



Cost-Sharing Roundtable: Sustainable Strategies for Providing Access to Critical Medications

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

Proceedings Report

February 24, 2017 • 8:30am – 3:00pm

Kaiser Family Foundation's Barbara Jordan Conference Center

1330 G Street NW, Washington, DC 20005

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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.

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About This Report

Written by a rapporteur, 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 Roundtable participants, PAN or *AJMC*. PAN and *AJMC* staff did not participate in writing these proceedings. This document does not establish any conclusions or recommendations by PAN or *AJMC*; instead, it focuses on the issues and ideas presented by the speakers and Roundtable participants.

Contents

SPONSORS	2
HOSTS	3
ABOUT THIS REPORT	4
CONTENTS	5
EXECUTIVE SUMMARY	6
C1 INTRODUCTION	10
Continuing the Conversation	10
The PAN Challenge	12
C2 CARING FOR HIGH-NEED PATIENTS	13
Who is High-Need?	13
OOP Drug Costs for High-Need Patients	15
C3 IMPORTANCE OF THE HEALTHCARE SAFETY NET	18
What is the Safety Net?	18
Critical Need for the Safety Net	19
Holes in the Net	20
Strengthening the Net	22
C4 SOURCES AND IMPACTS OF UNCERTAINTY	25
ACA “Repeal and Replace”	25
Looming Uncertainty for All Stakeholders	30
C5 SHORT-TERM NEEDS AND LONG-TERM SOLUTIONS	31
Immediate Needs	31
Sustainable Strategies	32
C6 UNDERSTANDING AND RESPONDING TO THE PATIENT EXPERIENCE	42
Struggling Below the Stratosphere	42
Helping Patients Navigate the System	44
C7 SUMMARY	50
Meeting the Needs	50
APPENDIX A. Roundtable Agenda	53
APPENDIX B. Roundtable Participants	54

Executive Summary

“The first day of the year, I got an infusion and my deductible was over \$12,000. I got the bill in the mail and I thought it was a joke.”

— MELISSA THOMPSON

The Cost-Sharing Roundtable, hosted for the second consecutive year by the Patient Access Network (PAN) Foundation and *The American Journal of Managed Care (AJMC)*, continued the conversation about the growing burden of out-of-pocket (OOP) expenses for economically vulnerable Americans. Focusing on sustainable strategies for providing access to critical medications, the Roundtable provided a forum for discussing the effects of high OOP costs on medication access, the critical need for an effective and sustainable safety net, the patient experience, and uncertainty surrounding proposed changes to the Affordable Care Act (ACA) that were being widely discussed at the time of the meeting. Speakers and audience members also explored potential solutions to these complex issues. This report synthesizes the daylong conference, which was held in Washington, D.C. on February 24, 2017.

Chapter 1 introduces the Roundtable, providing context about its genesis in 2014, and the momentum that carried the conversation into 2017. The chapter also describes the PAN Challenge: a call for research papers on strategies for eliminating barriers to medication for high-need patients.

In **Chapter 2**, “high need” is defined in clinical, social and economic terms. A confluence of factors that occurs when low-income individuals are diagnosed with diseases that require expensive medications that they cannot afford often results in financial toxicity, which has its own adverse effects. This chapter discusses pressures that create these high needs: lack of an OOP limit on Medicare Part B and Part D drugs, the effect of even low levels of cost sharing on economically vulnerable individuals, the rise in healthcare and health insurance costs; placement of more drugs on specialty tiers, medical conditions that require several expensive drugs, and the contributions of factors such as age and non-medical expenses such as transportation and lost wages.

“Who wants to put a value on a life and say ‘that’s not worth it to me?’ It’s obviously worth it. I would have paid whatever I had to. But in the real world, if you don’t have it to pay, you don’t have it, it doesn’t matter.”

— ANDREA BAER

The healthcare safety net is defined and explored in **Chapter 3**. The financial pressures described in the preceding chapter cause psychological hardship, and increase the likelihood of going into debt or filing for bankruptcy, highlighting the need for a sustainable safety net. The dangers of slipping through this net are explored, as is the disconnect between the remarkable advances in medicine that can now cure certain diseases or dramatically improve quality of life, and the reality that many patients simply cannot take advantage of these advances because of cost. This chapter introduces the concept of value-based insurance design (VBID) as a means of strengthening the safety net and explores the concept of value.

Chapter 4 explores the profound uncertainties associated with public policy debates that occurred early in 2017 concerning repeal of the ACA. Although the ACA currently remains in place, many of its components may become part of future policy initiatives that attempt to re-imagine it. Despite the desire of much of the population for at least parts of the current system (e.g., Medicare) to remain unchanged, there is widespread concern about changes that may be proposed now or in the future. Persistent uncertainty about the current political climate, as well as the role of patient advocacy groups and charitable foundations are also discussed in this chapter.

In **Chapter 5**, confusion about healthcare costs is discussed, and manufacturer and insurer roles in high drug prices for patients are explored, including specialty tiers and high deductibles. Several solutions with the potential for long-term positive effects are introduced, including using clinical pathways to standardize care and add transparency, including to issues of cost. This chapter also summarizes the sustainable strategies for providing access to critical medications that were proposed in the winning and runner-up PAN Challenge research papers. The first paper involves the use of value-based formularies to encourage the use of higher-value medications. The second tests an approach to even out drug costs for Medicare Part D beneficiaries so that their OOP costs do not spike at the beginning of the year.

Chapter 6 focuses on the patient experience, beginning with low-income patients who often have trouble meeting even relatively moderate OOP costs. This chapter also presents the experience of a cancer patient and her financial journey. Two case studies illustrating patient support initiatives to increase financial literacy and provide peer support add to the conversation about the challenges patients face in navigating the healthcare system. This exploration shows many of the difficulties facing patients; how varied their experiences can be; that certain interventions are effective in helping patients with specific challenges; and that navigation of the financial aspects of critical illness, including access to medications, remains a significant challenge.

The final chapter summarizes the themes of the Roundtable, especially the continued and growing need for the safety net, and emphasizes that stakeholder groups need to work together to effect change.

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 about high-need patients?

- » High-need patients may have a variety of conditions or situations (e.g., disease or disability) that increase their need for healthcare services.
- » The definition of “high need” frequently includes economic insecurity, which is often facilitated by the need for increased healthcare utilization, especially among low-income patients.
- » High OOP costs often prevent high-need patients from accessing needed medications.

Why does the safety net matter?

- » OOP costs can not only make medications unaffordable, they can also jeopardize financial security.
- » Without financial assistance provided by safety nets like charitable organizations, patients may be unable to access lifesaving, medications.

What are the sources and implications of uncertainty?

- » Efforts to “repeal and replace” the ACA make the future of healthcare uncertain, especially for economically vulnerable patients.
- » Although the initial “repeal and replace” initiative failed to move forward, its components are likely to be part of future initiatives, so examining their potential impacts is instructive.
- » In the current political environment, uncertainty surrounding cost sharing affects all stakeholders: patients, patient assistance organizations, healthcare providers, insurers and patient advocacy groups.

What are some sustainable strategies that may ensure access to medications?

- » Change the Medicare Part D cost-sharing structure by implementing monthly OOP maximums and spreading payments out evenly throughout the year.
- » Implement value-based coverage including use of value-based formularies.
- » Promote widespread use of clinical pathways.
- » Reassess how drug prices are arrived at by drug manufacturers and passed on to patients by insurers.

What can we learn from the patient experience?

- » Even relatively modest OOP costs can tip the scales into financial instability for low-income patients.
- » Patients with serious health conditions often lack knowledge about the costs of their treatment.
- » Patients need help with financial literacy and with navigating the support that may be available to them.
- » Peer support has been shown to promote favorable patient outcomes.

What is the bottom line?

- » It is important for advocacy organizations, charitable assistance programs such as PAN, industry and all stakeholder groups to work together to support 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. This is because costs are not decreasing, increased numbers of patients need assistance, as well as demographic factors such as the aging of the U.S. population.
- » 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.

Introduction

“Neither a 70-year-old man with asthma, or a 45-year-old woman with multiple myeloma should have to worry about the availability of financial support for medication out-of-pocket costs from one year to the next. Neither should have to worry that out-of-pocket costs for medications will send their families into debt or bankruptcy.” — AMY NILES

Continuing the Conversation

In fall 2014, the PAN Foundation hosted a patient advocacy roundtable that focused on the challenges of responding to the increasing numbers of patients who cannot afford OOP costs for their medications. The interest in continuing a dialogue on the topic of cost sharing resulted in PAN and AJMC co-hosting the February 26, 2016, Cost-Sharing Roundtable¹ held at the Henry J. Kaiser Family Foundation’s Barbara Jordan Conference Center in Washington, D.C. 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. Enthusiasm generated at the 2016 Roundtable led to efforts to continue the dialogue.

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

This year’s Roundtable, held on February 24, 2017, built on last year’s conversation about cost sharing, with a renewed focus on sustainable strategies for providing access to critical medications. Attendees included individuals from patient advocacy groups, the health insurance industry, professional/nonprofit organizations, government agencies, pharmaceutical companies and pharmacies, as well as healthcare providers, academicians, health economists and patients. Because of the timing of the meeting, considerable attention was paid to the Trump administration’s attempts to “repeal and replace” the ACA.

¹ PAN Foundation, Cost-Sharing Roundtable: Improving Patient Access to Critical Therapies. Proceedings Report. February 26, 2016. https://www.panfoundation.org/files/PAN_CostSharingRoundtable_FullReport.pdf. Accessed March 12, 2017.

Ultimately, in late March, the proposed replacement legislation was pulled from consideration by the U.S. House of Representatives due to lack of support. At the time of the 2017 Roundtable, however, the proposed measure was a prominent topic of conversation.

The Roundtable kicked off with a welcome from Amy Niles,² PAN's Vice President of External Affairs, who introduced the theme and its importance. "Today millions of Americans are underinsured and we believe that number is going to continue to increase," she said. "For so many, especially those with life-threatening and serious illnesses, having a safety net to rely on, one that ensures access to medications, is vitally important. In fact, it's often a matter of life and death."

Niles introduced Dan Klein, PAN President and CEO, who welcomed everyone and briefly reiterated two key features of PAN's mission: (1) to provide financial assistance to underinsured patients so they can get access to their critical medications and (2) to be an advocate for affordability and for improved access to all treatment. The latter, emphasized Klein, "is really what the Roundtable is all about today—to encourage all of us to think about these issues and to do what we can to make sure that patients are able to get access to the care they need." Klein gave an idea of PAN's impact by noting that, "Over the past two years, the PAN Foundation has provided over \$1.7 billion in assistance to patients who needed help getting access to their treatment. We helped over half a million patients." However, he said, "maintaining that level of support is growing increasingly challenging in today's uncertain environment."

Next to take the welcome podium was Jeff Prescott, PharmD, Senior Vice President, Managed Markets, Michael J. Hennessy Associates, Inc. (MJH) Associates (publisher of *AJMC*). A part-time pharmacist, he introduced *AJMC*, as "the leading publication in managed care, providing those that are making policy-based decisions with clinical and policy information that enables them to help stretch our limited economic resources to meet the healthcare needs of our population."

²Short biographies of all Roundtable participants are provided in Appendix B.

"Each time I get a treatment I'm well aware of the enormous cost of this medication — over \$30,000 a year — and I am abundantly grateful and thankful for my Medicare insurance and the huge costs that they cover. But I'm even more appreciative that the PAN Foundation covers my OOP costs, which would still be in the thousands of dollars each year. I realize that this is a special gift from people who really care, and that the funding they are supplying to me is never guaranteed from year to year."

— PATIENT WHO RECEIVES ASSISTANCE FROM PAN

"Despite the seemingly large numbers that PAN can point to in terms of numbers of people we help and have helped over the past years, we're a tiny part of the safety net, and we need to keep that in mind."

— DAN KLEIN

Prescott emphasized the dangers of non-adherence to medication regimens, and expressed concern about the role of cost/affordability in adherence decisions, challenges he encountered often as a pharmacist. “So from that perspective,” he said, “speaking for myself and for *AJMC*, we are very excited to partner with PAN for a second year on their mission to present strategies that will help relieve the cost burden and improve access for patients with life-threatening diseases.”

