Chapter 3 of this report have resulted in greater cost sharing through mechanisms such as higher co-pays, coinsurance, and deductibles. Compounding these issues are additional OOP costs that are incurred when patients use out of network providers—often without knowing it—and utilization management strategies like step therapy and specialty tiers.

Deductibles

Deductibles—a minimum OOP cost that must be expended before insurance coverage kicks in—are one of the better-known cost-sharing features. As noted above, the maximum initial Medicare deductible was \$320 in 2015. Health plans with high annual deductibles, defined as \$1,000 for individuals and \$2,000 for families, now comprise almost one-fourth of employer-based insurance, almost double the proportion in 2010.⁸ James Robinson explained, “In employment-based insurance, there’s a huge trend towards high deductibles...because it’s cheaper on the premium side.”

COST SHARING COMPONENTS

Deductibles

Out-of-pocket payments before insurer covers any costs

Co-pays

Fixed payments for services or prescriptions covered by health insurance

Coinsurance

Out-of-pocket payment of a percentage of insurer’s contracted fee

Yearly resets

Amounts paid toward annual deductibles reset back to zero

⁸ The Henry J. Kaiser Family Foundation. 2015 Employer Health Benefits Survey. [http://kff.org/health-costs/report/2015-employer-health-benefits-survey/September 22, 2015](http://kff.org/health-costs/report/2015-employer-health-benefits-survey/September%2022,%202015). Accessed March 19, 2016.

Co-pays

Co-pays are fixed amounts patients pay for healthcare services or prescriptions, such as a \$25 co-pay for a doctor's appointment or a \$250 co-pay for an emergency department visit. For people with chronic conditions who require frequent office visits and high co-pays for specialty drugs, co-pays can quickly add up to a considerable OOP burden. High co-pays are known to interfere with patients' adherence to therapeutic regimens.

Leah McCormick Howard said, "On average, a \$10 increase in co-pays yields a 4% increase in non-adherence, and... prescription abandonment rates increase significantly when the patient cost share exceeds \$100."⁹

Coinsurance

Coinsurance—when insurers charge patients a percentage of medication cost rather than a fixed co-pay—may impose a significant cost-sharing burden, especially among patients with plans that have high deductibles or who require high-cost medications. Approximately half of employer-sponsored commercial prescription drug coverage plans with specialty tiers charge coinsurance, with rates for specialty drugs averaging 30%, but reaching as high as 50%.¹² Almost all of Medicare Part D and Medicare Advantage Drug Plan beneficiaries have plans with a specialty tier, with nearly half of the former and most of the latter charging the maximum allowable 33% coinsurance rate (Figure 2).

⁹ Eddy MT, Cook CL, O'Day K, et al. How patient cost-sharing trends affect adherence and outcomes: A literature review. *Pharm Ther* 2012;37(1):45-55.

¹⁰ From Christine Rodriguez's case study. Source: Georgetown/NORC analysis of data from CMS for the Kaiser Family Foundation.

¹¹ Kaiser Family Foundation/New York Times Medical Bills Survey (conducted August 28-September 28, 2015).

¹² Buxbaum J, de Souza J, Fendrick AM. Using clinically nuanced cost sharing to enhance consumer access to specialty medications. *Am J Managed Care* 2014;20(6).

FIGURE 2.

Share of enrollment in Medicare Part D plans with specialty tiers, by coinsurance rate, 2010–2014¹⁰



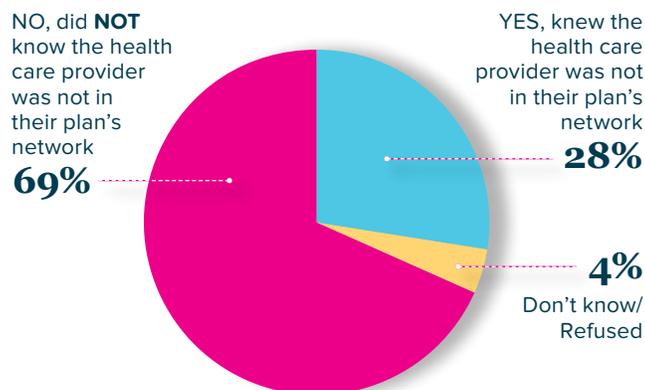
Specialty tier coinsurance rates:

■ 33% ■ 26-32% ■ 25% ■ <25%

PDP, prescription drug plan; MA-PD, Medicare Advantage Drug Plan. Estimates weighed by enrollment in each year. Analysis of MA-PD plans excludes special needs plans and plans with flat co-pays for specialty tiers.

FIGURE 3.

Most insured individuals aged 18–64 who had problems paying household medical bills in past 12 months and who received out-of-network care did not know the provider was out-of-network at time of treatment¹¹



“The trend toward coinsurance is highly problematic for patients, especially those of modest means, given the lack of generic alternatives,” said Christine Rodriguez, referring to hepatitis C. “This puts people...in the quandary of either paying the cost (potentially sacrificing other necessities or incurring debt) or giving up on curing their chronic, potentially fatal illness.”

In-Network, Out-of-Network

Although it is generally understood that using out-of-network providers means that patients will be responsible for a larger portion of their expenses than if they chose an in-network provider, in-network costs are not insignificant. Katherine Sharpe, MTS, Senior Vice President, Patient and Caregiver Support, American Cancer Society (ACS), noted that for many cancer patients, the maximum for an individual’s in-network OOP costs is too high, and patient knowledge about which providers are in or out of network is often lacking.

Mollyann Brodie’s data confirmed Sharpe’s experience. “In the vast majority of cases, of those who had [financial] problems because they saw an out-of-network provider, they didn’t know that the provider was out of network,” said Brodie.

Step Therapy

Step therapy is a cost-containment strategy that has patients begin with a low-cost, clinically appropriate treatment option (e.g., a generic), which must prove ineffective before the patient is allowed to progress to a more expensive option. For diseases like cancer, insurance companies often lag behind new drug approvals, and this delay can result in patients being directed toward less effective drugs because the newer, more effective treatments remain on “higher” steps. When this happens, some argue that the lower steps waste valuable time on less-effective therapies, putting patients at risk.

For psoriasis, Leah McCormick Howard said, “Too many patients report to us that financial implications are really the biggest barrier between them and appropriate care, alongside things like utilization management practices like step therapy.”

Specialty Tiers

Specialty tiers are another cost-containment strategy. Christine Rodriguez explained that prescription drug plans initially began with two formulary tiers, one for brand-name medications and

COST SHARING STRATEGIES FOR PRESCRIPTION DRUGS

Step therapy

Patients must “fail” a cheaper class of drug before going to the next (more expensive) class of drugs

Specialty or drug tiers

Insurance plans categorize drugs into tiers, based on cost, with higher tiers having higher associated cost sharing

one for generics, and that most insurers now have four or five tiers, with the highest being for “specialty” or high-cost medications.¹³ As the tiers rise, so do OOP costs, in the form of co-pays and coinsurance. Broadly implemented for the first time under Medicare Part D, specialty tiers are now standard practice in both exchange and commercial insurance plans.

“Any Part D drug which has a sponsor-negotiated price that exceeds a designated dollar-per month cost threshold can be placed on a specialty tier by any Part D plan, and this dollar threshold has been about \$600 for the past five years,” said Jalpa Doshi. “...whereas the three-tiered benefit structures on... Part D are typically charging fixed co-payments for the generics, preferred brands, and the non-preferred brands, these specialty tiers...across all plans are charging coinsurances anywhere from 25% to 33% as a direct function of the cost of the drug.”

One point raised at the Roundtable was that specialty drugs often offer significant clinical benefit over other treatments, yet their high OOP costs make them hard to access under Medicare Part D. Doshi and her colleagues found that high cost sharing was associated with reduced and/or delayed initiation of life-sustaining cancer treatment under Medicare Part D among beneficiaries who did not qualify for low-income subsidies. These findings have far-reaching implications concerning the connection between access and health because delayed initiation of treatment for certain cancers and other conditions is known to have deleterious effects on patient outcomes, including mortality risk.

Since the expansion of Medicare Part D in 2006, most new cancer drugs approved by the FDA have been oral agents. It is estimated that 30%–40% of cancer therapy is now oral, and of the more than 800 cancer drugs currently in the pipeline, 25% are oral agents. Some of these drugs cost hundreds to thousands of dollars per month, and they are often placed on the highest specialty tier.¹⁴ Despite remarkable forward movement in cancer drug development, the placement of these drugs on high tiers effectively limits access because of high OOP costs. Nancy Egerton, PharmD, BCOP, Vice President of the National Community Oncology Dispensing Association (NCODA), explained the link between cancer drug development costs and downstream costs to cancer patients.

“With the R&D required to bring these drugs to market, significant costs have been tagged to these novel agents. Currently, the going rate for a month’s worth of therapy for a new oncolytic drug is \$10,000,”

¹³ McCarty S, Cusano D. Specialty tier pharmacy benefit designs in commercial insurance policies: Issues and considerations,” State Health Reform Assistance Network Issue Brief, Robert Wood Johnson Foundation, Aug. 2014. Buxbaum J, de Souza J, Fendrick AM. Using clinically nuanced cost sharing to enhance consumer access to specialty medications. *Am J Managed Care* 2014;20(6).

¹⁴ <http://www.communityoncology.org/pdfs/fact-sheet-oral-oncolytics.pdf>.

said Egerton. “Insurance companies also struggle with costs of these specialty meds and have shifted more cost expense to the patient. As a result, cancer patients are faced with increased out-of-pocket expenses due to higher deductibles and co-pays.”

Echoing concerns about the impact of specialty tiers on access, Christine Rodriguez said that specialty tiers are among the biggest barriers to care for hepatitis C patients. She noted that all curative therapies for hepatitis C are “exclusively placed on specialty drug tiers. There is no other alternative to try first.”

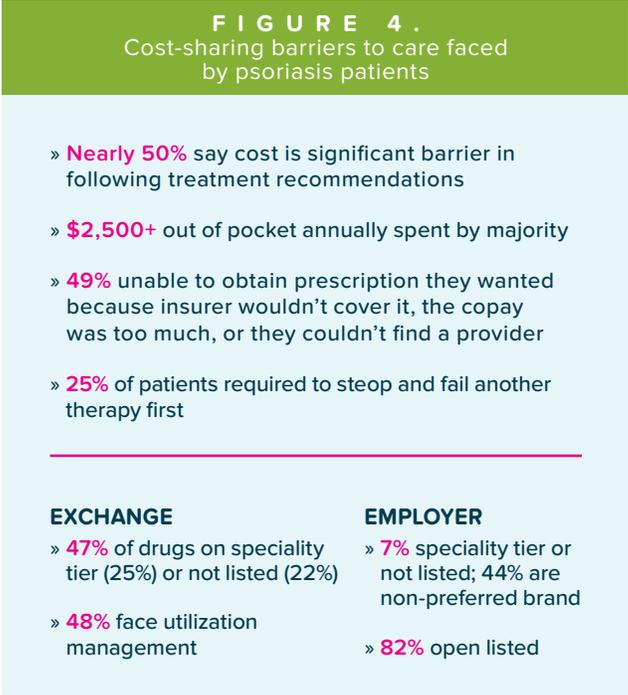
The benefits of the new hepatitis C medications were detailed by Andrew Reynolds, Hepatitis C Education Manager, Project Inform. “The risk of death either disappears, depending upon how early you cure the person, or it really gets reduced quite dramatically. It’s cost effective at all stages, whether you cure somebody early or in the later stages. It lowers healthcare spending. It improves worker productivity.” Reynolds described the irony that links the value of these medications with the difficulties in accessing them. “The benefits are profound. It’s just kind of hard to get there,” he said.