The Roundtable provided a forum for the exchange of ideas about sustainable strategies for ensuring medication affordability. The agenda, which can be found in **Appendix A**, covered healthcare challenges facing Medicare beneficiaries, a first-person account of the impact of cost sharing on a cancer patient, case study presentations focusing on patient support, two panel discussions (on mitigating the cost burden on patients, and sustainable strategies for ensuring access to medications), and presentations of the winning papers of the PAN Challenge. The case studies addressed the impact that OOP medication costs have on utilization of and adherence to medications, and on patient outcomes.

The PAN Challenge

The second annual PAN Challenge, *Beyond Charitable Assistance: Sustainable Strategies for Providing Access to Critical Medications*, solicited papers that described ways to reduce or eliminate barriers and disparities that Medicare and ACA enrollees face in obtaining medications needed for the treatment of life-threatening, chronic and rare diseases. Papers submitted to the PAN Challenge were required to propose strategies; provide theoretical models, research studies or real-world examples of these strategies; and indicate the incremental cost and how these strategies would be funded. The papers were juried by an expert panel and the winners were announced in January 2017. A \$10,000 prize was awarded to the sponsoring organization for the winning paper, the runner-up organization received \$5,000, and one organization received an Honorable Mention and \$1,500 (winners listed in sidebar, above).

PAN CHALLENGE WINNING PAPERS

Winner

Impact of a Value-Based Formulary in Three Chronic Disease Cohorts

Kai Yeung, Anirban Basu, Zachary A. Marcum, John B. Watkins, Sean D. Sullivan

University of Washington

Runner-Up

Reducing Out-of-Pocket Cost Barriers to Specialty Drug Use Under Medicare Part D: Addressing the Problem of “Too Much Too Soon”

Jalpa A. Doshi, Pengxiang Li, Amy R. Pettit, J. Samantha Dougherty, Ashley Flint, Vrushabh P. Ladage

University of Pennsylvania

Honorable Mention

Cost Sharing of Disease Modifying Treatments (DMTs) as Policy Lever to Improve DMTs Access in Multiple Sclerosis

Lizheng Shi, Hui Shao, Charles Stoecker

Tulane University

Caring for High-Need Patients

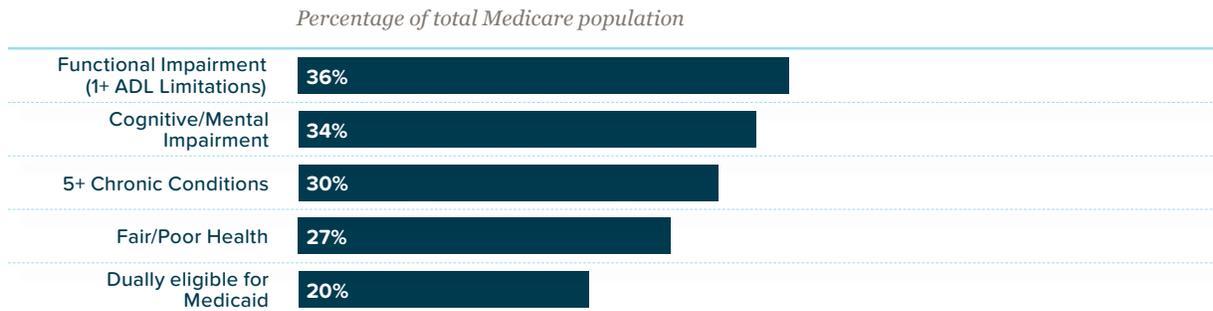
“I think the test of our healthcare system is how well it serves people with significant needs.” – TRICIA NEUMAN

Who is High-Need?

According to Tricia Neuman, ScD, Senior Vice President of the Henry J. Kaiser Foundation and Director of the Foundation’s Program of Medicare Policy, in her discussion, *What’s the Outlook for Medicare and High-Need Beneficiaries in 2017 and Beyond?*, the “high-need population” encompasses people with many different conditions and situations. Large proportions of the 57 million people over the age of 65 who are covered by Medicare have functional impairment (defined as one or more limitations in activities of daily living [ADL]), cognitive impairment, chronic conditions, fair/poor health or social isolation (**FIGURE 1**),³ all of which place them in high need of healthcare services.

Affordability goes hand in hand with increased utilization of healthcare services. This often makes economic insecurity another feature of high-need individuals. According to the Kaiser Foundation, half of all Medicare recipients have annual incomes below \$24,150, and 25% have incomes below \$14,350.⁴ “This is a group of very low-income people who have very high needs and account for a disproportionate share of both Medicare and Medicaid spending, about one in five people on Medicare,” said Neuman.

FIGURE 1. Common high-need conditions among Medicare beneficiaries³



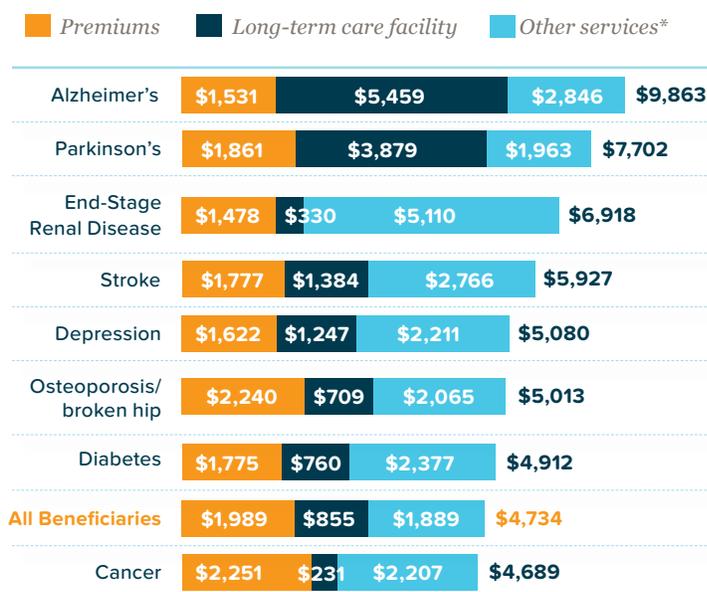
³Kaiser Family Foundation analysis of the Centers for Medicare & Medicaid Services Medicare Current Beneficiary 2013 Cost and Use file.

⁴Urban Institute / Kaiser Family Foundation analysis of DYNASIM data, 2015.

Many people in this income bracket are not eligible for low-income assistance, and when they are diagnosed with diseases that require expensive medications, they are ill-equipped to pay for them. “It’s a significant concern,” said Neuman, “when they get one high-priced drug, a specialty drug, or maybe multiple medications.”

Financial barriers to treatment access are particularly acute for Medicare Part D patients requiring specialty drug treatments. Since Part D went into effect in 2006, patients who do not receive low-income subsidies (non-LIS beneficiaries) have been subject to high coinsurance requirements for specialty drugs.⁵

FIGURE 2 . Average OOP spending on services is higher for Medicare beneficiaries with certain chronic conditions⁶



THE DONUT HOLE

Once patients hit the initial coverage limit when their total drug spending meets \$3,700, they then enter the Coverage Gap Phase, also called the “donut hole.” After spending a total of \$4,950, patients enter the Catastrophic Coverage Phase, during which they pay 5%. The 5% coinsurance can be significant, ranging from \$350 to \$500 each month.⁷

SPECIALTY TIERS

Insurance plans categorize drugs into tiers, based on cost, with higher tiers having higher associated cost sharing.⁷

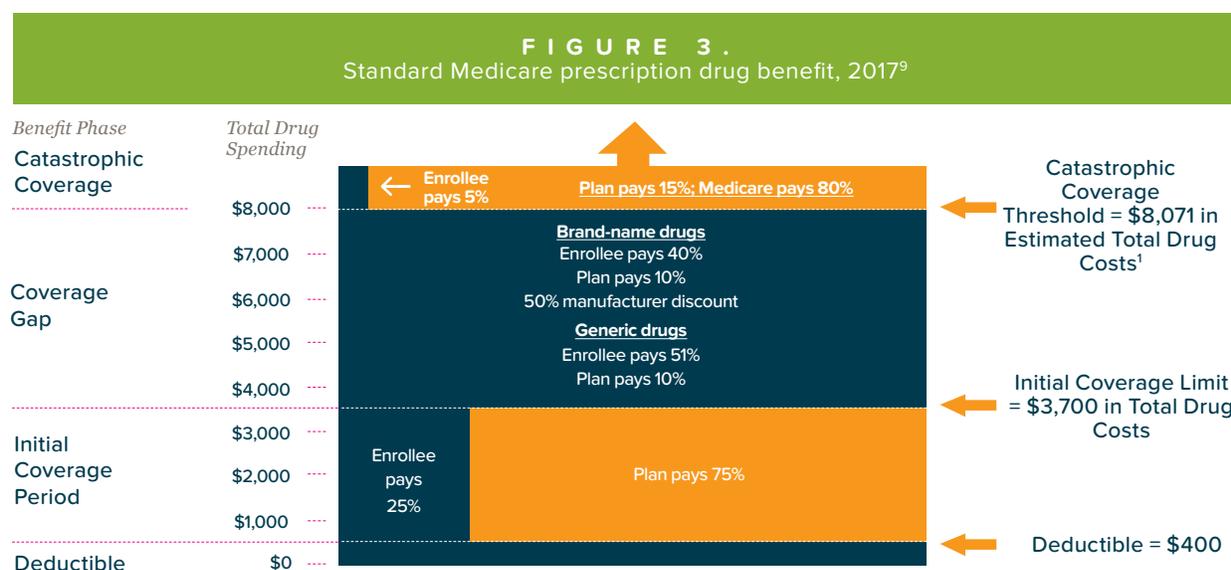
⁵Doshi JA, Li P, Pettit AR, Dougherty JS, Flint A, Ladage VP. Reducing out-of-pocket cost barriers to specialty drug use under Medicare Part D: Addressing the problem of “too much too soon.” PAN Challenge runner-up. December 22, 2016.

⁶Kaiser Family Foundation analysis of the Medicare Current Beneficiary 2010 Cost and Use file.

⁷PAN Foundation, Cost-Sharing Roundtable: Improving Patient Access to Critical Therapies. Proceedings Report. February 26, 2016. https://www.panfoundation.org/files/PAN_CostSharingRoundtable_FullReport.pdf. Accessed March 12, 2017.

OOP Drug Costs for High-Need Patients

Medicare recipients have relatively high OOP costs, which vary by condition (**FIGURE 2**) and the types of drugs they use. For example, median OOP costs for a single drug for RA, hepatitis C or multiple myeloma may range from \$4,800 to \$11,500. Neuman explained that these figures clearly illustrate how high medication costs can quickly consume a sizable share of the \$64,000 median savings of Medicare recipients,⁸ which they had planned to save for long-term care. The reason people have such high OOP costs on Medicare, Neuman explained, is that there is no OOP limit on Part B drugs (those administered in a doctor’s office or hospital outpatient setting). For drugs covered under Medicare’s Prescription Drug Plan (Part D), she noted, the lack of a hard limit on OOP costs causes people to incur significant OOP costs for their prescriptions (**FIGURE 3**). She said that supplemental coverage may help, although it comes with additional premiums and cost sharing.



When Kaiser researchers looked at OOP spending for certain drugs covered under Part D, they were struck by how high the OOP costs could be, both because of the lack of a hard cap and because of the donut hole/coverage gap. Another factor is the placement of certain drugs on specialty tiers, which have high associated OOP costs that can vary from year to year.

⁸Jacobson G, Swoope C, Neuman T. Income and assets of Medicare beneficiaries, 2014–2030. Kaiser Family Foundation. September 10, 2015. <http://kff.org/medicare/issue-brief/income-and-assets-of-medicare-beneficiaries-2014-2030/>. Accessed April 19, 2017.

⁹Kaiser Family Foundation illustration of standard Medicare drug benefit for 2017.