Jalpa Doshi summarized her findings concisely: “Although Medicare Part D was created to increase beneficiary access to prescription drug treatments...our data clearly suggest that current policies are interfering with that goal, especially as they relate to specialty drugs.”

Actual Costs to Patients

For most patients, multiple barriers create a cumulative burden that inhibits access. Leah McCormick Howard explained that although psoriasis is the most common autoimmune disease in the United States—with annual OOP treatment costs that can exceed \$8,000—patients face numerous treatment barriers including specialty tiers, step therapy, formulary restrictions, and co-pay confusion/restrictions (Figure 4).

Christine Rodriguez discussed the fact that because hepatitis C medications are expensive, both Medicare and commercial insurance carriers have instituted utilization and cost-sharing mechanisms. She echoed McCormick Howard’s remarks, explaining that barriers to care for hepatitis C patients include specialty tiers, coinsurance and prohibitive OOP maximums.



Impact

“Not only do people worry about costs, but about half of Americans... are...taking some action because of costs. They’re skipping or postponing care. They skip dental care. They postpone getting the healthcare they need. They skip recommended medical tests or treatment.” —MOLLYANN BRODIE

“It’s hard enough being diagnosed [with cancer] without having to try to figure out how to pay your co-payments.” —PATIENT FEEDBACK TO JONAS DE SOUZA

“Expenses paid by patients increasingly obstruct them from obtaining the therapy their physician recommends.” —LEAH MCCORMICK HOWARD

Increasing Burden of Cost Sharing on Individuals

Mollyann Brodie described two Kaiser Family Foundation projects that shed light on the impact of cost sharing on peoples’ lives. The first is the monthly Kaiser Health Tracking Poll,¹⁵ which surveys adults about their experiences with and opinions about the US healthcare system. The second was the Kaiser/*New York Times* Medical Bills Survey. Conducted in September 2015, the survey included 2,575 insured adults aged 18–64, of whom 1,204 reported having problems paying medical bills in the past year.

Describing the medical bills survey, Brodie said, “This allowed us to really see what’s different about these groups and to think about what it might mean for...policy...interventions, and some of the new approaches to try to address this problem.”

¹⁵ <http://kff.org/tag/tracking-poll/>.

GREATEST CONTRIBUTORS TO FINANCIAL BURDEN OF COST SHARING

Deductible	20%
Health insurance premiums	15%
Prescription drugs	9%
Doctor visits	8%
Other	3%
Total	55%

—Kaiser Family Health Tracking Poll, August 2015

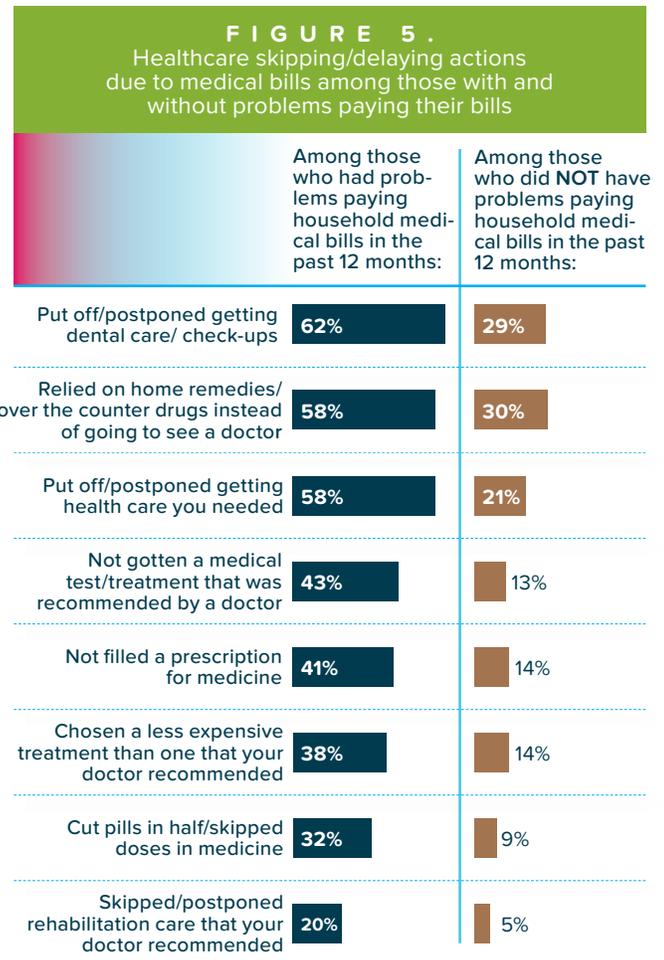
Brodie framed her remarks by saying, “When we ask about a variety of things people might worry about, having to pay more for healthcare or health insurance, or not being able to afford the healthcare services they need rank about third, right behind their income not keeping up or not having enough money for retirement. Six in ten say they’re “very worried” or “somewhat worried” about those things. Not being able to afford prescription drugs...also worries half of adults—it’s about the same share who say they’re worried about being a victim of a terrorist attack.”

Brodie explained that almost half (49%) of respondents indicated that they had put off care due to costs—they did not fill a prescription, relied on home remedies or over-the-counter drugs instead of going to see a doctor, or skipped dental care or checkups.

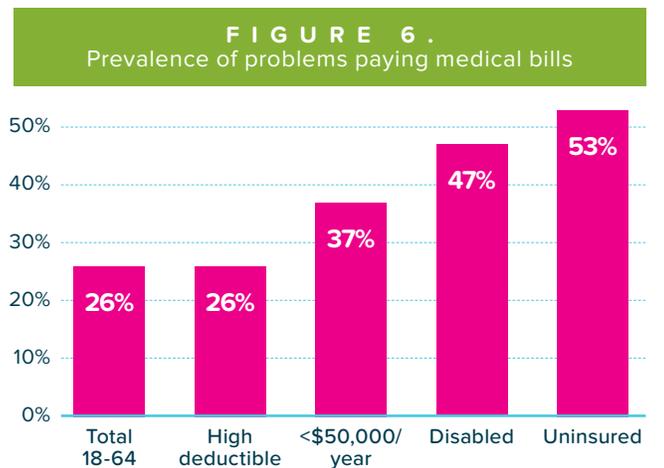
“This is quite concerning because it means somebody actually went to the trouble and expense of seeing a doctor for a condition, and then subsequently decided that they couldn’t afford the recommended test or treatment,” she said.

A comparison of healthcare skipping or delaying behaviors among those who had problems paying their medical bills (dark blue, left) and those who did not (brown, right) is shown in **Figure 5**. In many cases, people who had problems paying their medical bills engaged in skipping or delaying behaviors at a rate that was at least twice that of their counterparts who did not have problems paying their medical bills.

The Kaiser data indicated that 26% of Americans aged 18–64 and those with high deductibles had problems paying their medical bills in the past year. This proportion increased among people with low incomes, disabilities, or no health insurance (**Figure 6**). Among insured people who had a problem paying medical bills in the past year, 49% had medical debt of at least \$2,500, and 23% had more than \$5,000 (**Figure 7**).



Kaiser/NY Times Medical Bills Survey, 2015

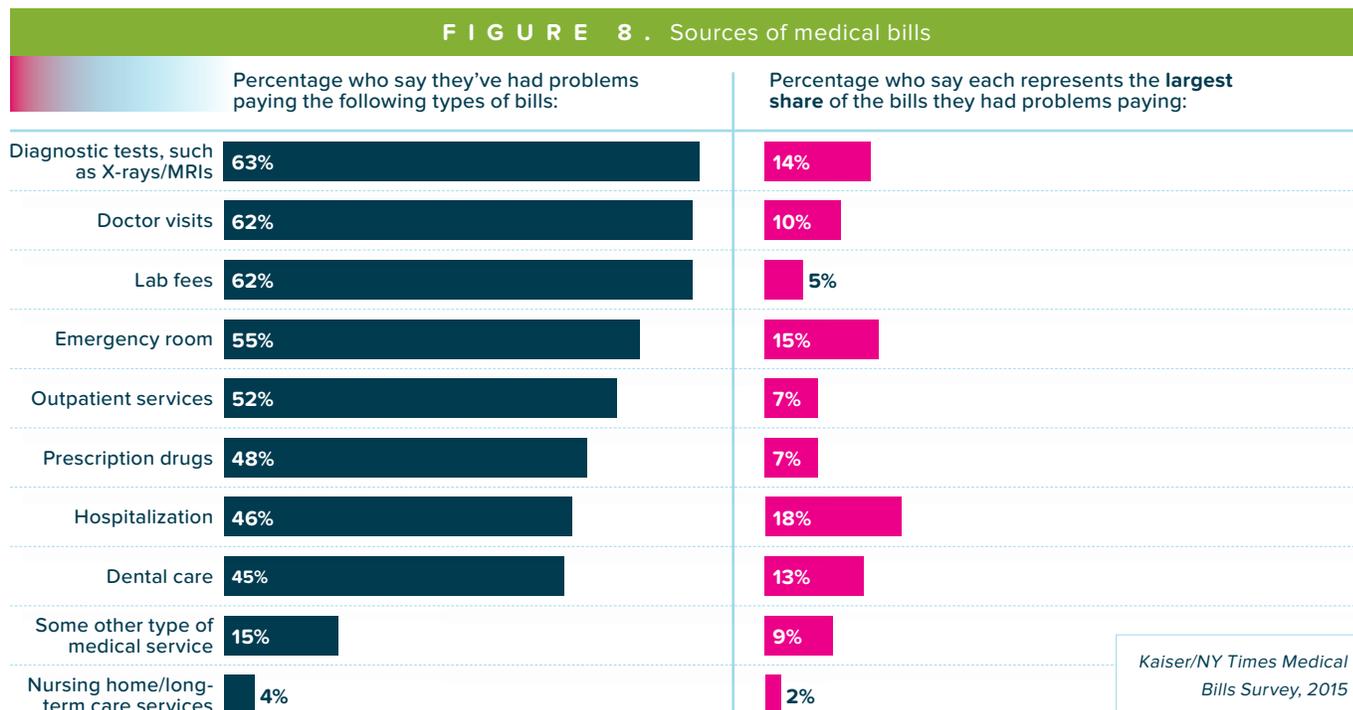
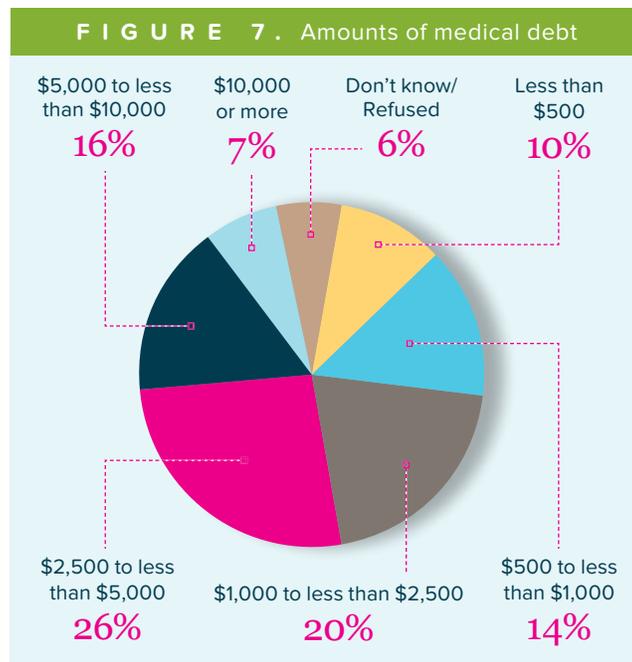


Kaiser/NY Times Medical Bills Survey, 2015

“Given the disproportionate share of low-income adults that are among this group, even bills as small as \$500 can represent a real problem for people. We’re talking about a financially vulnerable population, even though they have health insurance,” remarked Brodie.

The types of expenses that were most problematic were for diagnostic tests, doctor visits, and lab fees, with other categories of charges (Figure 8) following closely behind. About 75% of insured Kaiser survey participants indicated that cost sharing was the reason they could not pay their medical bills—that co-pays, deductibles or coinsurance were more than they could afford.

Respondents took various actions to attempt to pay these bills, including reducing spending on food, clothing and basic household items (75%); using up all or most of their

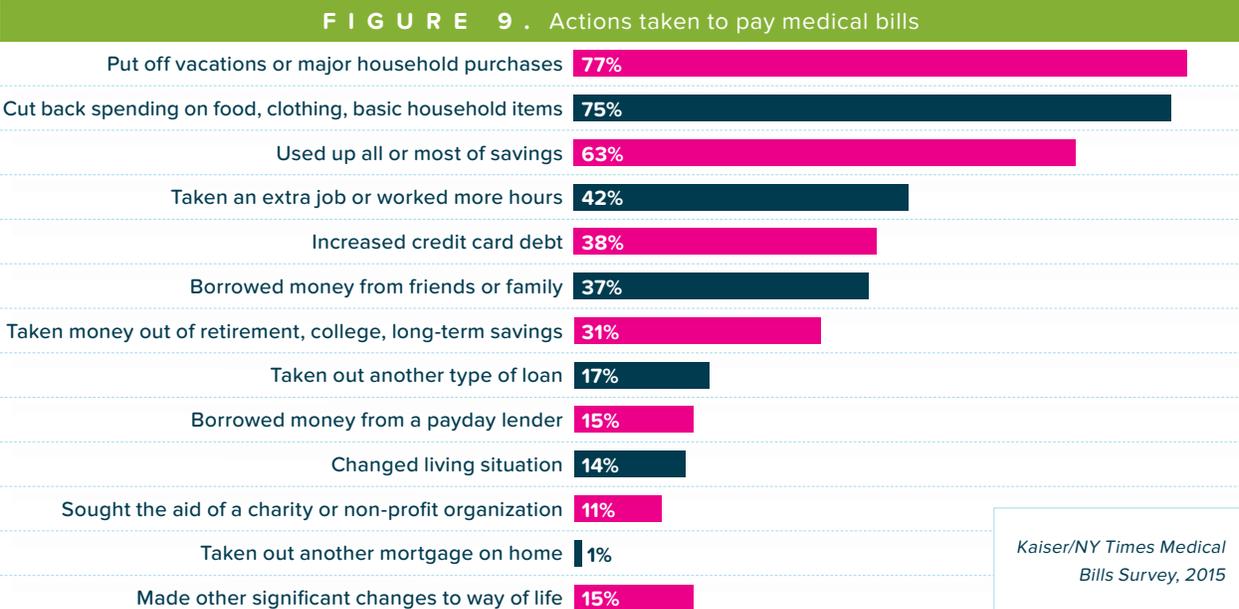


savings (63%), and other strategies (Figure 9). Open-ended survey responses revealed that people often took drastic and potentially life-threatening measures to pay their medical bills, such as not heating their homes or reducing their insulin doses.

Brodie noted that the illness that leads to problems with paying medical bills also has broader financial consequences for the household that makes paying the bills even more difficult. The illness itself may cause job loss or a pay cut that results in fewer resources to deal with medical bills. These scenarios hit the underinsured on several fronts because they impose a significant cost-sharing burden, while simultaneously reducing income, thereby increasing patients’ overall debt. Not surprisingly, the study found that 21% of people who had problems paying medical bills had declared bankruptcy at some point.

Brodie pointed out that cost-conscious behaviors on the part of survey respondents, such as shopping around for the best service or trying to negotiate lower prices, did not result in much actual savings. Almost 70% of survey respondents reported that not only was it difficult to shop and negotiate prices before a visit, but that these efforts were unsuccessful 61% of the time. Overall, the Kaiser data showed that medical bill problems can have real and lasting impacts on individuals and families.

“We know that the higher deductibles in cost sharing have certainly been one of the factors that have helped lead to historic slowdown in the growth of health insurance premiums, but we’re seeing that the fundamental consequences of that growth are really quite dire,” summarized Brodie.



As noted above, high cost sharing reduces adherence to treatment, including drug regimens. In his PAN Challenge paper, James Robinson cited research showing that doubling OOP costs for rheumatoid arthritis drugs reduced the probability of initiating and continuing use by 9.3% and 3.8%, respectively.¹⁶ He explained that reduced medication adherence, “worsens the prognosis of patients suffering from treatable conditions... such as coronary artery disease, hypertension, diabetes, and chronic obstructive pulmonary disease.”

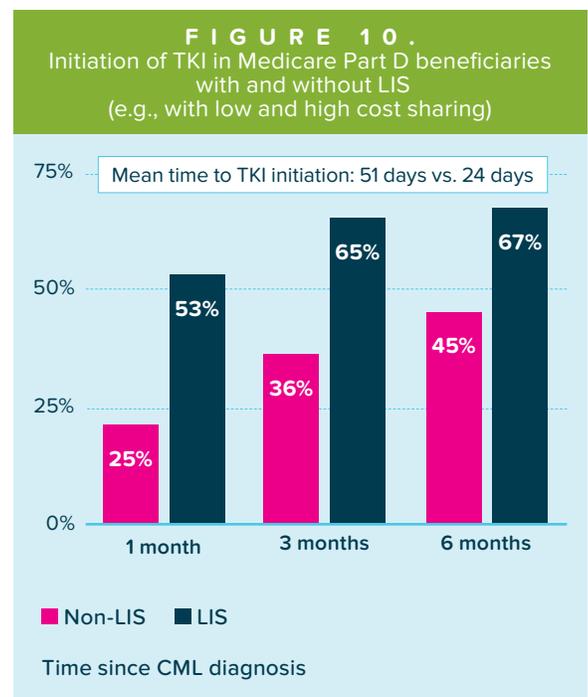
Leah McCormick Howard noted that approximately half of patients with moderate/severe psoriasis or psoriatic arthritis are not being treated to established standards of care because insurance would not cover their first-choice prescription, they could not afford their co-pay, or they could not find (due to costs or narrow networks) a healthcare provider. Half of these patients report that cost is a “significant barrier” to following treatment recommendations.

Cost Sharing and Use of Lifesaving Drugs: The TKI Example

In her winning PAN Challenge paper, Jalpa Doshi described the association between high cost sharing and initiation of tyrosine kinase inhibitor (TKI) treatment in Medicare Part D patients who had recently been diagnosed with chronic myeloid leukemia (CML). TKIs are covered under Medicare Part D, and no equivalent lower-cost drugs are available to CML patients.

“With continuous and typically lifelong treatment, TKIs allow most patients with CML to enjoy a near- normal life expectancy, compared to a median survival of less than three years in the pre-TKI era,” said Doshi.^{17, 18}

It was against this backdrop that she used 2011–2013 data from the Centers for Medicare & Medicaid Services (CMS) to compare how quickly two groups of patients—categorized according to their level of cost sharing—initiated TKI treatment. Low income subsidy (LIS) patients (low cost sharing) paid \$6.60 for their initial TKI prescription, whereas non-LIS patients (high cost sharing) had OOP costs exceeding \$2,600, almost twice the average monthly Social Security benefit. As shown in **Figure 10**, non-LIS patients were



¹⁶ Karaca-Mandic P, Joyce GF, Goldman DP, Laouri M. Cost sharing, family health care burden, and the use of specialty drugs for rheumatoid arthritis. *Health Serv Res.* 2010; 45(5): 1227-1250.

¹⁷ Sasaki K, Strom SS, O’Brien S, et al. Relative survival in patients with chronic-phase chronic myeloid leukaemia in the tyrosine-kinase inhibitor era: Analysis of patient data from six prospective clinical trials. *Lancet Haematol.* 2015;2(5):e186-93.

¹⁸ Mandal R, Bolt DM, Shah BK. Disparities in chronic myeloid leukemia survival by age, gender, and ethnicity in pre- and post-imatinib eras in the US. *Acta Oncol.* 2013;52(4):837-841.

significantly less likely to initiate TKI therapy in a timely fashion and when they did, they took more than twice as long to do so as LIS patients.

Adding to Doshi's findings concerning the association between cost sharing and treatment seeking behavior—even in the setting of cancer—Dr. Jonas de Souza, Assistant Professor, Section of Hematology/Oncology, The University of Chicago, explained that high cost sharing not only inhibits initiation of TKI therapy, it also reduces adherence. In his discussion of financial toxicity, he cited a 2014 study by Dusetzina et al. on the effect of cost sharing on adherence to the TKI imatinib¹⁹, which showed that patients with higher co-pays were 42% less likely to adhere to the TKI regimen.

“I'm not talking about co-payments of \$5,000, I'm talking about co-payments of \$150 a month,” he emphasized. “This was enough to get some patients to stop or uninitiate TKI therapy. It's almost a crime to not give patients this drug. It can basically cure them or help them live for a long time.”