In their PAN Challenge paper, *Reducing Out-of-Pocket Cost Barriers to Specialty Drug Use under Medicare Part D: Addressing the Problem of “Too Much Too Soon,”*¹⁰ Jalpa Doshi, PhD, Associate Professor of Medicine, University of Pennsylvania, and her colleagues examined annual OOP drug costs for Medicare Part D patients with one of three conditions warranting continuous use of three of the top-spending specialty drugs: rheumatoid arthritis (RA), multiple sclerosis (MS), and chronic myeloid leukemia (CML). Of the \$3,949, \$5,238 and \$6,322 OOP costs for these conditions, respectively, 88%, 91% and 95% (respectively) were for specialty drugs. For MS and CML, Doshi et al. found that “the average OOP cost of the first disease-specific specialty drug fill for the calendar year nearly equaled or exceeded the average monthly social security benefit.”¹¹ Doshi explained, “Having 5% catastrophic coverage cost-sharing is problematic because even during the catastrophic coverage phase, patients are basically spending OOP anywhere from \$1,200 for RA to \$3,500 for CML.”

Clifford Goodman, PhD, Senior Vice President, The Lewin Group, noted, “When the Medicare program was designed, and when Blue Cross and Blue Shield were designed, 5% or 20% didn’t sound like such a big deal, but now because of the nature of the breakthroughs and other advances in pharma-bio and company prices, that’s real money.”

Veena Shankaran, MD, MS, Associate Professor, Division of Medical Oncology, University of Washington and Associate Member, Clinical Research Division, Fred Hutchinson Cancer Research Center, introduced her case study, *Development of a Financial Literacy and Navigation Program for Cancer Survivors*, with the following statistics about U.S. healthcare costs:

- » According to an Institute of Medicine report,¹² if food prices had grown as quickly as healthcare costs since 1945, a gallon of milk would cost \$48, a dozen eggs would cost \$55 and a dozen oranges would cost \$134.
- » Annual insurance costs doubled between 2009 and 2014, and increased from \$2,943 in 2008 to \$5,138 in 2015.¹³
- » There was a large increase in the proportion of health plans with multi-tiered formularies in which specialty drugs fall into the highest cost-sharing category, from zero in 2003 to 23% in 2013.¹⁴

¹⁰Doshi JA, Li P, Pettit AR, Dougherty JS, Flint A, Ladage VP. Reducing out-of-pocket cost barriers to specialty drug use under Medicare Part D: Addressing the problem of “too much too soon.” PAN Challenge runner-up. December 22, 2016.

¹¹Social Security Administration. Monthly statistical snapshot, November 2016. Official Social Security website. https://www.ssa.gov/policy/docs/quickfacts/stat_snapshot/. Published December 2016. Accessed April 4, 2017. D: Addressing the problem of “too much too soon.” PAN Challenge runner-up. December 22, 2016.

¹²Yong PL, Saunders RS, Olsen LA, eds. Institute of Medicine, The Healthcare Imperative: Lowering Costs and Improving Outcomes. Roundtable on Value & Science-Driven Health Care. Workshop Series Summary. Washington, D.C., The National Academies Press. 2010.

¹³Japsen B. Worker out-of-pocket health costs have doubled in five years. Forbes.com. November 13, 2014, <https://www.forbes.com/sites/brucejapsen/2014/11/13/worker-out-of-pocket-health-costs-have-doubled-in-five-years/#587258a71756>. Accessed March 17, 2017. 2015 figure is an estimate. 2010.

Shankaran said, “This [shift] is particularly relevant in oncology, where many of the oral chemotherapies that have been approved over the last five years have monthly costs in excess of \$10,000.”¹⁵

The fact that one in five Medicare recipients is dually eligible for Medicaid means that there are a lot of older high-need patients, emphasized Mary Richards, Executive Director of the patient advocacy group, Partners for Better Care. Of those still in the workforce, she said, “There are a lot of people who rely on multiple expensive medications in order to maintain employment and participate in the economy, their families and their lives.” In thinking about affordability, she added that the type of solutions we find may be influenced by whether we view consumers as patients, or patients as consumers. Consumers are typically viewed as those who access healthcare for minor conditions, and patients as those who have multiple chronic conditions or a functional limitation. “The outcomes conversation looks a lot different when the outcome that you’re seeking is the ability to work, the ability to not go on SSDI [Social Security Disability Insurance], the ability to be able to maintain a life while living with a complicated health condition, vs. an outcome which is the resolution of an ear infection.”

“There are a lot of people who rely on multiple expensive medications in order to maintain employment and participate in the economy, their families and their lives.”

“We typically think about consumers as being folks who have a couple of ear infections a year and that sort of thing; they go to the doctor once or twice a year, and then we also think about people who are patients. A ‘patient’ to us typically means someone who has multiple chronic conditions or a functional limitation.”

— MARY RICHARDS

Additional OOP Costs

Other non-medical expenses contribute to the cost of care, especially for high-need patients. “There’s also the issue of employment challenges, that people have to not work; some people are fortunate enough to have salaries and can take off a day without losing their income, but plenty of people can’t. So there are those kinds of costs,” said Neuman. “There are daily costs that are hard to quantify, but if you have to travel and you’re low-income and you need to get to another part of town and you have to take a couple of buses to get there and again give up a day to get to a clinic, that’s a cost that is hard to quantify, but in real terms it matters a whole lot.” For example, in a city such as Baltimore, she said, lack of “good public transportation can mean that people don’t get the care they need because they can’t get to where they need to get.”

¹⁴Kaiser/HRET Survey of Employer Sponsored Health Benefits 2000-2013.

¹⁵Pharmacy Red Book Redbook Online. Greenwood Village, CO: Truven Health Analytics (accessed 2016 May 29).

3 Importance of the Healthcare Safety Net

“The one thing we do know for sure is that the need for the safety net is growing. The safety net isn’t the answer, it’s a temporary fix. We need to look longer-term.”

“What PAN is concerned about is patients becoming financial casualties.”

— DAN KLEIN

What is the Safety Net?

As discussed in Chapter 2, high-need patients are unlikely to be able to afford required medications on their own. Assistance with costs, including insurance premiums and travel-related expenses, is often called the “safety net,” and this support comes from charitable assistance programs, manufacturer-sponsored programs, and other entities. Neuman explained, “These charitable assistance programs go from church-based programs in local communities to big programs, such as PAN and the other OIG [Office of the Inspector General, U.S. Department of Health and Human Services]-approved charitable assistance programs, [and include] significant patient assistance programs and free drug programs [operated by] many of the drug manufacturers.” Many of these programs, she continued, “provide free medications, as well, and more and more free medication programs, which originally were intended for people who didn’t have insurance, are now being extended to people who are underinsured.”

“Just considering Medicare Part D, there are about 16 million people who fall between 150% and 400% of the Federal Poverty Level. So that’s a group whose income is too high to qualify them for the low-income subsidy, but many who fall in that range are unable to afford their critical medications without some form of assistance, and that number is growing.”

— MARY RICHARDS

“This group of people has trouble getting through the \$400 front-end deductible, getting through their 25% coinsurance, let alone getting into the coverage gap.”

— CLIFFORD GOODMAN

Critical Need for the Safety Net

OOP healthcare costs, particularly for chronic and rare diseases, can wreak economic havoc, easily wiping out savings, and jeopardizing ability to access needed therapies. Shankaran shared data from a 2016 paper by Yabroff and colleagues entitled *Financial Hardship Associated with Cancer in the United States: Findings from a Population-Based Sample of Adult Cancer Survivors*,¹⁶ which showed that more than 20% of patients experience material or psychological financial hardship (i.e., anxiety and stress) associated with paying for cancer care (**TABLE 1**). She also highlighted data from Ramsey et al. showing a substantially higher rate of bankruptcy filings in individuals with cancer (**FIGURE 4**).¹⁷ “[There is a] pathway,” said Shankaran, “between cancer diagnosis and financial hardship. There are factors around the high price of cancer drugs, cost-sharing and insurance plan design that might influence this pathway, but also factors at the patient level and clinic level”

[**FIGURE 5**]. Many Roundtable panelists agreed that the pervasiveness and severity of the financial toxicity associated with unaffordable OOP costs is why the safety net is so critical.

“Many of these studies have really made us aware of this problem of financial toxicity in the cancer world, which is really a constellation of symptoms: bankruptcy, debt, anxiety, loss of work, and difficulty meeting basic expenses,” Shankaran continued. “We’ve started to see some reports suggesting

that financial toxicity can lead to impacts in outcomes, treatment adherence, poor quality of life, lower clinical trial participation, and, perhaps even worse, survival.”

Citing a 2016 study in the *Journal of the National Cancer Institute*,¹⁸ she added, “Patients with cancer also experience changes in employment in terms of missed work days, number of days spent

FINANCIAL HARDSHIP	WEIGHTED % (95% CI)
Had to borrow money or go into debt	7.1 (5.7 - 8.9)
Filed for bankruptcy	1.7 (1.0 - 2.8)
Unable to cover share of costs for medical care	11.9 (9.8 - 14.3)
Other financial sacrifices	9.4 (7.6 - 11.5)
Any material financial hardship	20.4 (17.7 - 23.4)
Any psychological financial hardship	22.5 (19.6 - 25.6)

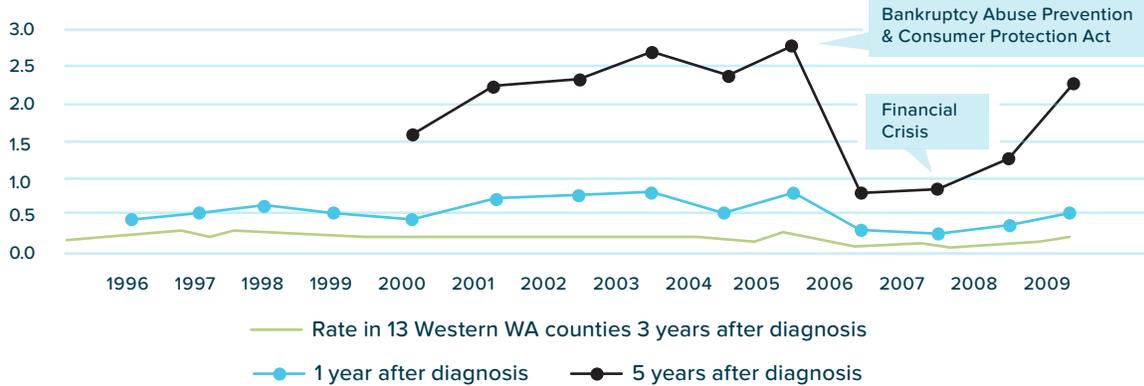
2011 Medical Expenditures Panel Survey (MEPS) Experiences with Cancer Supplement (N=1202)

¹⁶Yabroff KR, Dowling EC, Guy DP Jr, Banegas MP, Davidoff A, Han X, et al. Financial Hardship Associated with Cancer in the United States: Findings from a Population-Based Sample of Adult Cancer Survivors. *J Clin Oncol* 2016;34(3):259-267.

¹⁷Yabroff KR, Dowling EC, Guy DP Jr, Banegas MP, Davidoff A, Han X, et al. Financial Hardship Associated with Cancer in the United States: Findings from a Population-Based Sample of Adult Cancer Survivors. *J Clin Oncol* 2016;34(3):259-267.

¹⁸Zheng Z, Yabroff KR, Guy GP Jr, Han X, Li C, Banegas MP, Ekwueme DU, Jemal A. Annual medical expenditure and productivity loss among colorectal, female breast, and prostate cancer survivors in the United States. *J Natl Cancer Inst* 2016;108(5):djv382.

FIGURE 4 .
Cancer diagnosis and bankruptcy¹⁷



in bed, and in general disability related to their diagnoses” (TABLE 2). These outcomes also have an unfavorable impact on patients’ ability to cover their OOP and other medical costs.

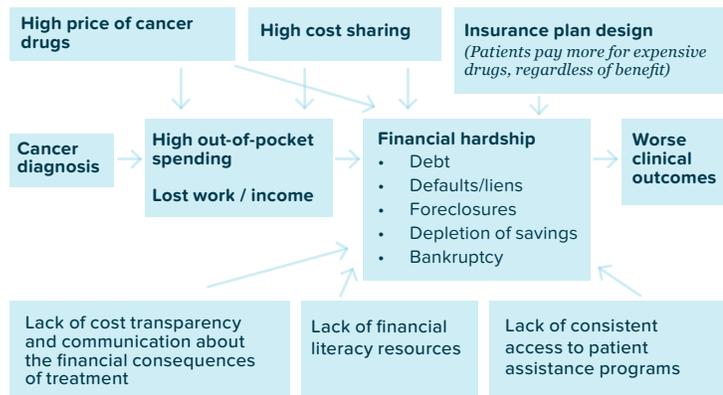
Holes in the Net

Given that severe financial pressures are affecting growing numbers of patients, it is easy to understand why organizations such as PAN are becoming increasingly concerned about their ability to keep up with patient needs, even among those with relatively modest OOP costs. “Most of our grants are for thousands, not tens or hundreds of thousands of dollars,” said Klein, emphasizing that most of PAN’s support goes to people who need a relatively limited level of support.