Case Studies

The Roundtable included case presentations from patient advocacy organizations that addressed the impact of cost sharing and described programmatic and policy solutions that they have implemented to address cost-sharing issues. These cases illustrated the human impact of cost sharing and the critical need to identify innovative solutions for people with life-threatening, chronic, and rare conditions who are often disproportionately impacted by cost sharing.

American Cancer Society

Katherine Sharpe described the National Cancer Information Center (NCIC), the entry point for calls to the ACS. Open around-the-clock, NCIC receives close to 1 million calls per year. Because callers often experience significant financial distress when they receive a cancer diagnosis, NCIC initiated the Health Insurance Assistance Service (HIAS) in 2005 to provide cancer patients with information about financial resources, connect them with health insurance specialists, and try to ensure that they have the coverage they need.

¹⁹ Dusetzina SB, Winn AN, Abel GA, et al. Cost sharing and adherence to tyrosine kinase inhibitors for patients with chronic myeloid leukemia. *J Clin Oncol* 2014;32(4):306-3011

IMPACT OF COST SHARING FOR CANCER

“Co-pays and coinsurance are really problematic. If you look at the cost of cancer care, when you start looking at the cost associated with chemo, radiation, cost per visit, it really can quickly accumulate to pretty unacceptable and unaffordable levels.

“Part of the challenge is that nobody ever thinks they're going to get sick, and people certainly don't think they're going to get cancer. And when you do, and you couple it with this, it becomes, unfortunately, an educational moment that should have occurred much further upstream.” —Katherine Sharpe

Typical problems fielded by the HIAS include:

- » Inability to acquire coverage
- » Inadequate or unaffordable coverage
- » Loss of employer coverage due to a layoff
- » Inability to obtain/maintain health insurance coverage
- » Facilities requesting cash up front before treating an uninsured patient
- » Coverage initially thought of as “good” but actually having high deductibles and/or large OOP expenses
- » Inability to afford co-pays, monthly premiums and deductibles
- » Coverage that does not adequately cover an aspect of their treatment

At first, the HIAS mainly received calls from uninsured patients seeking insurance. Since implementation of the ACA, Sharpe said that issues associated with high cost sharing for covered benefits are now the norm. She said that almost one-fourth of cancer patients with health insurance who call have problems with high cost sharing for covered benefits.

“Unaffordable co-pays and coinsurance were generally problematic,” she noted. “For cancer patients undergoing chemotherapy and radiation therapy, per-visit cost sharing can quickly accumulate to un-affordable levels.” Sharpe described two patients’ experiences that she shared with permission (Table 4). These examples highlighted the complexity and high OOP associated with cancer diagnoses.

T A B L E 4 . American Cancer Society case studies	
SANDIE	TAMMY
<ul style="list-style-type: none"> » Breast cancer patient with recurrence » Husband’s company contributes to cost of health insurance, a PPO Silver Plan with the Advanced Premium Tax Credit » Frequent \$65 co-pays » A new plan would result in a new annual deductible and could be more expensive than keeping current plan » Family does not qualify for Social Security Disability Insurance (SSDI) 	<ul style="list-style-type: none"> » Diagnosed with breast cancer in 2015 » Cumbersome physician referral process, limited network, \$4,000 deductible, and high OOP costs » Current plan may not cover a PET or MRI scan; may require her to pay full cost until she meets her high deductible » Certain bills will require payment prior to treatment; others will be billed at a later date » She has identified a surgeon for her treatment, but may not be able to see him/her if her referring primary care physician does not have a contract with them, potentially delaying her ability to obtain imaging and diagnostic tests and treatment

PET, positron emission tomography; MRI, magnetic resonance imaging

MS Center of St. Louis

Katherine Upshur, LCSW, Care Manager at the Multiple Sclerosis Center of Saint Louis, presented a case study focused on treatment barriers for people with MS. She explained that these barriers are often based on the cost of treatment and the impacts it has on patients, caregivers and providers. Upshur presented the case of a fictional patient who encounters cost-related barriers typical of those seen at the MS Center of Saint Louis.

Maxine, a 45-year-old, married woman was diagnosed with MS. She started Tecfidera, an often effective, but expensive, MS medication. Maxine will need yearly MRIs and bloodwork every three months to monitor for a potentially lethal infection that has been known to occur in patients on Tecfidera. Although she has private health insurance through her employer, the cascading effect of Maxine's cost sharing results in a downward spiral for her and her family (summarized at right). Maxine's actions in response to the cost-sharing burden of her condition and Katherine Upshur's accompanying comments are shown in **Table 5**.

Upshur concluded, "As providers working with MS patients, we frequently refer patients like Maxine to the MS Foundation, the MS Association of America, and the National MS Society for help in paying for medical equipment and services. It is increasingly common for patients to be unable to obtain assistance, however, as these organizations are facing increasing financial pressure due to high demand."

COST BURDEN

- » Disease-modifying medications
- » MRIs and bloodwork to monitor patient safety on medication and disease progression

INABILITY TO MEET COST BURDEN

- » Discontinues medication
- » Forgoes tests

IMPACT ON PATIENT

- » Increased disability
- » Reduced income
- » Increased need for services

IMPACT ON HOUSEHOLD

- » Husband and daughter become caregivers
- » Reduced household income due to increasing demands
- » Increased stress

IMPACT ON PROVIDERS

- » Unpaid services
- » Increasingly crowded emergency departments
- » Administrators crating ways to reduce debt
- » Increasing demands for financial assistance

TABLE 5 . Effect of cost-sharing burden on health of “Maxine,” a fictional yet typical MS patient

COST-SHARING BURDEN	MAXINE’S RESPONSE	KATHERINE UPSHUR’S COMMENTARY
Cost of MS drug is prohibitive	Seeks patient assistance via drug manufacturer, Biogen	“Almost all of our patients, regardless of their insurance, rely on assistance from pharmaceutical companies or third-party foundations to pay for medications. In addition, insurance companies require prior authorizations for specialty medications and MS medications fall into that category. This drives up administrative burden and unreimbursed healthcare costs, often causing delays in access to medications.
Prohibitive OOP cost for baseline MRI	Cancels test and asks to stop medication due to unaffordable cost of the associated necessary testing	<p>“It is becoming an increasingly common practice for hospitals to quote the patient’s estimated cost when they schedule testing and ask for payment at time of service.”</p> <p>“This is a good example of patients refusing medication therapies based on ancillary treatments that are necessary, and not just the cost of the drug. This compromises their health, as MRIs are needed for appropriate oversight with medications and monitoring of their disease progression.”</p> <p>“Without yearly MRIs, new lesions develop in the brain, but are not detected quickly. This leads to the progression in Maxine’s disease, leading not only to increased physical disability, but increased depression.”</p>
When she becomes eligible for Medicare, she is no longer eligible for Biogen’s assistance with drug costs	Eventually finds financial assistance but gets MRIs every other year instead of every year because of cost	<p>“PAN is a common example of a foundation that will help patients cover the cost of medications, but funding may or may not be available. [Further,] third-party foundations routinely require a 30-page application, which is onerous for someone with a cognitive challenge.”</p> <p>“Although Maxine is able to use assistance from PAN, her disease progression necessitates other services that have only limited coverage under Medicare.”</p>
Increased disability leads to need for additional treatments with zero or restrictive coverage	Relies on an organization such as PAN	“As Maxine’s MS progresses, comprehensive treatment involves more than the tests needed for appropriate oversight while on Tecfidera. This includes mental health services, symptom management medications, physical therapy, occupational therapy, and home health services. These treatments involve additional co-pays or other out-of-pocket costs.”

Financial Toxicity

Overwhelming financial hardships are a cardinal feature of cost sharing. In his keynote address, Jonas de Souza described a colleague in the United Kingdom who had a patient who committed suicide because the patient’s insurance had denied his cancer treatment.²⁰ His colleague referred to this as “financial toxicity grade five,” which de Souza explained is “a side effect in oncology that is so bad a patient dies from it.”

²⁰ Camber R. Suicide of cancer patient refused a lifeline. Daily Mail (London), June 25, 2008. <https://www.highbeam.com/doc/1G1-180572832.html>. Accessed March 10, 2016.

Citing the 200% increase in health insurance premiums between 1999 and 2013 that are five times the rate of inflation (40%),²¹ de Souza noted that the 2010 National Health Interview Survey indicated that financial problems are the strongest independent predictor of poor quality of life among cancer survivors.²² A 2013 study showed that financial problems caused significant or catastrophic subjective financial burdens in 42% of 254 patients, requiring use of savings to defray OOP expenses (46%), having to take less than the prescribed amount of medication (20%), only partially filling prescriptions (19%), and/or avoiding filling prescriptions altogether (24%).²³ De Souza said that medical bills are the biggest cause of US bankruptcies, and that they cause more bankruptcy than credit card bills or unpaid mortgages, affecting nearly 2 million people per year.²⁴ He argued that financial toxicity is a side effect of drugs in the same way that the US Food and Drug Administration (FDA) sees neuropathy or cardiac problems as side effects. “Financial toxicity... decreases the quality of life, and it may decrease survival,” he said.

²¹ Kaiser/Health Research & Educational Trust (HRET) Survey of Employer-Sponsored Health Benefits, 1999-2013. Bureau of Labor Statistics, Consumer Price Index, US City Average of Annual Inflation, 1999-2013; Bureau of Labor Statistics Seasonally Adjusted Data from the Current Employment Statistics Survey, 1999-2013.

²² Fenn KM, Evans SB, McCorkle R, et al. Impact of financial burden of cancer on survivors' quality of life. *J Oncol Pract* 2014;10(5):332-338.

²³ Zafar SY, Peppercorn JM, Schrag D, et al. The financial toxicity of cancer treatment: A pilot study assessing out-of-pocket expenses and the insured cancer patient's experience. *Oncologist* 2013;18(4):381-390.

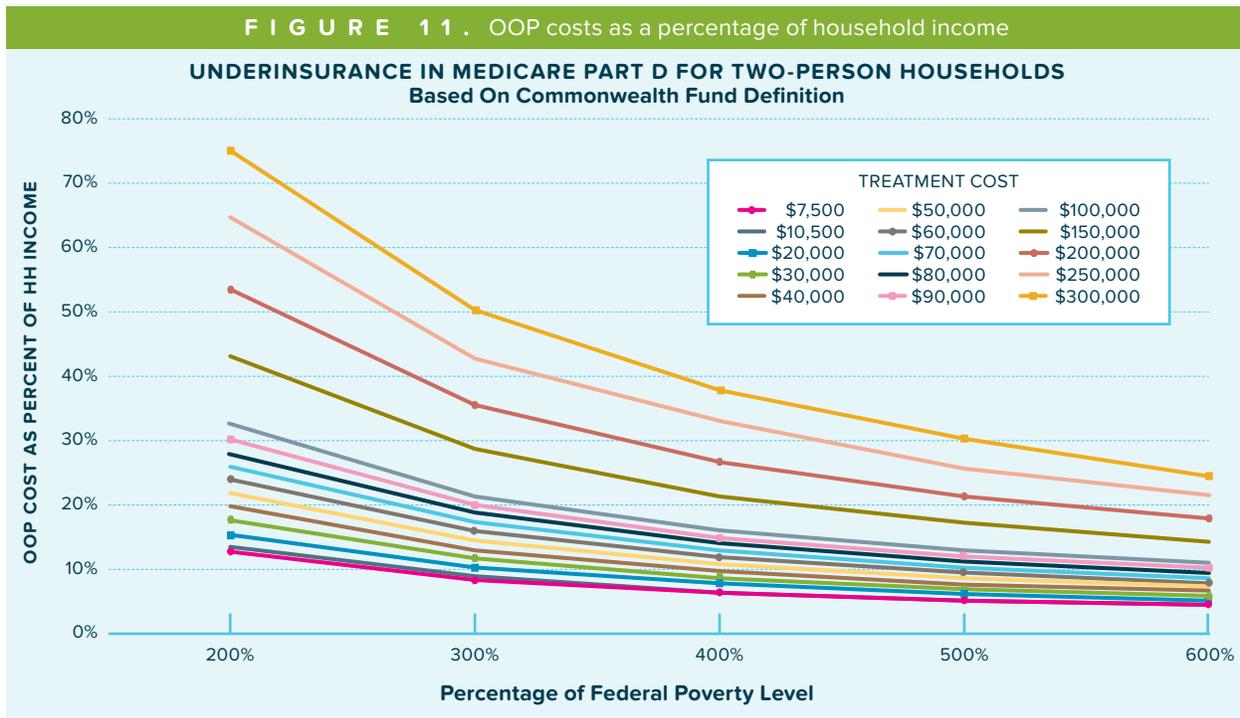
²⁴ Mangan D. Medical bills are the biggest cause of US bankruptcies: Study. CNBC. www.CNBC.com/id/100840148. Accessed March 10, 2016.

6 Current Initiatives to Mitigate the Impact of Cost Sharing

“We try to weave together a quilt, as it were, of resources to help them get through this, but it is not an ultimate solution by any stretch.” —KATHERINE SHARPE

“There are a number of ways that the community [is]... trying to address these issues.” —CHRISTINE RODRIGUEZ

The extent of the national problem of underinsurance was put into sharp focus by Dan Klein, who illustrated how OOP costs for specialty drugs can consume as much as 75% of household income for Medicare Part D enrollees (**Figure 11**). Millions of people with income at 400% above the poverty level are ineligible for federal assistance programs, and must rely on other types of initiatives and programs to help them pay high deductibles, co-pays and coinsurance.



People deal with cost sharing by cutting back on expenses ranging from vacations to food, and they frequently cut back on the same treatments that are essential to managing their condition(s)—often at the expense of their health. As noted earlier in this report, patients’ attempts to engage in cost-conscious behaviors such as price comparison and negotiation are largely unsuccessful.

Organizations attempt to reduce the cost-sharing burden on patients with innovative programs such as in-office dispensing (IOD) of medications, working to effect legislative and regulatory changes, patient assistance and support programs (including those offered by pharmaceutical companies), and engaging in constructive dialogue with insurers.

In-Office Dispensing

The National Community Oncology Dispensing Association (NCODA) is a grassroots organization that advances the practice of in-office dispensing (IOD) for community oncology physicians and practices. IOD is a recent trend, but one that is growing rapidly. NCODA currently has 60 members across the United States, with about 2,000 clinical providers.

“The dispensing of these critical cancer drugs is best for patients if it’s done right in the physician’s office,” said Nancy Egerton. She said that at New York Oncology Hematology (NYOH), it had become increasingly apparent that oral therapy management was becoming a more critical part of comprehensive cancer care, and that offering IOD would promote better patient management, better overall care and greater convenience for patients. Using the electronic medical record (EMR), NYOH physicians can e-prescribe a prescription directly over to the NYOH IOD pharmacy. The pharmacist immediately identifies whether the prescription requires prior authorization, and, if so, routes an e-message to prior authorization staff. Authorization starts immediately and is usually completed on the same day the prescription is ordered. At this point, co-pay and OOP expenses are identified, and patients receive financial counseling to explain the charges and help them enroll in assistance programs.

“With patients on cancer therapies, there are very frequent dose changes and treatment interruptions... just saving on a few unnecessary refills, if a patient has a change in therapy, can lead to thousands of dollars in cost savings,” Egerton explained. “Just for our Medicare population, patients with prostate, breast, colon, lung cancer and hematologic disorders, [NCODA] has garnered about \$400,000 worth of assistance...the IOD practices that adhere to NCODA quality standards are perfectly positioned to help patients and hopefully relieve some of the anxiety patients experience related to covering the costs for their oral cancer medications.”

Federal- and State-Level Efforts

In 2014, the National Psoriasis Foundation (NPF) launched a five-year strategic plan with goals that included accelerating research to cure psoriatic diseases, improving health outcomes by increasing access to treatment and enhancing treatment outcomes. Particularly relevant to the Roundtable was the second goal, which included increasing by 50% the number of patients who get therapy appropriate to their level of disease.

“This agenda is really driven by a recognition that no matter how many life-altering therapies exist, if patients can’t get their hands on them, then they’re meaningless,” said Leah McCormick Howard. The NPF has begun developing and implementing solutions aimed at reducing high OOP costs. Legislative and regulatory initiatives involve working through the Coalition for Accessible Treatments to call on Congress to pass the Patients’ Access to Treatments Act, which would reduce the adverse impact of specialty tiers by limiting cost sharing in these tiers.

Katherine Upshur explained, “Potential long-term solutions to [the cost-sharing] problem include federal regulations that would cap profits for insurance companies. This would provide incentives for coverage providers to lower their contracted rates and deductibles. Such regulations could include less restrictive prior authorization procedures, reducing administrative burden and cutting delays in patients getting access to their medications.”

In addition to advocating for Medicaid expansion, Upshur suggested that government programs provide more financial assistance to nonprofits to enable them to offer financial aid not just for therapy, but for related costs of illness such as transportation, vehicle/home modifications, and durable medical equipment.

At the state level, the NPF has partnered with other patient advocacy organizations, provider groups, and some members of industry through the State Access to Innovative Medicines Coalition to advance legislation that would cap monthly OOP costs.

“Our state-level action has already yielded results. Last October, Gov. Jerry Brown of California signed into law three bills—including one focused on capping out of pocket expenses—that will improve access to care for people with psoriatic disease,” said Leah McCormick Howard.

To assist with cost sharing among hepatitis C patients, Project Inform—an organization that advocates on behalf of those with HIV and hepatitis C—and the National Viral Hepatitis Roundtable (NVHR) are pursuing independent and collaborative strategies at the individual, state policy, and federal policy levels. Project Inform worked with other organizations to pass California Assembly Bill (AB) 339, which limits cost sharing on specialty drugs in both exchange and private plans and ensures coverage for drugs with no therapeutic equivalent across all plans. This bill also states that placing most or all drugs to treat

a condition on the highest cost formulary tiers may be considered discriminatory, and that plans shall not reduce benefits for those with chronic conditions.

“These state-level policy changes not only improve Californians’ access to medications by limiting cost sharing, but also serve as useful examples for advocates in other states,” said Christine Rodriguez. “With a large, national unifying force like NVHR, state and federal policy advocates like Project Inform, and committed medical providers, policy experts, and patients, we have made significant accomplishments.”

Patient Assistance and Support

Financial Aid

Since its founding in 2004, PAN has provided over 500,000 underinsured patients with more than \$1 billion in financial assistance through more than 50 disease-specific programs. The number of patients that PAN has served has increased considerably, as has the level of support provided to each patient.

“Between 2013 and 2015 at PAN, we’ve seen a tripling in the number of people coming to us for assistance...it’s gone from about 99,000 people we provided assistance to [in 2004 to]...364,000 people in 2015...the average amount of assistance we provide per year has gone from \$1,750 [in 2013] to \$2,600 [in 2015] per person per year,” said Dan Klein.

The need for patient assistance programs was acknowledged by many Roundtable speakers.

Leah McCormick Howard said that patient assistance programs are extremely important because policy solutions do not respond quickly enough to meet patients’ needs. She added that more than half of the calls received by the NPF’s Patient Navigation Center each year pertain to access challenges, with cost topping the list.

Katherine Sharpe touched on a few of the services offered through the NCIC, including the Health Insurance Assistance Service and the American Cancer Society Cancer Action Network.

“By evaluating several case studies that illustrate common issues faced by underinsured individuals, [the American Cancer Society] identified solutions ranging from exploring financial assistance programs such as co-pay relief, providing appeal information, as well as searching for more adequate or affordable insurance options,” said Sharpe. “Additionally, ACS has worked to find strong partnerships with other nonprofit organizations to aid in cost relief. But these are not ideal solutions and much is needed to better manage rising healthcare costs.”

“While patient education and resources is a short-term solution in some cases, it will ultimately not be sustainable as funding dries up due to increasing demand.”—KATHERINE UPSHUR

Nancy Egerton noted that eligibility for patient assistance depends on the patient's health insurance plan. Patients with commercial insurance coverage can get assistance from pharmaceutical companies in the form of co-pay programs and coupons, and patients with no coverage can sometimes get their drugs free via patient assistance.

“Medicare beneficiaries are barred by law from participating in these pharma programs. For Medicare patients, expensive drugs have significant OOP expenses based on deductibles and donut-hole dollar amounts,” explained Egerton. At NYOH, Medicare patients with OOP expenses are enrolled into foundations such as PAN, the Leukemia Lymphoma Society, and the Chronic Disease Fund.

Echoing concerns expressed by Dan Klein and others, Katherine Upshur said that financial pressure on patients puts increasing demands on patient assistance organizations and programs that limits their ability to help, and sometimes threatens their viability.

Pharmaceutical Company Patient Assistance Programs

Both Emily Gibb and Nancy Egerton touched on the fact that many pharmaceutical companies have co-pay assistance programs. Egerton said that some of these charge as little as \$10–\$25 co-pays for very expensive drugs. Gibb mentioned that GlaxoSmithKline has a Reimbursement Resource Center, co-pay assistance, and coupon programs. She explained that the company gives grants to foundations like PAN to help Medicare patients whom government regulations prevent pharmaceutical companies from assisting directly. Although Gibb said that the patient assistance programs she manages provide important services to vulnerable patients, she added that these programs do not fully meet the needs of these populations.