TABLE 2 .¹⁶
Lost productivity in cancer patients compared with individuals without a cancer history

PRODUCTIVITY LOSS	COLORECTAL CANCER	BREAST CANCER
Employment disability	13.6% (6.1%–25.9%)	4.8% (1.7%–9.2%)
# Missed work days	7.2 days (2.1–17.1 days)	3.3 days (1.0–6.6 days)
# Days staying in bed	4.5 days (1.4–9.5 days)	3.3 days (0.9–6.8 days)

FIGURE 5 .
Financial toxicity conceptual model



Gerard Anderson, PhD, Professor, Bloomberg School of Public Health, Johns Hopkins University, focuses on people before they get to the catastrophic amount, but there are a number of drugs that automatically tip the scales. “What we don’t have is somebody to deal with these people who enter the catastrophic amount,” he said. “If you’re living on Social Security and you’re making \$22,000 or \$24,000, \$8,000 or even \$3,000 is prohibitively expensive.” With advances in drug development and personalized medicine, several speakers pointed to an increase in the number of drugs that fall in specialty tiers because of their high costs.

What happens when people slip through the holes in the net? When high-need patients can’t pay for their medications? For low-income patients with life-threatening, chronic and rare, diseases such as cancer, hepatitis C, RA and MS, the significant medical advances offered in the form of specialty drugs are often unaffordable. Doshi pointed out, “There’s a growing body of evidence linking higher cost sharing with reduced utilization of specialty drugs.^{19,20,21,22,23,24} High Medicare Part D cost sharing [is linked] to all kinds of suboptimal specialty drug utilization—beginning from delayed or reduced initiation of treatments, greater incidence of interruptions in treatment once patients start off, and eventually just quitting the medication completely. We found this across a whole variety of diseases.”

¹⁹Doshi JA, Li P, Ladage VP, Pettit AR, Taylor EA. Impact of cost sharing on specialty drug utilization and outcomes: a review of the evidence and future directions. *Am J Manag Care* 2016;22(3):188-197.

²⁰Dusetzina SB, Winn AN, Abel GA, Huskamp HA, Keating NL. Cost sharing and adherence to tyrosine kinase inhibitors for patients with chronic myeloid leukemia. *J Clin Oncol* 2014;32(4):306-311.

²¹Doshi JA, Li P, Huo H, et al. High cost sharing and specialty drug initiation under Medicare Part D: A case study in newly diagnosed chronic myeloid leukemia patients. *Am J Manag Care*. 2016;22:S78-S86.

²²Streeter SB, Schwartzberg L, Husain N, Johnsrud M. Patient and plan characteristics affecting abandonment of oral oncolytic prescriptions. *J Oncology Practice*. 2011;7(3):46s-51s.

²³Shen C, Zhao B, Zhou S, et al. Low income subsidy status outweighs insurance cost-sharing in predicting adherence to tyrosine kinase inhibitors among Medicare Part D beneficiaries with chronic myeloid leukemia. Abstract #6531. Presented at the 2016 ASCO Annual Meeting, June 4, 2016; Chicago, IL.

²⁴Kaisaeng N, Harpe SE, Carroll NV. Out-of-pocket costs and oral cancer medication discontinuation in the elderly. *J Manag Care Spec Pharm*. 2014;20(7):669-675.

“There are a number of great drugs coming along and they’re very expensive. Assuming a drug works awfully well and accomplishes everything it ought to, I think paying for it makes sense. But, I also think asking ordinary insurance carriers to pay for these kinds of extraordinary products and services is probably not a reasonable approach.”

— GRANT LAWLESS

“Advances such as specialty drugs, which represent vital treatments for patients who often have few or no effective alternatives, can only be effective if patients can afford to utilize them.”

— JALPA DOSHI

“Recent pharmaceutical advances hold the promise of transforming the medical care of serious life-threatening, chronic, and/or rare diseases and significantly improving the lives of those afflicted,” Doshi reiterated. “Yet these advances may be out of reach for many Americans because of high OOP costs.”^{5,25}

This is particularly true for Medicare Part D patients who do not qualify for low-income subsidies (LIS), who face high and variable cost sharing. Advances such as specialty drugs, said Doshi, “which represent vital treatments for patients who often have few or no effective alternatives, can only be effective if patients can afford to utilize them, [so finding] sustainable strategies for providing access to critical medications is an important issue as it relates to specialty drugs.”

Strengthening the Net

“The need is clearly increasing and the safety net is going to have to grow to keep up with the need,” said Klein. Organizations like PAN are certainly a part of that safety net. We’ve seen our utilization more than double in the past three or four years.” He continued, “How much we can help is really limited by how much funding is available. Charitable organizations like PAN rely almost entirely on funding from the drug manufacturers.” These relationships are under increased pressure, he explained, “because of the concern over high OOP costs and the uncertainty surrounding the ACA.”

Jenny Bryant, Senior Vice President, Policy and Research, Pharmaceutical Research and Manufacturers of America (PhRMA) added, “I think [pharmaceutical] companies are taking a look at what they can do in all forms of assistance and recognizing that there are going to be lots of challenges.”

When asked whether pharmaceutical companies are likely to continue contributing to patient assistance programs, Bryant replied, “Individual companies are going to make different calls about what’s sustainable and what makes sense from a business perspective. What I can say is that all of the companies are concerned about the trends. They are very concerned about where coverage is going.”

“I think there is a policy issue here about what the purpose of insurance is,” said Bryant. “We don’t need to be moving toward an insurance system that tries to have the patient who needs a very expensive medicine cover the full cost. That really defeats the purpose. I think where we need to be focused is: do we have the types of insurance mechanisms for spreading and sharing risk that’ll be sustainable in an era where we have many medicines that will have high costs and that will be used by small populations?”

“It’s an open question whether our risk adjustment systems and reinsurance systems are really fully

“No safety net can survive if every high-cost patient falls into it.”

— JENNY BRYANT

²⁵Doshi JA, Li P, Ladage VP, Pettit AR, Taylor EA. Impact of cost sharing on specialty drug utilization and outcomes: a review of the evidence and future directions. *Am J Manag Care.* 2016;22(3):188-197.

up to the task to do that,” she said. “I think that’s where the focus ought to be, on how we share risk and how we assess what is a reasonable approach to formulary design and to cost sharing.” She concluded, “No safety net can survive if every high-cost patient falls into it.”

Incorporating Value

Pioneered by Mark Fendrick, MD, Director, University of Michigan Center for Value-Based Insurance Design and Co-Editor in Chief, *AJMC*, Value-Based Insurance Design (VBID) aims to align patients’ OOP costs with the value of the health services they receive.^{26,27} It was 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. Although it implies increases in cost sharing for some services, it may indicate reductions for others. VBID is based on clinically nuanced cost sharing, which includes the idea that different medical services offer different benefits, and that the clinical benefit of a medical service depends on the individual patient, on his/her location on the disease trajectory, and on the healthcare provider and facility.²⁷ “The more you support clinically nuanced payment and consumer incentives, the better you’ll be able to function as a true safety net organization,” said Fendrick.

Grant Lawless, RPH, MD, FACP, Associate Professor of Clinical Pharmacy and Pharmaceutical Economics and Policy, University of Southern California, and Vice Chair, Board of Directors, PAN Foundation, suggested that pricing should be determined from a more patient-oriented standpoint. We might try, he said, “to have a different group of people thinking about pricing, making that more reflective of patient and medical needs, and not just something that’s mathematically figured out in a blind alley.”

The term, “value,” is a widely used term, maintained Lawless. Does it mean the most financially prudent drug with a reasonably good outcome? Or is it the very best possible drug for a patient’s individual outcome? “Are we really trying to find out what the very best possible drug is for that patient or are we looking for one that’s going to be a reasonably good enough drug at a very good discount price? Sometimes the cheapest drug is good enough, but not always. I think the long-term value is the best possible outcome, particularly in something like a cancer, MS, RA. Something like that where you’re going to have lifetime consequences.”

VBID AND MEDICARE

Can you design an insurance benefit that (1) would encourage the use of high value healthcare interventions, including a lot of diverse interventions that are not necessarily cost-saving, and (2) maintain the financial sustainability of such plans?

— JENNY BRYANT

²⁶www.vbid.health.com.

²⁷PAN Foundation, Cost-Sharing Roundtable: Improving Patient Access to Critical Therapies. Proceedings Report. February 26, 2016. https://www.panfoundation.org/files/PAN_CostSharingRoundtable_FullReport.pdf. Accessed March 12, 2017.

Lawless continued, “Employers are always trying to keep the premiums down as low as they can [because] they’re trying to protect the affordability of the premium so they can offer reasonable-cost health insurance to their employees. But the sicker the employee is, the longer he/she stays. If you don’t give them good care up front, if you don’t offer them the very best drug for the most effective and efficient outcome, they’re going to get sicker and sicker and actually over the course of their tenure, cost you more money than anybody else.”

More efficient spending and patient assistance dollars that go further are things we [pharmaceutical companies] can live with, explained Bryant. “[PhRMA] was at an event just this week to launch a new value collective that’s about trying to drive policies and projects to get us closer to a value-based system.” She continued, “A lot of the companies are saying essentially, ‘we’ll do risk sharing,’ ‘we’ll pay for performance,’ ‘we want to be part of the evolution of the whole healthcare system toward one that’s more geared toward value.’ I believe that the safety net will be less strained if we can be more value-based.”

“I think that what’s important to be thinking about strategically is how to make sure that, especially as we look at the Medicare benefit, there’s a lot of attention to helping that move in a value-based direction so that patients who need the medicine can afford it and that we don’t allow plans to be assessing cost sharing, which will force people into the safety net for medicines that they absolutely need to be on,” said Bryant.

Klein concurred: “To the degree that the health plans are using VBID and high-need, high-cost patients are not being asked to pick up a disproportionate share of OOP cost, they’re not coming to PAN.” However, he added, the cost barriers are just too high to be able to eliminate the need for patient assistance.

“Yes, we want innovative new therapies. Everybody does. But at some point, society can’t really afford all of them or we’re going to have to find some other ways to pay for them, just given the way that our current system is designed.”

— MATT EYLES

Sources and Impacts of Uncertainty

“I think we are all here in these uncertain times with a common interest and concern for how our healthcare system responds to the needs of patients.” — TRICIA NEUMAN

ACA “Repeal and Replace”

PAN’s second Roundtable was held in February 2017, at the height of Congressional debate on the ACA. The meeting included much discussion on uncertainties associated with this policy debate. After the meeting, efforts to repeal and replace the ACA did not move forward in Congress, leaving the ACA intact. However, much uncertainty remains on the topic of cost sharing for economically vulnerable patients, and panelists’ thoughts about the uncertainty of the ACA policy debate provide insight into future efforts to craft policies that address the needs of these patients. Many of the specific features of suggested alternatives to the ACA provide hints into what future policy changes may involve, and what the possible impacts may be.

“So here’s something that’s very troubling to me,” said Goodman. “Before November 8 or January 20 it was already pretty complicated. In all the . . . research that’s been done, and the experiences shared [today, it’s clear that] we weren’t doing so well [before] with managing the financial challenges, and now it seems to be far less certain and more risky. Who’s going to be ready to start to be able to adapt on the fly here, when it sounds like the financial burden may even be higher if the ACA recedes?”

Neuman agreed, “I think there’s a lot of uncertainty in terms of what the future holds. Lower prices in terms of Medicare, raising the age of eligibility, ACA repeal. There’s a lot we do not know. There’s a lot of

“There is a lot of concern about what ACA ‘repeal, replace, rebuild, remodel’ will mean for people with cancer and other serious diseases who were able to access coverage as a result of the ACA.”