Patient Support

The NPF's PNC recently expanded to support disease management, health literacy, access to care, and adherence assistance. It is also beginning to collect blinded, aggregated patient data on a range of issues related to psoriatic disease care to inform priorities and identify new access challenges as they arise.

Other patient support initiatives described by Christine Rodriguez included Project Inform's co-hosting of HELP-4-HEP, a toll-free help line for people with hepatitis C. HELP-4-HEP helps patients find assistance

FIGURE 12.
The National Psoriasis Foundation's multifaceted approach to improving access to therapy for the patients they serve

MULTIFACETED & PATIENT CENTRIC

- » Legislative and Regulatory Solutions
- » Patient Assistance and Support
- » Engagement with Health Insurers



with co-pays, and assists with navigating insurance appeals. It also refers patients to local support groups, and helps them with the challenges that come with health-related financial burdens. In California, Project Inform and other health advocates formed the Covered California²⁵ Specialty Drug Task force, which established OOP cost estimates for drugs and cost limits for the various metal plans. Project Inform also publishes an annual *Covered California Plan Choice Guide*²⁶ and *Formulary Analysis*²⁷ addressing HIV, hepatitis B and hepatitis C medications. The plan choice guide provides information and resources for consumers to choose the most appropriate marketplace plan to meet their needs. The formulary analysis helps consumers understand which hepatitis C drugs are on each plans' formularies, discover which tier the medications are on and identify some of the utilization controls placed on the medications.

Katherine Upshur spoke about three interventions at the MS Center that help patients address cost of care. The Center's patient education initiative helps patients understand their OOP costs so they can begin to budget, if possible, depending on income. A care management intervention helps teach patients how to advocate for setting up a payment plan or applying for financial assistance. A Nurses Line allows patients to discuss MS-related exacerbations of symptoms, learn what they need to do and possibly avoid a trip to the hospital.

Susan M. Schneider, PhD, RN, AOCN, FAAN, President-Elect of the Oncology Nursing Society, discussed patient support offered by oncology nurses. She offered the perspective of those who interact directly with patients and hear about the difficult choices they must make, such as the choice between paying for cancer treatment and sending a child to college. She explained that oncology nurses are on the front lines, talking about these difficult issues with patients and trying to patch together patient assistance programs or alternative treatments.

Engaging with Insurers

Leah McCormick Howard said that the NPF has taken the initiative to work with insurers to advance innovative and cost-effective coverage policies. NPF supported leading dermatologists in launching an effort called International Dermatology Outcomes Measures to develop and validate patient-centered outcomes measures with an initial focus on psoriatic disease. By creating better tools to compare and assess

²⁵ California's ACA health insurance marketplace.

²⁶ Project Inform, APLA Health & Wellness, San Francisco AIDS Foundation, Los Angeles LGBT Center, Access Support Network, San Francisco City Clinic. How to choose a health plan in Covered California. November 19, 2015. <http://www.projectinform.org/pdf/CCguide.pdf>. Accessed March 31, 2016.

²⁷ Project Inform, APLA Health & Wellness, San Francisco AIDS Foundation, Los Angeles LGBT Center, Access Support Network, San Francisco City Clinic. Covered California's 2016 formularies. December 2, 2015. <http://www.projectinform.org/pdf/CCformularies.pdf>. Accessed March 31, 2016.

outcomes, and through creative collaboration with payers, NPF aims to improve mechanisms to get patients on the right treatment earlier and reduce the downstream impacts of failing to get needed treatment.

“Just last month, the NPF partnered on a payer roundtable where we brought together six payer representatives,” said McCormick Howard. “We had someone from one of the top three plans in the country. Several regional plans were represented, a Blues affiliate, a former Medicaid director, and an actuarial representative, to spend the day together talking about access challenges, and really listening to them, hearing what their pain point[s are], sharing our frustrations, and trying to identify potential common areas of interest.”

“The NPF appreciates that payers provide millions of dollars of benefit to our community each year and recognizes the numerous complexities that go into a payer’s coverage decisions.”

How can we think through possible solutions...and ultimately get patients treated so that they don’t have the continued long-term impact of the disease?” —LEAH MCCORMICK HOWARD

Meeting the Challenge

“We need to have insurance design initiatives that actually attenuate the cost of care as well as protect the patient from onerous cost-sharing burdens.” — JAMES ROBINSON

“I’m hopeful that the stakeholders will come together to have people in insurance products that actually cover people for the things that are deemed by the evidence-based community to be those that produce the health for the money. Please join me in changing the healthcare discussion in this country from how much we spend to how well we spend it.” — MARK FENDRICK

Practical Solutions

One of the mandates of the PAN Challenge was to identify policy solutions for breaking down the cost-sharing-associated barriers to critical therapies for individuals with chronic and rare diseases.

In her paper on the Medicare population, Jalpa Doshi identified two problems and offered possible solutions. The first problem is that cost sharing/specialty tier assignment is based on drug cost, with high associated coinsurance costs. To address this, she suggested lowering the cost-sharing burden on patients to “remove it as a barrier to patient initiation of, and adherence to high-value specialty medications.” She said that specialty drug cost sharing that accounts for medication value, as is the case with value-based insurance design (VBID) approaches, “may be more appropriate than these current one-size-fits-all Part D policies wherein cost sharing is directly a function of the medication cost.”²⁸

²⁸ Fendrick M, Buxbaum J, Westrich K. Supporting consumer access to specialty medications through value-based insurance design. Center for Value-Based Insurance Design. 2014. <http://vbidcenter.org/wp-content/uploads/2014/10/vbid-specialty-medications-npc2014-final-web.pdf>. 2014. Accessed April 1, 2016.

Policy changes to lower cost sharing for high-value specialty drugs may be financially feasible because the cost of eliminating Part D specialty tiers could be offset by small increases in traditional three-tiered co-payments.²⁹

The second problem is that OOP costs are variable and front-loaded. “The complex and variable cost sharing required by the current Medicare Part D benefit structure poses challenges, particularly for elderly beneficiaries who are on a fixed income,” said Doshi. She and her coauthors showed that mean OOP cost for a first prescription was twice the average monthly Social Security benefit, a significant source of income for Medicare beneficiaries.³⁰ To mitigate this problem, the authors suggested that Medicare patients be allowed to distribute their OOP costs more evenly during the benefit year (similar to the budget plans offered by many utility companies) and to institute OOP maximums such as those in the ACA exchanges and many private insurance products.

“A combination of these approaches would then allow very stable monthly OOP costs for these patients and cap how much they are paying on a monthly basis as well...[thus reducing] cost-related adherence and persistence problems,” Doshi explained. She emphasized that there is a critical need for regulators to consider approaches to providing Medicare Part D patients with additional protection against extremely high and variable cost sharing for specialty medications, and recommended using large datasets to produce empirical evidence on the impact of aggressive cost sharing policies for specialty drugs to inform policy.

James Robinson’s presentation described a redesign of health benefits for specialty drugs at Covered California. “The catalyst for benefit redesign came from advocacy organizations representing patients suffering from HIV, multiple sclerosis, epilepsy, hepatitis C, and other chronic conditions,” he explained. The benefit redesign had three components:

“The California initiative ...[is] a modest initiative. It’s not solving the problem, but it leads [by] example.....” — JAMES ROBINSON

- 1 A separate deductible for pharmaceutical expenditures, with a corresponding reduction in the deductible for other medical expenditures
- 2 A requirement for health plans to assign at least one specialty drug for each therapeutic class to a non-specialty tier, offering patients a treatment option without coinsurance
- 3 A monthly OOP limit of \$250 for each specialty drug prescription, to buffer patients against the \$6,250 individual or \$13,500 family annual medical payment limit

²⁹Dieguez G, Pyenson B, Johnson R. Specialty tiers: Benefit design considerations for Medicare Part D. Milliman client report. June 25, 2013. www.milliman.com/uploadedFiles/insight/2013/specialty-tiers.pdf. Accessed April 1, 2016.

³⁰Social Security Administration. Social Security basic facts. www.ssa.gov/news/press/basicfact.html. October 13, 2015. Accessed April 1, 2016.

“The Covered California redesign indicates that patients can be shielded from the most onerous cost sharing burdens while keeping premiums affordable for the entire enrolled population,” said Robinson. However, he cautioned, “Sustainable access to care requires reductions in the underlying cost of new clinical technologies.”

Other solutions discussed at the Roundtable included:

- » “Reverse deductibles,” in which patients would begin paying only after their benefits had been exhausted, instead of before
- » Innovative, disease-specific models such as in-office dispensing (discussed above)
- » More prepaid care through Health Maintenance Organizations (HMOs) or Accountable Care Organizations (ACOs)
- » Having organizations such as those participating in the Roundtable support alternative payment models

Mark Fendrick said that one thing all players can do is to get serious about eliminating waste. Commenting on the impact of waste on the larger cost sharing policy discussion, he said waste “deflects the conversation away from the high-value, high-cost services that are actually being used as opposed to ‘whatever-the-cost’, but no-value services.” He explained that one way to do this is to forgo low-value care, and focus more heavily on evidence-based clinical recommendations such as those developed by the US Preventive Services Task Force. Even when these types of resources are not directed specifically toward pharmaceuticals, Fendrick said that eliminating waste in general allows increased subsidization of needed therapies.

A Move Toward Value

A number of Roundtable participants emphasized that a systemic problem with the current health insurance landscape is that payments are based on volume instead of value.

Value-Based Insurance Design (VBID) aims to align patients’ OOP costs with the value of the health services they receive.³¹ Developed to eliminate the problem of “one-size-fits-all” cost sharing, in which consumers pay the same for all medical services and providers despite differences in the evidence-based and clinical benefit, VBID is based on clinically nuanced cost sharing. VBID architect Mark Fendrick said that clinical nuance has two important tenets: (1) medical services differ in the benefit they provide and (2) the clinical benefit of any medical service depends on the patient, the point in the course of their disease, the practitioner, and the facility. In turn, clinical nuance influences cost sharing by enhancing

³¹www.vbidhealth.com

coverage for the neediest beneficiaries, encouraging providers to recognize quality, and helping direct consumers to appropriate care.³² “VBID is not the answer [but]...it helps care delivery, and it certainly helps payment,” said Fendrick.

“VBID is the first demonstration program ever to touch upon the foundation of the Medicare statute of nondiscrimination,” explained Fendrick. “In 1965 when Medicare was signed into law, it was important that every beneficiary have the exact same plan to address concerns about sexism, ageism, and racism. Now that we’re in 2016, precision medicine is one of the buzz words...however, precision medicine requires precision payment reform and precision benefit design.... To practice precision medicine based on the advances over the past 25 years, I cannot tolerate a payment system or a benefit design that treats everyone the same.”

During the plenary session, Clifford Goodman, PhD, Senior Vice President, The Lewin Group, indicated that there has been a positive trend in the commercial insurance industry “away from volume...[and now] mostly in the value range.” He asked Matthew Eyles, “What did it take to convince an industry to move from volume to value, and is your industry able to prepare to discern value and act on it?” Eyles responded, “It took a number of plans working with, especially the large employer community, to really accelerate efforts, at least in the commercial space.”

Eyles added that there has also been a transformation in Medicare through Medicare Advantage plans. “The incentives are such that we’re seeing a much greater expansion of these value-based arrangements between health plans and providers to make sure that value-based care is being delivered. We’re seeing better care coordination, better identification of diagnoses of underlying health risks because of the way that plans are compensated.” Conceding that this process is not happening fast enough, Eyles emphasized that some progress is definitely being made. “We’re already at 20%, but we’re going to get there through better plan and provider collaborations that are based

VALUE-BASED INSURANCE DESIGN

Built on the principle of lowering or removing financial barriers to essential, high-value clinical services

Align patients’ out-of-pocket costs, such as co-payments, with the value of services—<http://vbidcenter.org/about-us/>

On January 1, 2017, CMS will initiate a VBID demonstration in seven states for seven chronic diseases.



IMPLEMENTATION & IMPACT

- » Bipartisan political support
- » Reduces health care disparities
- » Multi-stakeholder endorsement
- » Implemented by hundreds of public and private organizations
- » Enhances access to preventive care for 137 million Americans
- » CMS implements MA V-BID model test

³²Patel K, Cliff E, Fendrick AM. Clinical nuance: Benefit design meets behavioral economics. Health Affairs Blog, April 3, 2014. <http://healthaffairs.org/blog/2014/04/03/clinical-nuance-benefit-design-meets-behavioral-economics/>. Accessed March 10, 2016.

on aligned clinical and financial incentives, focused quality metrics, and better support tools for consumers to make better, more informed decisions.”

Mark Fendrick described some notable successes of the new emphasis on value. “A tortoise-like, baby step reform movement has gone from the private sector into the ACA in primary prevention...pap smears, mammograms, colonoscopies, flu shots, etc. are now zero cost sharing.”

Emily Gibb of GlaxoSmithKline agreed that progress is being made, noting that under the new ACA exchange plans, vaccines are now being covered with zero-dollar cost sharing. She added that the ability to incorporate and replicate an individual, nuanced approach depends on health information technology (HIT) systems that can identify segments of the population that need either “high-touch” or “lower-touch, less-cost” intervention to help plans design a benefit framework that stratifies need. Gibb offer the example of how HIT facilitated GlaxoSmithKline’s work on comprehensive medication management with Community Care of North Carolina (CCNC), North Carolina’s Medicaid program, by helping identify high utilizers and provide them with more comprehensive service. She explained that the CCNC model, “takes a much more holistic approach—brings in the provider, brings in the pharmacist, brings in caregivers and ancillary people in the hospital to really wrap around a person that has multiple chronic conditions, [i.e., the] high utilizer...and high spender.”

Susan Schneider stressed the need for oncology nurses to get patients more involved in making value-based decisions about their care. She said, “We’re going to sit down with that patient with stage 4 lung cancer and say, ‘we have some new treatments coming out. We think this one is pretty good but it’s going to cost us this much money from your cost sharing, and it’s going to increase your life expectancy by five months, as opposed to this particular treatment that costs less and may just keep you comfortable for the next few months, allow you to get to your daughter’s wedding.’ We’re going to sit down with those patients and help them make the value decisions.”

Strengthening the Safety Net

Charitable foundations such as PAN provide a critical safety net for patients with chronic conditions whose treatments are threatened by cost sharing. Although there was agreement that these organizations were not a long-term solution, Dan Klein pointed out that because policy solutions take a long time to implement, it is imperative to be practical today. “We think right now there’s a critical safety net that charitable foundations have to continue to provide, and we need to work closely with the patient advocacy groups [and] alliances...to keep providing that safety net for the foreseeable future.”

“There’s clearly a need to develop more equitable and affordable approaches to cost sharing, some of which we’ve heard about today.... We’re still a long way off from finding the secret sauce...that drives down moral hazard but still provides access to the...people who need the critical therapies and who are the least able to afford them” — DAN KLEIN

Summary

With input from advocacy organizations, academia, and the insurance and pharmaceutical industries, the Cost-Sharing Roundtable achieved its goal of providing a forum for stakeholders to continue the conversation about the impact of cost-sharing on patients and families. The Roundtable placed the issue of cost-sharing in an historical context that began with the RAND Health Insurance Experiment and continues today with the passage of the ACA. Case studies, as well as new research supported by the PAN Challenge, provided a rich context in which the many facets of cost-sharing could be examined. These discussions included the “real life” impact of cost-sharing on issues ranging from factors that impact patients’ choice of health plans based on the deductible, to patients’ decisions to initiate life-saving treatment based on OOP drug costs. Although there was broad agreement that efforts on the part of charitable foundations and advocacy organizations to mitigate the financial toxicity of cost sharing have a meaningful impact, Roundtable participants said that to effectively address this complex issue, existing efforts need to be supplemented by innovative solutions that address cost sharing on a broader scale.

Appendix A. Roundtable Agenda

WELCOME (9:00 AM) Amy Niles

INTRODUCTORY REMARKS Dan Klein; Brian Haug

KAISER HEALTH TRACKING POLLS (9:10 AM) Mollyann Brodie, PhD

Taking the Pulse of Americans: Cost-Sharing and Access

Questions and Answers

CASE STUDY PRESENTATIONS: INTRODUCTION (9:35 AM) Amy Niles

» American Cancer Society Katherine Sharpe, MTS

» National Community Oncology Dispensing Association, Inc. Nancy Egerton, PharmD, BCOP

» National Psoriasis Foundation Leah McCormick Howard, JD

» National Viral Hepatitis Roundtable/Project Inform Christine Rodriguez, MPH; Andrew Reynolds

» The MS Center of Saint Louis Katherine Upshur, LCSW

Questions and Answers

CALL FOR PAPERS: INTRODUCTION (11:00 AM) Amy Niles

» Presentation #1: PAN Challenge Winning Paper Jalpa Doshi, PhD

» Presentation #2: PAN Challenge Winning Paper James Robinson, PhD, MPH

Questions and Answers

LUNCH AND GUEST SPEAKER (12:00 NOON)

Understanding Financial Toxicity: It's a Matter of Life or Debt Jonas de Souza, MD

KEYNOTE CONVERSATIONS PANEL: (1:00 PM)

Exploring Innovative Strategies to Mitigate Cost-Sharing Burden for Patients

Moderator Clifford Goodman, PhD

Panelists Emmett Keeler, PhD; A. Mark Fendrick, MD; Emily Gibb; Susan Schneider, PhD, RN, AOCN, FAAN; Dan Klein

Questions and Answers

CLOSING REMARKS/ADJOURN (3:00 PM) Amy Niles

Appendix B. *Roundtable Participants*



« MOLLYANN BRODIE, PHD

Executive Director, Public Opinion and Survey Research, Kaiser Family Foundation

Dr. Brodie is responsible for all aspects of the Kaiser Family Foundation's public opinion survey efforts, including the monthly Kaiser Health Tracking Poll, the Foundation's work on Americans' attitudes toward global health policy, and ongoing survey partnerships with media organizations, including *The Washington Post*, *The New York Times*, and National Public Radio (NPR). Her research efforts focus on understanding public opinion and knowledge of healthcare policy issues, and the role of opinion in health policy debates. Dr. Brodie's work has been published in *JAMA*, *New England Journal of Medicine*, *Journal of Health Politics, Policy, and Law* and *Health Affairs*, and she is co-editor of the book, *American Public Opinion and Health Care* (CQ Press, 2011). Dr. Brodie received a master's degree in health policy and management and a PhD in health policy from Harvard University. She currently serves as president of the American Association of Public Opinion Research.

JONAS A. DE SOUZA, MD »

Assistant Professor, Section of Hematology/Oncology, The University of Chicago

Dr. Jonas de Souza is Assistant Professor of Medicine at the Section of Hematology/ Oncology at The University of Chicago. As a physician, he is involved with treating patients with cancers of the thyroid, head, and neck. His research is focused on the impact of finances on cancer patients' outcomes. He developed the Comprehensive Score for financial Toxicity (COST) and is the leader of the www.costofcancer.org initiative at the University of Chicago. Dr. de Souza is the recipient of several honors including an American Society of Clinical Oncology Award and the Abbott-Gonzalez Fellowship Award from the University of Chicago. He completed a fellowship at the University of Chicago, and conducted his internship and residency at the University of Texas Health Science Center. Dr. de Souza is also board certified in internal medicine.



« JALPA A. DOSHI, PHD

Associate Professor of Medicine; Director, Economic Evaluations Unit, Center for Evidence-Based Practice, Director, Value-Based Insurance Design Initiatives, Center for Health Incentives and Behavioral Economics, University of Pennsylvania

Dr. Doshi's work examines the impact of prescription benefit design and reimbursement policies on access to prescription drugs, and the quality and cost of healthcare in vulnerable patient populations. She is coauthor of *Economic Evaluation in Clinical Trials* (Oxford University Press), the first book dedicated entirely to this topic. Dr. Doshi has been principal investigator on numerous research grants from federal agencies, private organizations, and foundations, and has published widely in leading health policy and clinical journals. In recognition of her research, she has received several awards and honors from national and international organizations. She is coeditor of the journal, *Value in Health*. Dr. Doshi was one of the PAN Challenge winners for this meeting.

NANCY EGERTON, PHARM D, BCOP »

Manager, Pharmacy Services, New York Oncology/Hematology; Vice President, National Community Oncology Dispensing Association, Inc. (NCODA)

Dr. Egerton earned a PhD from the Albany College of Pharmacy and attained board certification in oncology pharmacy in 2006. She is responsible for managing all aspects of



Appendix B. *Roundtable Participants (continued)*

drug therapy at NCODA, including chemotherapy infusion services, stem cell transplant, in-office dispensing of oral medications, clinical pathways, pharmacy and therapeutics/formulary and investigational drug management. Dr. Egerton has extensive experience in collaborative discussions with managed care organizations/payer-related drug therapy issues, including clinical pathways, therapeutic interchange, and contracting. She serves on the US Oncology Pharmacy & Therapeutics and Collaborative Care Subcommittees.