“The ACA was a carefully constructed political compromise puzzle, and taking out some of the pieces has the potential to really unravel some of the agreements that made it possible in the first place, making it harder to do the rebuilding that people are talking about.”

— TRICIA NEUMAN

disagreement within the policy environment, and the outcome of these policy decisions has enormous implications for patients.”

In particular, there is a lot of concern about what ACA “repeal, replace, rebuild, remodel” will mean for people with cancer and other serious diseases who were able to access coverage as a result of the ACA, and the implications are not only for those on Medicare.

“One way to approach this is to think about the Congress vs., or in conjunction with, the Administration,” said Neuman. “We’ve been looking at and tracking what President Trump has been saying and what Speaker Ryan²⁸ has been saying, and. . .it’s not easy to say exactly where the Congress is and where the President is. In general, there’s not a lot of agreement, at least in what we’ve heard so far.”

The broad policy options in the proposed Republican healthcare alternative to the ACA, with President Trump’s position and Neuman’s comments, are shown in **TABLE 3**. Although this initiative did not have enough votes to move forward, many of its components may resurface in future attempts to reshape the nation’s healthcare system, and Neuman’s remarks give context for understanding their potential future implications.

Other proposed inclusions in the *A Better Way* agenda were health savings accounts (HSAs) and high-deductible health plans (HDHPs). Neuman noted that Medicare at one time offered HSAs, but these were very unpopular because, although they offered some tax benefits, they did not offer security. She said, “People are looking to have help with their healthcare costs and are looking for insurance that will soften the blow when they encounter a medical professional and there’s a high expense.” Goodman added, “The HDHP is a barrier to what can be highly cost-effective care for many patients, including a lot of patients with chronic diseases. You would keep the deductible in place, but not for certain things that are clearly beneficial. You’d set it aside and there would be no deductible for those services.”

“There’s interest in repealing the Medicare tax on high earners. That in and of itself would reduce revenue by \$130 billion, [which] affects the Medicare trust fund. When you affect the Medicare trust fund, you bring it to insolvency sooner, and that creates an environment, a sense of crisis sooner, which could lead to other changes.”

— TRICIA NEUMAN

²⁸House Speaker Paul Ryan (R-WI) put together the A Better Way agenda as a conservative initiative to repeal and replace the ACA.

TABLE 3 .
Medicare policy decisions on the horizon

OPTION	PRESIDENT TRUMP	SPEAKER RYAN: A Better Way	TRICIA NEUMAN'S COMMENTARY
Repeal ACA Medicare provisions	Unclear ²⁹	Some but not all	<ul style="list-style-type: none"> • Many ACA provisions, e.g., payment reductions, directly affect Medicare. • Changes such as new revenues, income-related premiums, payroll tax increase for high earners, fees, and delivery system reforms could impact high-need people. • If all ACA Medicare provisions were repealed, Medicare spending would increase by \$800 billion, so I suspect they will not be repealed.
Reduce drug prices	Supports	No Position	<ul style="list-style-type: none"> • The president seems willing to do something about drug prices and the public is enthusiastic about having the government engage in this issue. In a Kaiser study, 82% of the U.S. public favors allowing the federal government to negotiate drug prices for Medicare beneficiaries (93% Democrats, 85% Independents, 68% Republicans).³⁰
Raise age of eligibility	No Position	Supports	<ul style="list-style-type: none"> • Although the President has not taken a position on raising the age of eligibility, Speaker Ryan and the House have supported it numerous times in the past.
Change cost-sharing rules	No Position	Supports	<ul style="list-style-type: none"> • Changing Medicare cost-sharing rules is a complicated issue for people with high needs. Essentially, it refers to creating one deductible instead of two for Medicare Parts A and B, as well as a new OOP limit. This would result in lower deductibles for some, but higher deductibles for others. • Congress could avoid this dilemma by adding an OOP limit to traditional Medicare, which would level the playing field between Medicare Advantage plans and traditional Medicare, because Medicare HMOs and PPOs are now required to have an OOP limit, unlike traditional Medicare.
Restrict Medigap coverage	No position	Supports	<ul style="list-style-type: none"> • Restricting Medigap coverage³¹ has been raised as an option to reduce Medicare spending, responding to concerns that supplemental coverage leads to higher use of services because enrollees have less "skin in the game."

²⁹As of date of presentation. President Trump and Speaker Ryan since supported the American Health Care Act (AHCA), which would have repealed the Medicare payroll tax increase on high earners included in the ACA, but retained other ACA Medicare provisions, including all Medicare savings provisions, benefit improvements (including the phased in coverage in the Part D coverage gap), and payment and delivery system reforms.

³⁰Kaiser Family Foundation Health Tracking Poll (conducted September 14-20, 2016).

³¹Extra insurance to pay healthcare costs not covered by Medicare.

TABLE 3 .
Medicare policy decisions on the horizon

OPTION	PRESIDENT TRUMP	SPEAKER RYAN: A Better Way	TRICIA NEUMAN'S COMMENTARY
Allow private contracting between doctors and patients	No position	Supports	<ul style="list-style-type: none"> • Allowing private contracting would loosen current legal restrictions to make it easier for doctors enter into private contracts with some but not all of their Medicare patients. • Private contracting could potentially unravel financial protections under current law for Medicare beneficiaries, in which Medicare sets fees and most doctors accept these fees. • This could have both positive and negative effects on access to doctors. • Easing up on rules for private contracting could be appealing to physicians but could also raise costs for some patients, if their doctors charge more than Medicare now allows.
Premium support	No position	Supports	<ul style="list-style-type: none"> • Premium support refers to the idea of providing people on Medicare with a defined contribution that can be applied toward the cost of a private Medicare plan or traditional Medicare. This is a complicated proposal and a fundamental change to Medicare that would have uneven effects for beneficiaries across the country.
Medicaid block grants and/or Medicaid per-capita caps ³²	Supports	Supports	<ul style="list-style-type: none"> • This would be a fundamental change to the program. Key design features, such as how base payments are calculated and how payments would rise over time, have major implications for the ability to states to maintain coverage and services for covered populations, many of whom are considered "high need." • The impact on any given state would depend on numerous factors, including the growth in its older adult population on Medicaid. • Today, Medicaid supports 11 million people on Medicare, by paying Medicare's premiums and cost-sharing, and filling in critical gaps, such as long-term services and supports it provides.

³²A fixed amount given to each state to provide health care to low-income Medicaid recipients.

Neuman reiterated the uncertainty surrounding Medicaid block grants. “How will the block grant be structured?” she asked, “If spending is constrained by [a] factor that doesn’t keep up with healthcare costs then there could be a gap [that will grow] over time” [FIGURE 6].

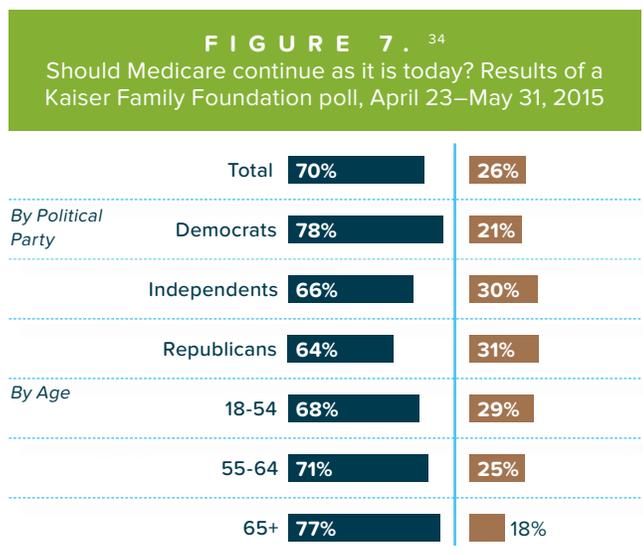
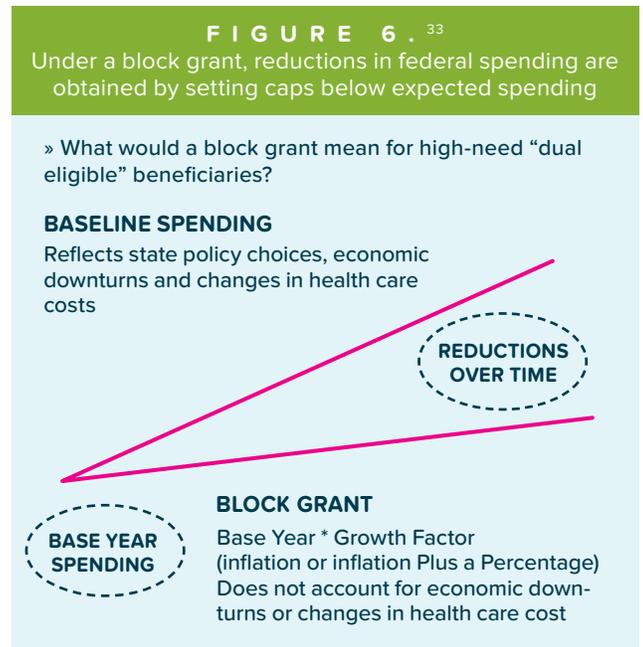
However, she continued, “we have an aging population, and there is a need to finance care for them, but at the moment there’s not an urgent crisis as we’ve seen in the past (in 1995, the trust fund was projected to be insolvent six years later in 2001). That said, if the ACA and the payroll taxes are repealed and spending goes up, that will bring [the trust fund] to insolvency sooner because Medicare spending would rise more rapidly and revenues would go down. But for now it’s not really a crisis.”

On the 50th anniversary of Medicare in 2015, the Kaiser Family Foundation conducted a survey to learn the views of the public on the program.³³ Results [FIGURE 7] indicated that most people think Medicare should continue unchanged, and about one-fourth would prefer that Medicare be changed to a premium support system, whereby the government would give each senior a fixed subsidy that they could apply to the purchase of traditional Medicare or private insurance.

Will Medicare go Broke?

The discussion about altering the ACA led to a question about the solvency of the Medicare program. “At the moment the Medicare trust fund is actually in pretty good shape,” Neuman said. It’s solvent, though there’s not an urgent crisis as we’ve seen in the past (in 1995, the trust fund was projected to be insolvent six years later in 2001). That said, if the ACA and the payroll taxes are repealed

³³Norton M, DiJulio B, Brodie M. Medicare and Medicaid at 50. July 17, 2015. Kaiser Family Foundation. <http://kff.org/medicaid/poll-finding/medicare-and-medicaid-at-50/>. Accessed March



70% Medicare should continue as it is today, with the government guaranteeing seniors health insurance and making sure that everyone can get the same defined set of benefits.

26% Medicare should be changed to a system in which the government would guarantee each senior a fixed contribution toward the cost of their health insurance. Seniors would apply that contribution toward the purchase of traditional Medicare from a list of private health plans

and spending goes up, that will bring [the trust fund] to insolvency sooner because Medicare spending would rise more rapidly and revenues would go down. But for now it's not really a crisis.

Looming Uncertainty for All Stakeholders

The current uncertainty surrounding cost sharing affects all stakeholders: patients, patient assistance organizations, healthcare providers, insurers, and patient advocacy groups. “There’s just so much uncertainty [and] we don’t have a crystal ball,” Doshi said. “We heard a lot of different stories around what is going to be proposed, or what might happen. But clearly the ACA’s repeal [will affect] a lot of patients—insurance exchanges, the Medicaid expansion—plus the specific elements in the ACA that are protective for Medicare beneficiaries, like closing off the donut hole.” Although the many questions about the ACA that were discussed at the Roundtable have been put on the back burner for the time being, there is still considerable uncertainty about how to ensure access to medications among millions of economically vulnerable Americans. The task of crafting policies to address this basic issue will continue to be a priority among clinicians, advocacy organizations, insurers, pharmaceutical companies and other stakeholders.

From the pharmaceutical industry perspective, Bryant predicted, “To the extent we’re looking at repeal and replace, it doesn’t look like coverage will be substantially more generous than what we have today. There’s clearly a concern that cost sharing might go up.” Klein raised the downstream effect on patient assistance organizations several times. “I think there is some worry that the need is going to outstrip the availability of funding and that there are pressures on the drug manufacturers that are not necessarily directed to patient systems, but impact on how they think about supporting patient assistance programs,” he said. To adapt to the OOP cost issue, especially in an era of increasing uncertainty, patient advocacy organizations have begun offering patient support programs (discussed further in Chapter 6).

“I’ve been talking so much about Medicare, but when we’re thinking about the needs of people who have significant illnesses and take expensive medications and have problems supporting their care, there is a tremendous uncertainty as to what would happen with the non-Medicare population, and that’s obviously the issue on peoples’ minds.”

— TRICIA NEUMAN

Short-Term Needs and Long-Term Solutions

“The ground is moving beneath our feet. What are going to be some sustainable strategies for providing access to medications?”

— CLIFFORD GOODMAN

Immediate Needs

A recurring theme of the Roundtable was the immediate need for sick people to get their medicine and the long-term need to find sustainable ways to make this possible. The upward trajectory of science—medical advances, precision medicine, gene therapy—was frequently contrasted with the price tag and the issue of access.

Another topic of discussion was the need for patients to be involved in conversations about the costs of their care. The details of what these conversations should involve, however, were less clear. Shankaran asked, “Do we talk about the specifics around how much a drug or a service is going to cost? Do we talk about, or do we simply acknowledge, that the cost of care is substantial and that we understand and we acknowledge and appreciate the struggle the patients are going through? What exactly does that communication involve? How do we incorporate that into the flow of clinical care?” In the oncology community, she said, “there’s been a lot of interest from organizations like ASCO (the American Society of Clinical Oncology) to improve communication between patients and physicians about the cost of care.” However, she noted that clinicians are not typically trained in discussing financial hardship with patients.

Shankaran continued, “I think the first step is acknowledging that there might be financial side effects of treatment and assembling a team around trying to address that [gap], because I think it’s challenging for doctors alone to navigate that.” She recommended (1) trying to figure out how individual care providers and health systems can programmatically improve communication around the cost of care, (2) involving patient advocacy and community organizations in the discussion and (3) developing health-system strategies to provide patients with realistic cost estimates prior to treatment. The importance of this was reiterated by Andrea Baer, MS, Director of Patient Advocacy, Mended Hearts, Inc., who said, “There are

people who are having to make the decision of ‘do I take this medicine that costs even \$15 a month, or do I buy food for my children?’ There’s a very big reality in the gap of information.”

Sustainable Strategies

To address the Roundtable’s topic of sustainable strategies for providing access to critical medications, several solutions were discussed. A recurring topic was the high price of drugs and the suggestion that prices be lowered. Other strategies included reconfiguring/eliminating specialty tiers and using clinical pathways, and the ideas proffered in the PAN Challenge winning and runner-up papers: value-based formularies and changes to Part D cost-sharing policies that favor spreading out OOP payments over the course of the calendar year.

Drug Prices and Specialty Tiers

“I would ask the fundamental question,” said Matt Eyles, Executive Vice President, Policy & Regulatory Affairs, America’s Health Insurance Plans. “How did we arrive at a \$750,000 price as being the right price [for a medication]?” If the price were lower, he said we wouldn’t be having a debate. But as it is, he said, “When you look at the trends across the industry, there are grave concerns among payers about excessive launch prices/ excessive price increases. When you look at the growth of prices just for old therapies over time and now looking at new therapies and what happens in the market, I mean it’s extraordinarily concerning.”

Bryant said that federal estimates for drug spending are more or less in line with healthcare spending in general. Projected general health spending and prescription drug spending are projected to grow at average rates of 5.8% and 6.7% (respectively) per year until 2025.³⁴ Drug spending does not appear to be the “Pac-Man that is eating the entire healthcare budget,” she said.

“There are people who are having to make the decision of ‘do I take this medicine that costs even \$15 a month, or do I buy food for my children?’ There’s a very big reality in the gap of information.”

— ANDREA BAER

“People who work in the pharmaceutical industry get up and go to work every day because they are engaged in developing medicines to treat patients. If patients can’t get those medicines, that really defeats the entire purpose.”

— JENNY BRYANT

³⁴Centers for Medicare & Medicaid Services. NHE (National Health Expenditure) Fact Sheet. Updated December 2, 2016. <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html>, Accessed March 19, 2017.

Regardless, patients disproportionately feel the pain of OOP costs when it comes to their medications (i.e., much more than with their other healthcare expenses). “Most OOP exposure to patients for drugs in almost all types of plans is substantially higher than the other sectors.” said Fendrick.

The high drug prices reported in the press are the list prices, not the net prices, said Bryant, and even though pharmaceutical companies sometimes lower drug prices, these discounts (some as high as 50%) are not passed on to patients. “Those savings are real and those savings flow back to employers and to the government and to patients through lower premiums,” she said. “But [the savings] didn’t happen for the patient taking that medicine because their coinsurance was still tied to that higher price.”

Goodman clarified, “That list price, that sticker price is typically not the real price. The real price is largely non-transparent. But ultimately the patient still has his or her percentage of what is still a large number based on the sticker price.” Fendrick added, “It’s interesting that those two different prices. . .are now equal in the world of a HDHP.” He continued, “the EpiPen phenomenon³⁶ would not have been known if many of those moms who were going to fill their EpiPen [prescription] this summer had been moved into a new type of health plan that instead of paying \$50 when the price was \$100, \$200, \$400, \$600, they were now seeing \$600, which is not what anyone else was paying. This idea of what it costs patients is what really matters.”

Doshi agreed, “When I pay co-insurance on a drug right now under my insurance plan, I’m paying on the list price and not the discounted price that the payers and all the other folks, the PBMs [pharmacy benefit managers] and everybody else gets. Most patients don’t know that. I think that’s shocking.”

According to Bryant, the pharmaceutical industry is very concerned with the ability of patients to access their medications. She said, “People who work in the pharmaceutical industry get up and go to work every day because they are engaged in developing medicines to treat patients. If patients can’t get those medicines, that really defeats the entire purpose.” She acknowledged that pharmaceutical companies do expect a return on their investment, but realize that there’s a cultural value to ensuring access. “[Lack of

“Allergan CEO Brent Saunders issued in the fall a statement that industry should have a social contract with patients and pledge that for his company there wouldn’t be more than a 10% price increase over time per year.³⁵ Is that something that you find attractive? Because certainly industry has a role here in terms of predictability of costs; the pushback is always the high cost of research.”

— L. STEPHAN VINCZE
*Interim Chief Compliance Officer, Kastle
Therapeutics*

³⁵Carroll J. Allergan CEO Brent Saunders takes a pricing pledge: Predatory practices must end. Endpoints News, September 6, 2016. <https://endpts.com/allergan-ceo-brent-saunders-takes-a-pricing-pledge-predatory-practices-must-end/>. Accessed March 23, 2017.

³⁶Between 2009 and 2016, the pharmaceutical company Mylan raised the base price of its two-pack of EpiPens from \$100 to over \$600, attracting negative media attention and resulting in questioning of Mylan’s CEO before the House Oversight Panel in September 2016. Source: Bomey N. 5 Things we learned from the EpiPen price hike hearing. USA Today. September 22, 2016. <http://www.usatoday.com/story/money/2016/09/22/epipen-congress-hearing-mylan/90827270/>. Accessed March 23, 2017.

access has] been really challenging in recent years,” she said. “In the commercial market and in Medicare, as we see more and more patients who are facing very high deductibles.”

However, Bryant explained that insurers share responsibility for high OOP drug costs (i.e., high deductibles), the Medicare benefit structure, and the specialty tier mechanism. She commented, “placing high-cost sharing on medicines in an arbitrary way without the ability to have a patient seek an exception even when it’s been prior-authorized by the plan, [when] they’ve gone through step therapy, and it’s absolutely the right medicine because they have a genetic marker for the medicine is an example of where Part D could be more value-based.”

According to Fendrick, there is undue focus on the drug portion of OOP costs, and not enough emphasis on understanding the value of other healthcare sectors that could be driving up costs unnecessarily. “Drugs, unlike the other sectors, have to have two randomized clinical trials to show evidence of benefit, at least safety and efficacy. . . If you’re going to apply that scrutiny, please apply the scrutiny to the entire healthcare sector and not just drug.”

Lawless made a few additional points: (1) there are many new drugs that are very expensive; (2) if they have high value (i.e., accomplish their clinical goals), they are worth paying for; but (3) it may not be reasonable to ask insurers to pay for “extraordinary products and services.” He suggested that there should be a stop-loss type of program in which the expenses of patients who are extremely sick are jointly funded by multiple payers (including government underwriting) so that regular insurance carriers (Medicare, Medicaid, commercial) do not have to pick up the entire cost. “It’s kind of like what happens in auto insurance,” he explained. “You [separate out the] high-risk groups of people so that insurers can price towards the ordinary. Then the premiums stay reasonable for ordinary individuals and those extraordinary, very small number [but high-cost] people can be dealt with as a separate bucket.”

Clinical Pathways

As part of the larger conversation about drug costs and value, Baer asked, “What is going to be the sustainable solution to make sure that patients regardless of their income are receiving quality healthcare?” She continued, “I can tell you that through our organization we see patients who have the

“Americans do not care about drug prices. They care about what it costs them.”

— MARK FENDRICK

“I think [the question] we need to focus on is: Do we have the types of insurance mechanisms for spreading risk and sharing risk that’ll be sustainable in an era where we have many medicines that will have high costs and that will be used by small populations?”

— JENNY BRYANT

money to pay these high-premium costs for their healthcare getting way better care than people who are stuck in the Medicare or Medicaid system, where their choices aren't being made by their doctors, they're being made by their insurance companies." She concluded by putting into words the question that gave rise to the Roundtable: What are we going to be able to do to ensure that how much you're paying for your healthcare doesn't regulate what your healthcare provides to you?

"You're asking the universal question of all questions," said Anderson. "How do I get good medical care? One of the things that has been tried is something called 'clinical pathways.' It started in oncology and it's gone to other areas as well. The idea is to (1) snip off the low-end stuff that's inexpensive, but doesn't work, and the very high-end stuff that costs a lot of money that's just not worth it, then (2) try to follow a standard kind of a cookbook pathway." Anderson concluded that extending the clinical pathways concept from purely clinical care to financial obligation as well might be a way to get a handle on costs.

"As we start thinking about having better markers and having better biologics in order to understand what the right drug is for the right patient," Goodman said, "if the patient and that doctor follow the right guideline, than maybe that OOP cost should either be minimal or none at all. Because [using clinical pathways,] ultimately you're going to have the best outcome, even if it's the most expensive drug. But it gives you the best possible outcome because you're on the right drug."

Goodman commented that there is a systemwide chain of reasoning inherent in this global question, i.e., "collect data; build the evidence; gain a knowledge base; then translate it into clinical practice guidelines, which can often be transformed into pathways, which are more specific. Then you've got the pathways, but you have to make sure the incentive's in place to actually use them." It's important to make sure you're investing in the right data analytics, added Eyles, "to understand exactly what's happening to the patients that you're serving."

³⁷<http://www.chop.edu/pathways>.