« MATTHEW EYLES, MA

Executive Vice President, Policy & Regulatory Affairs, America's Health Insurance Plans (AHIP)

At AHIP, the national trade association representing the health insurance industry, Mr. Eyles leads the policy and regulatory affairs function, including the government programs, state policy, and product policy departments. Mr. Eyles joined AHIP from Avalere Health, where he was Executive Vice President for the health plans and providers' business, strategic communications, and the health reform team. Previously, he was Corporate Vice President, Public Affairs & Policy at Coventry Health Care, Inc. (now Aetna). In that function, he led public policy, government affairs, and corporate communications, and was a key advisor to the board of directors on all matters related to health reform. Prior to joining Coventry, Mr. Eyles was Vice President, Corporate Public Policy at Wyeth (now Pfizer) and led its public policy office for the pharmaceutical, consumer health, and animal health divisions in the United States and worldwide. He has a master's degree in public policy from the University of Rochester.

A. MARK FENDRICK, MD »

Director, University of Michigan Center for Value-Based Insurance Design; Founding Partner, VBID Health; Co-Editor in Chief, The American Journal of Managed Care

Dr. Fendrick conceptualized and coined the term Value-Based Insurance Design (VBID) and directs the VBID Center at the University of Michigan. His research focuses on how clinician payment and consumer engagement initiatives impact access to care, quality of care, and healthcare costs. Dr. Fendrick's perspective and understanding of clinical and economic issues have fostered collaborations with numerous government agencies, health plans, professional societies, and healthcare companies. He is an elected member of the National Academy of Medicine (formerly IOM), serves on the Medicare Coverage Advisory Committee, and has been invited to present testimony before the US Senate Committee on Health, Education, Labor and Pensions and the US House of Representatives Ways and Means Subcommittee on Health. He received his medical degree from Harvard Medical School.



« EMILY GIBB, MA

Director, Public Policy & Patient Assistance, GlaxoSmithKline

Ms. Gibb oversees GlaxoSmithKline's US patient assistance programs across all therapeutic areas including respiratory, immunology, vaccines, and HIV. She also develops public policy and advocacy strategies to educate state and federal officials on the role that innovative pharmaceuticals and vaccines play in reducing overall healthcare costs and improving health in communities. In recent years, Ms. Gibb has led efforts to address some of today's most dynamic public policy issues, including healthcare reform legislation, deficit/debt reduction, access to medicines in the Medicare Part D program, healthcare quality improvement, and patient safety. Prior to joining GlaxoSmithKline, Ms. Gibb worked at Eastern Maine Medical Center and Novartis Pharmaceuticals. Ms. Gibb holds an MA in corporate and public communications from Seton Hall University.

Appendix B. *Roundtable Participants (continued)*



« **CLIFFORD GOODMAN, PHD**
Senior Vice President, The Lewin Group

Dr. Goodman has 30 years of experience in health technology assessment, evidence-based healthcare, comparative effectiveness research, health economics, and studies pertaining to healthcare innovation, regulation, and payment. He directs studies and projects for an international array of government agencies; pharmaceutical, biotechnology, and medical device companies; healthcare provider institutions; and professional, industry, and patient advocacy groups. Dr. Goodman is an internationally recognized health policy issues moderator and facilitator of expert panels, health industry advisory boards, workshops, and focus groups. He served as Chair of the Medicare Evidence Development & Coverage Advisory Committee for the Centers for Medicare and Medicaid Services. He received a PhD from The Wharton School of the University of Pennsylvania, and an MS from The Georgia Institute of Technology.

BRIAN HAUG »
President, Managed Markets, Pharmacy and Rare Diseases, Michael J. Hennessy Associates

Mr. Haug joined Michael J. Hennessy Associates (MJH) in April 1998 as a national accounts manager and is now responsible for day-to-day oversight and operation of three franchises of the MJH portfolio. Anchored by MJH's flagship publications, *The American Journal of Managed Care*, *Pharmacy Times*, and *Rare Disease Reports*, Mr. Haug is responsible for extending the product lines of the franchise through product innovation, developing strategic partnerships, and overseeing the sales and marketing efforts of each of the franchises. Mr. Haug started his career as a mutual fund analyst for Merrill Lynch Asset Management, covering the healthcare sector for multiple open- and closed-end mutual funds.



« **LEAH MCCORMICK HOWARD, JD**
Vice President, Government Relations and Advocacy, National Psoriasis Foundation

Ms. McCormick Howard manages the National Psoriasis Foundation's (NPF) federal and state government relations and advocacy program, which focuses on growing and supporting investment in psoriasis and psoriatic disease research and expanding access to treatments and healthcare providers. She guides the NPF's strategies on step therapy, specialty tiering/cost sharing, and biosimilars, and leads NPF's efforts to engage with health insurers. Ms. McCormick Howard serves in the National Health Council's Government Relations Affinity Group Leadership as co-chair of the Health Care Reform Action Team. She has extensive experience in federal public health policy development, focusing on the intersection of public health, patient advocacy, and communities. She earned her JD *cum laude* from George Mason University School of Law, and is a member of the Virginia State Bar Association.

EMMETT B. KEELER, PHD »
Senior Mathematician, RAND; Professor, UCLA and Pardee RAND Graduate School

Dr. Keeler teaches medical cost-effectiveness and decision analysis, and led both the Management of Childbirth Patient Outcomes Project and the Improving Chronic Illness Care Evaluation. In the RAND Health Insurance Experiment, he studied the effects of alternative insurance plans on physiological health, and on the costs of episodes of treatment. The resulting micro-simulation model has been used to study spending and insurance choice. He was Academy Health's 2003 Distinguished Investigator, and is a member of the Institute of Medicine. Dr. Keeler received his PhD in mathematics from Harvard University.



Appendix B. Roundtable Participants (continued)



« DAN KLEIN

President and CEO, PAN

Mr. Klein brings more than 35 years of executive experience in healthcare and information technology services to the PAN Foundation. Previously, he served as Senior Vice President for the Cystic Fibrosis (CF) Services specialty pharmacy, and then Senior Vice President for Patient Access Programs at the Cystic Fibrosis (CF) Foundation. His leadership at the CF Foundation was exemplified by the steady growth and eventual sale of the CF Services pharmacy to Walgreens. He also developed the CF Patient Assistance Foundation, which provided financial assistance and case management services. Mr. Klein has had numerous leadership roles in the health and information technology sectors, including as Chairman and CEO of Panurgy Corporation, a leading mid-market information technology services company, and as a consultant on health promotion and planning for the US Department of Health and Human Services and the World Health Organization, respectively.

AMY NILES, MBA »

Vice President, External Affairs, PAN

Ms. Niles oversees the development and implementation of provider and professional relations, and public advocacy strategies at the PAN Foundation. Before joining PAN, Ms. Niles served for eight years as Chair, Medical Relations and Advocacy for the Together Rx Access program. Prior to that, she was President and CEO of the National Women's Health Resource Center, now known as Healthy Women, for more than a decade. Ms. Niles has an MBA from Baruch College, City University of New York, and began her career in hospital administration.



« ANDREW REYNOLDS

Hepatitis C Education Manager, Project Inform

Mr. Reynolds writes health education booklets, factsheets and articles on hepatitis C virus (HCV) treatment education, HIV/HCV coinfection, and HCV prevention and screening, including the annual *Positively Aware HCV Drug Guide*. He serves on the American Association for the Study of Liver Diseases/Infectious Diseases Society of America HCV Guidance Panel, Executive Committee of the Forum for Collaborative HIV Research, Board of Directors of the San Francisco Drug Users Union, and San Francisco Safety and Wellness Coalition. A counselor for a national hepatitis phone line, HELP-4-HEP, Mr. Reynolds also educates patients across the country on HCV treatment and access to healthcare.

JAMES ROBINSON, PHD, MPH »

Leonard D. Schaeffer Professor of Health Economics; Director - Berkeley Center for Health Technology School of Public Health, University of California, Berkeley

Dr. Robinson's research focuses on the biotechnology, medical device, insurance, and healthcare delivery sectors. He has published three books and more than 130 papers in journals such as the *New England Journal of Medicine*, *JAMA*, and *Health Affairs*. His most recent book, *Purchasing Medical Innovation: The Right Technology for the Right Patient at the Right Price*, analyzes the roles of the FDA, health insurers, hospitals, and consumers in the assessment, purchasing, and use of high-cost implantable devices. Professor Robinson's econometric research centers on the impact of reference pricing on consumer choices, employer spending, and health outcomes for inpatient and outpatient surgery, laboratory tests, diagnostic imaging, and pharmaceuticals in the United States. Dr. Robinson was one of the PAN Challenge winners for this meeting.



Appendix B. *Roundtable Participants (continued)*



« CHRISTINE RODRIGUEZ, MPH

Senior Policy Manager, National Viral Hepatitis Roundtable

Ms. Rodriguez focuses on federal-level hepatitis B- and hepatitis C-related policy. Her priorities include hepatitis C treatment access, health equity, appropriations, and drug user health. Ms. Rodriguez also sits on the Board of Directors of HIPS, a DC-based harm-reduction organization that promotes the health, rights, and dignity of individuals and communities impacted by sexual exchange and/or drug use due to choice, coercion, or circumstance. She earned her MPH at the University of California at Berkeley.

SUSAN M. SCHNEIDER, PHD, RN, AOCN, FAAN »

President-Elect, Oncology Nursing Society; Associate Professor, Duke University School of Nursing

Dr. Schneider will assume a two-year term as President of the Oncology Nursing Society (ONS) in May 2016. She is an associate professor and lead faculty for Duke's Oncology Nursing Specialty, and holds certifications as a clinical nurse specialist and an advanced oncology certified nurse. Her research interests include management of symptom distress in cancer patients, use of distraction interventions to enhance coping, and use of tailored protocols to promote chemotherapy adherence. She has received research funding from ONS, the American Cancer Society, and the NIH, and she is a Fellow of the American Academy of Nursing. Dr. Schneider earned a PhD in nursing from Case Western Reserve University in Ohio and a Master of Science from Texas Woman's University.



« KATHERINE SHARPE, MTS

Senior Vice President, Patient and Caregiver Support, American Cancer Society

Ms. Sharpe provides strategic direction for the American Cancer Society (ACS) patient and caregiver support and post-treatment survivorship initiatives, ensuring that they are evidence-based, evaluated for impact and quality improvement, and consistent with ACS patient support/survivorship goals and objectives. She previously served as ACS's Managing Director of Prevention and Survivorship Strategy. In that role, she led a team that facilitated development of clinical guidance for post-treatment survivorship care, including strategies to enhance provider and survivor education and establishing survivorship as a priority for public health policy. Prior to her tenure with ACS, Ms. Sharpe was a clinical case manager and counselor. Ms. Sharpe holds a master's degree from Seabury-Western and a postgraduate certificate in public health from the University of Florida.

KATHERINE UPSHUR, LCSW »

Care Manager, The MS Center of Saint Louis

Ms. Upshur has a Master of Social Work degree from Washington University in St. Louis and is a licensed clinical social worker. She serves as the Care Manager at the MS Center of Saint Louis, where she provides counseling services and helps patients navigate healthcare resources. In addition, she provides individual psychotherapy services.