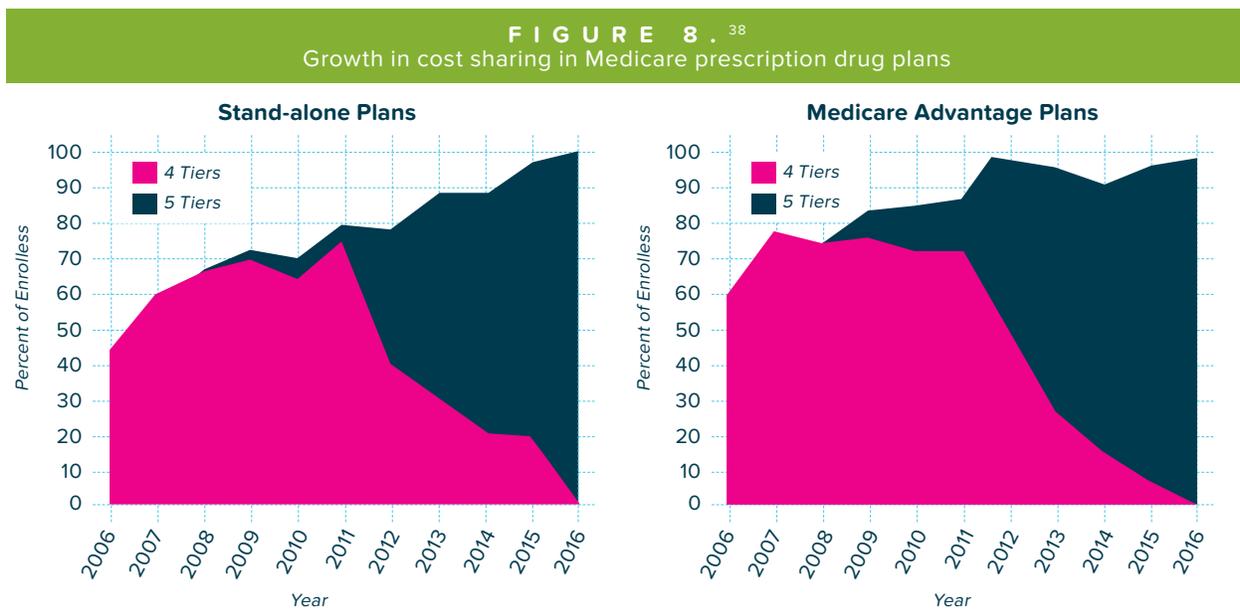
"What are we going to be able to do to ensure that how much you're paying for your healthcare doesn't regulate what your healthcare provides to you?"

— ANDREA BAER

A clinical pathway is a task-oriented care plan that details essential steps in the care of patients with a specific clinical problem and describes the patient's expected clinical course. The goal of clinical pathways is to standardize care, improve outcomes, and reduce cost.³⁷

Value-Based Formularies

In his presentation of the winning PAN Challenge paper, *Impact of a Value-Based Formulary in Three Chronic Disease Cohorts*,³⁸ lead author Kai Yeung, PharmD, PhD, Scientific Investigator, Group Health Research Institute, began by pointing out the tremendous growth in cost sharing in Medicare prescription drug plans in the past decade (**FIGURE 8**, left side). Since 2006, he said, “in Medicare stand-alone plans, the members that are covered by high cost-sharing tiers, which include the specialty medication tiers, have increased dramatically,” a trend that “has largely been mirrored in the Medicare Advantage plans”³⁹ [**FIGURE 8**, right side].



Yeung continued, “The problem with these increases in cost sharing is that they’re based on the cost of the drug to the plan, rather than the value that these drugs provide to the patient, potentially leading to the inefficient use of drugs.” Designing insurance to encourage higher-value use of healthcare interventions is one approach to cost sharing more intelligently, he said, as he began discussing VBID (introduced in Chapter 3) in the context of Medicare Advantage. In their paper, Yeung and colleagues wrote that “There has been recent federal interest in the exploration of effects of VBID for patients with particular chronic conditions.⁴⁰ Beginning in January 2017, the Center for Medicare and Medicaid

³⁸Yeung K, Basu A, Marcum AZ, Watkins JB, Sullivan SD. Impact of a value-based formulary in three chronic disease cohorts. PAN Challenge winner. December 20, 2016.

³⁹Medicare Advantage plans can offer extra coverage (<https://www.medicare.gov/what-medicare-covers/medicare-health-plans/medicare-advantage-plans-cover-all-medicare-services.html>).

Innovation (CMMI) will be granting Medicare Advantage plans in seven states the ability to pilot VBID for enrollees with at least one of seven chronic conditions.”

In this context, Yeung explained, VBID is used as an approach to reduce cost sharing for certain high-value healthcare services, including pharmaceuticals, with the dual goals of improving patient health outcomes and creating cost savings to Medicare. Yeung continued, “In 2010, Premera Blue Cross, which is the largest nonprofit health plan in the Pacific Northwest, implemented a value-based formulary [VBF] approach, which I consider to be a fuller realization of [the VBID] philosophy, that explicitly estimates the value of each individual drug within a formulary using cost-effectiveness analysis.” Yeung explained that this involves placing drugs on co-pay tiers based on estimated value. Potentially cost-saving drugs, or ones in which benefits greatly outweigh costs, are placed on lower co-pay tiers to incentivize use, and drugs of lower value are placed on higher co-pay tiers to de-incentivize use.

In their paper, Yeung et al. examined the effect of Premera’s VBF implementation on health plan expenditures and medication adherence in diabetes, hypertension and hyperlipidemia. The study design was a retrospective cohort analysis of employer-sponsored plans from 2006 to 2013. The intervention group consisted of beneficiaries exposed to the VBF, and the control group included beneficiaries in similar plans with unchanged pharmacy benefits (i.e., without VBF). “Proportion of days covered” (PDC) was used as a proxy for medication adherence. This outcome is important because it provides insight into whether a beneficiary is accessing his or her medication. Previous research has shown that higher OOP costs decrease drug access.

Results of the study indicated that VBF reduced OOP costs for diabetes and hypertension and increased costs for hyperlipidemia [TABLE 4]. For the diabetes cohort, there was a statistically significant

“I think all of us want to see more progress faster so that we can move towards these value-based benefit designs.”

— MATT EYLES

TABLE 4.⁴¹
Effect of VBF on medication adherence and expenditures

MEDICATION	OVERALL CO-PAY	PDC	EXPENDITURES	PRICE SENSITIVITY
Anti-diabetic	↓	=	↓ member, ↓ total	Y
Anti-hypertensive	↓	=	↓ member, ↑ plan	N
Anti-hyperlipidemic	↑	=	=	Y

PDC, proportion of days covered – a proxy for medication adherence

⁴⁰Hanley S. Announcement of Medicare Advantage Value-Based Insurance Design Model Test. 2015; <https://innovation.cms.gov/Files/reports/VBID-Announcement-REVISED-10-9-15.pdf>. Accessed March 19, 2017.

⁴¹Yeung K, Basu A, Marcum AZ, Watkins JB, Sullivan SD. Impact of a value-based formulary in three chronic disease cohorts. PAN Challenge winner. December 20, 2016.

reduction in member and overall expenditures of \$5 per member per month (PMPM) and \$9 PMPM respectively. For the hypertension cohort, there was a statistically significant reduction in member expenditures of \$4 PMPM and increase in health plan expenditures of \$3 PMPM. There were no statistically significant effects on hyperlipidemia cohort expenditures or on medication adherence in any of the three disease cohorts. The lack of impact on overall adherence is not surprising, commented Yeung, as some medications had increased co-pays, which is associated with lower adherence, and some with decreased co-pays, and thus higher adherence. Exploratory analyses suggest that patients in the diabetes and hyperlipidemia cohorts were switching toward higher-value medications.

Although the United States has a fragmented healthcare system, one advantage of this system is that it contains diverse health plans that allow for experimentation, such as was done by Premera. Yeung said, “The neat thing about this particular implementation is [that] they did not set a binary threshold, but a series of thresholds that were tied to co-payments such that even drugs which were ‘average,’ for the average patient, not of high value, could be obtained and funded by the health plan, but just at a higher cost. So that provides a little bit of incentive, which is what cost-effectiveness is attempting to do, and also provides potential information signals to the patient with regards to the value of the medication.” Yeung continued, “I believe our results have important implications for design of future VBFs,” with the impact largely dependent on the four factors listed in the sidebar above.

To facilitate VBF adoption, drug manufacturers can help clarify value by sharing cost-effectiveness data and participating in partnerships with organizations such as Premera, and should also be rewarded for their innovation when they create high-value medications. “Having additional partnerships and communications as VBFs grow is important,” said Yeung.

He concluded by explaining that it is important to take clinical nuance into account when designing VBF plans, with the caveat that we must avoid creating systems that are of lower value. “In an ideal world,” said Doshi, “we’d want a personalized VBF. As we move to this world of personalized medicine and companion diagnostics, ideally if a diagnostic tells you that this drug is going to work for this patient or is going to be less toxic, the patient should be paying minimal or no cost sharing for that drug because of its high value.”

IMPACT OF VBF DEPENDS ON FOUR FACTORS

- » Magnitude and direction of co-pay changes
- » Sensitivity of individuals to co-pay changes (i.e., elasticity of demand)
- » Incremental effect of change in medication utilization on costs and outcomes
- » Relative number of individuals on high- vs. low-value drugs prior to VBF implementation

— KAI YOUNG

Potential Changes to Part D Cost-Sharing Policies

In their PAN Challenge paper, Doshi et al. examined OOP costs patterns under the existing Part D cost-sharing policies for non-LIS specialty drug users, and the impact of these costs if (a) their own recommendations or (b) recommendations of the Medicare Payment Advisory Commission (MedPAC) were implemented (both sets of recommendations are listed in **TABLE 5**). Using Medicare claims data for patients who were full-year users of three of the top-spending specialty drug categories (RA, MS, and CML), they found that Medicare Part D OOP cost patterns were characterized by (1) varying medication co-pays, (2) fluctuating specialty drug coinsurance costs being concentrated at the beginning of the year, (3) substantial OOP costs even during the catastrophic coverage phase and (4) no annual OOP spending cap: a cycle that has been described as a “cost-sharing roller coaster” (see **FIGURE 9**).⁴²

Mean monthly OOP prescription drug spending under the current Part D structure is shown in **FIGURE 10**, and what they would be under the proposed MedPAC changes are shown in **FIGURE 11**. The dotted line in **FIGURE 12** shows what the costs would look like in the Doshi et al. plan, in which monthly OOP maximums are imposed and the total yearly cost is divided by 12. In the Doshi et al. plan, patients would pay a maximum of \$392 OOP each month, thus avoiding spikes in cost and providing financial predictability throughout the year.

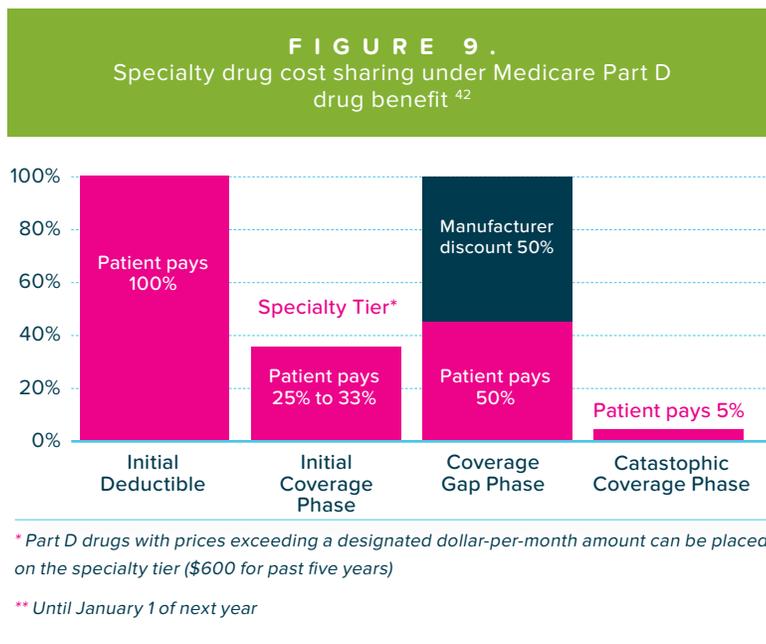


TABLE 5 .
Proposed Medicare Part D changes: MedPAC and Doshi et al.

MEDPAC	DOSHI ET AL.
During the catastrophic coverage phase, eliminate the 5% cost-sharing requirement, effectively creating an OOP spending maximum equal to the true OOP (TrOOP) spending limit that triggers catastrophic coverage (\$4,700 in 2012)	During the catastrophic coverage phase, eliminate the 5% cost-sharing requirement, effectively creating an OOP spending maximum equal to the TrOOP spending limit that triggers catastrophic coverage (\$4,700 in 2012)
During the coverage gap phase, no longer credit the 50% manufacturer discount for brand-name medications towards calculation of patients' TrOOP spending	Continue to credit manufacturer discounts for brand name medications toward calculation of patients' TrOOP spending
	Divide annual OOP spending maximum by 12 to create a monthly OOP spending maximum (i.e., smooth out costs akin to payment options offered by energy companies for heating bills)

⁴²Stuart B, Briesacher BA, Shea DG, Cooper B, Baysac FS, Limcangco MR. Riding the rollercoaster: The ups and downs in out-of-pocket spending under the standard Medicare drug benefit. Health Aff (Millwood). 2005;24(4):1022-1031.

FIGURE 10.
Observed mean monthly OOP prescription drug spending under current Part D structure (2012)

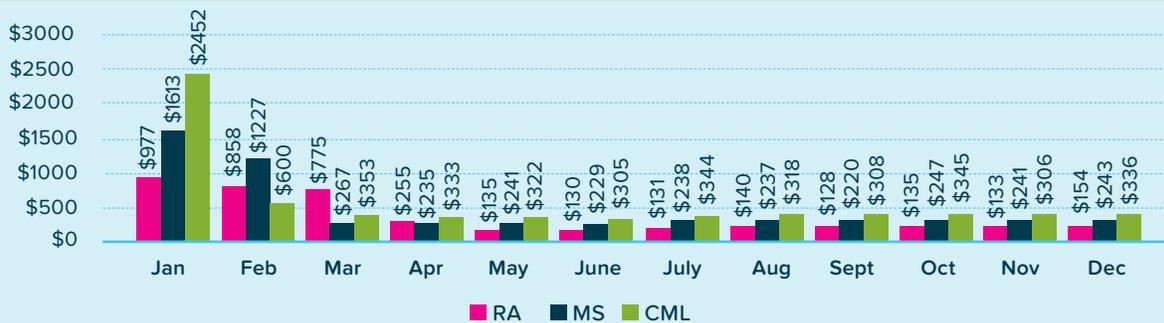


FIGURE 11.
Simulated mean monthly OOP prescription drug spending under proposed MedPAC changes

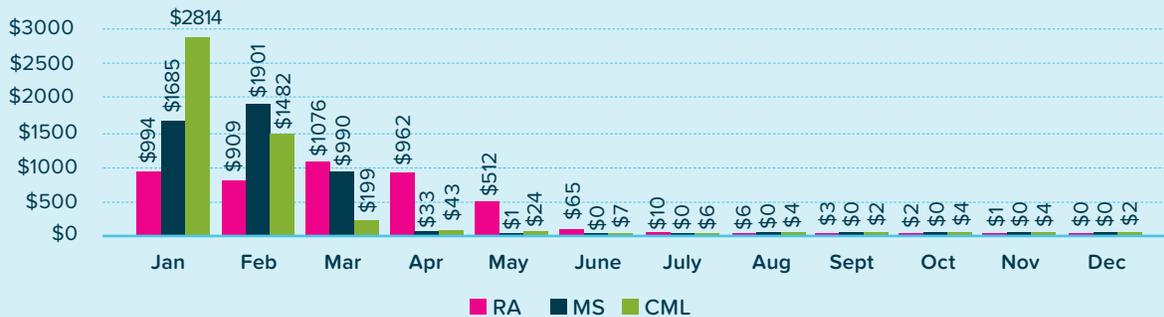


FIGURE 12.
Simulated mean monthly OOP prescription drug spending under Doshi et al.'s proposed changes



To determine the incremental costs of implementing this strategy, and whether it would be financially sustainable, Doshi and her colleagues used publicly available data to estimate what it would take to provide this kind of coverage to all non-LIS beneficiaries, not just those with one of the three diseases studied. They found that the incremental cost for a beneficiary per year would be \$24, or \$2 per month. Doshi said, “The increased cost would not be a straight pass-through cost via increased premiums, but would be borne out through the Part D plan bidding process, so it would in fact turn out to be even a lower cost burden for all of these patients.”

To those who might say that this plan will be complicated for pharmacies to implement (e.g., the patient pays \$400 toward the initial \$2,400 obligation, and pays the rest in \$400 increments each month), Doshi said her answer is simple: working out the logistics is truly a worthwhile goal given how high the stakes are. Further, she pointed out, it is only in the case of prescription drugs where patients are required to make payments upfront; for other services, patients receive bills after the fact.

Long-term solutions such as those described above are needed because current strategies present roadblocks to medication access and ultimately are not sustainable. For many conditions, concluded Doshi, “Specialty drugs represent treatments for patients who often have few or no effective alternatives, but treatments can only be effective, and patients can only derive true benefits if they can actually access them.”

“Our proposed strategy would essentially distribute costs across the year and likely increase patients’ ability to meet cost-sharing obligations. The strategy has manageable incremental costs, regardless of the ultimate financing mechanism.”

— JALPA DOSHI

Understanding and Responding to the Patient Experience

“When you’re in a critical care situation, who has the time or the energy or the emotional ability to make 17 phone calls?” — ANDREA BAER

Struggling Below the Stratosphere

The range of high-need patients—from those on high-tier drugs with high OOP costs to those on lower-tier drugs with lower OOP costs who still can’t afford them—was discussed often during the Roundtable, although it is the latter group that is most often supported by organizations like PAN. The patients whom PAN typically helps are not all on “\$700,000 drugs,” said Klein. “The average amount of assistance we provide is several thousand dollars a year. I want to reframe this around the notion that there is a group of people within Medicare in particular between 150% and 400% of Federal Poverty Level who have trouble getting access even before they get to the donut hole, getting through the \$400 front-end deductible, getting through their 25% coinsurance, let alone getting into the coverage gap. By the time you get up to the catastrophic limit, the total spend is around \$8,000. We’re talking about total spend: health plan and OOP. We’re not in the stratospheric realm of \$700,000.”

He continued, “The people we’re helping are people who are above the LIS who, without the kind of help we provide, aren’t going to get access to fairly standard drugs.” Klein explained that even some relatively common drugs are “categorized within Medicare as specialty drugs because they’re more than \$600, but there are a lot of drugs that fall into that category.”

“A critical point is really around the distributional effects of who needs the assistance,” said Eyles. “When we’re talking about income-related assistance, it’s very different than when you’re trying to provide assistance to the entire universe of people who can afford it and who can’t. People who have fewer resources can have difficulty affording access to treatments. That’s why there are greater subsidies in many programs for low-income people. In Medicaid, there’s almost no co-payment. We have made some of those adjustments, but we need to think more holistically as a society around some of those adjustments.”

I am the Patient. This is Cancer.

In the 2016 Roundtable, case studies of patients were presented by patient advocacy organizations to illustrate the impact of cost sharing. In the 2017 Roundtable, a cancer patient was invited to share her experience directly with panelists and attendees. Melissa Thompson, MBA opened her presentation, *I Am the Patient*, by noting that most patients are not aware of the costs of their treatment. She indicated that when people get a serious diagnosis, they are laser-focused on their care, and it is hard for them to grasp the complicated details of costs and insurance benefits. From the patient advocacy perspective, Richards elaborated, “I think there’s an overarching experience across the different disease states, in which you take [individuals] who are either receiving their own complicated and highly emotional healthcare diagnosis, or one of a child, a parent [or other] loved one, and then we put them into the most complicated financial instruments, then we dump them into the coverage world, which is both highly critical, but also really complicated.”

“Last year,” said Thompson, “I had over \$1.2 million in paid-out claims for my healthcare, and this year almost all of the marketplace insurance companies dropped out of the plans for Connecticut, where I live.” After her marketplace insurance became unavailable, Thompson discovered that her only two plan options had no cap on OOP expenses. At that point, she realized that if she had gotten diagnosed one year later, she would have been personally responsible for \$373,000.

Thompson was unable to find a millennial gap, supplemental or individual plan to help with OOP costs, so she filed for a co-pay assistance program. “The first day of the year,” she said, “I got an infusion and my deductible was over \$12,000. I got the bill in the mail and I thought it was a joke.” She tried to estimate her annual costs in an effort to budget (e.g., one monthly injection at the hospital times 12, times 30%) but then additional unexpected costs would arise. “I’m totally frightened of what I will need, what’s going to happen,” Thompson admitted. She ended her remarks with a sincere thank you to PAN and others that offer OOP cost assistance and serve as a safety net. “The need for helping patients is, as you can see, very great and very appreciated,” she concluded, “thank you for all you do.”



“Now I’m at a place where I don’t know what to do going forward. I have this insurance where I have to try to think ahead because there’s no cap. . .”

— MELISSA THOMPSON

“If I had gotten diagnosed one year later, I would have been responsible for \$373,000 worth of healthcare costs, personally.”

— MELISSA THOMPSON

Helping Patients Navigate the System

The Roundtable agenda included case study presentations focusing on patient support, and featured work from the Fred Hutchinson Cancer Research Center and Mended Hearts, Inc.

Financial Literacy

Fred Hutchinson Cancer Research Center Case Study

Shankaran's case study laid out the financial hardships often faced by cancer patients (see Chapters 2 and 3), and then, tying in with Thompson's comments on patients' need for help navigating the system, described some practical strategies to deal with financial toxicity. To respond to the lack of cost transparency, lack of communication and lack of consistent access to patient assistance programs, the Fred Hutchinson Cancer Research Center set out to design a financial literacy and navigation program that addresses these issues. The development process consisted of three phases.

Phase 1: Patient Engagement

In Phase 1 of the process, researchers conducted interviews to understand patients' financial experiences during treatment, perspectives on communicating about costs, and their interest level in a financial literacy course. They found that:

- » After a cancer diagnosis, patients often became unemployed, filed for disability or took early retirement, with an overall post-diagnosis decline in income followed by debt, non-adherence to medication and use of savings and retirement benefits to pay for care;
- » Patients did not routinely discuss cost with their providers or seek outside advice about finances, very few patients had prior knowledge about treatment costs and only half thought that physicians should discuss costs when making treatment recommendations (see sidebar above); and
- » Most patients wanted a financial literacy and counseling program that was (1) in person; (2) started at diagnosis and continued throughout treatment; and (3) covered money management, where to look for co-pay assistance, and how to choose and navigate an insurance plan.

FOUR PATIENT NEEDS

- » Quality and safety
- » Access to medication, care, and information
- » Navigation of costs (i.e., clarification of costs and benefits)
- » Dignity rooted in communication

— MELISSA THOMPSON

“Discussing costs were potentially viewed as being a way of steering patients away from optimal care.”

— VEENA SHANKARAN

Phase 2: Program Development and Pilot

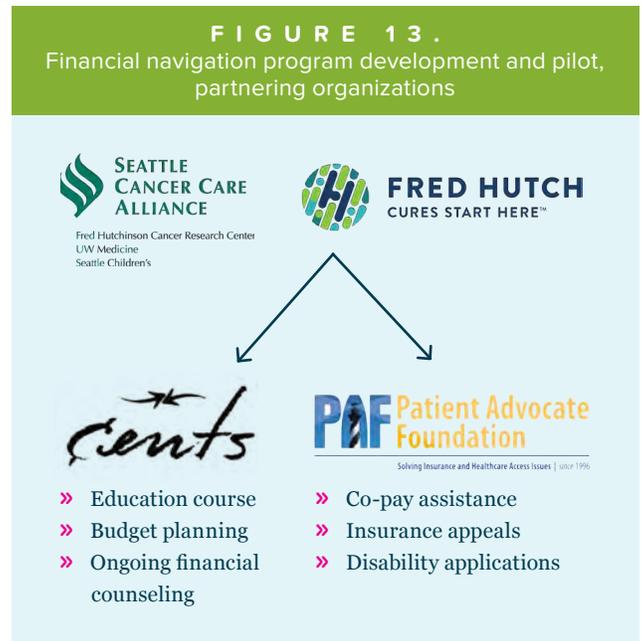
Based on results from the survey, the financial navigation program was developed as a partnership among several organizations (FIGURE 13). It included financial literacy (basics of insurance, employment rights, interpreting medical bills and patient assistance resources) and financial assistance (financial counseling/ budget management, assistance for cancer drugs, insurance appeals and transportation) topics. Patients who were within one year of non-metastatic cancer diagnosis, received/were soon to receive some form of therapy (chemotherapy, radiation, hormonal therapy), and were able to read and speak English, took the financial literacy class then met with a financial coach and were contacted periodically by a patient advocate over a six-month period. These patients were given information about their own insurance benefits, including their deductibles, OOP limits, and co-pays and coinsurance for typical services.

Of 34 patients who entered the program, 20 completed at least some part of it. Many who dropped out were overwhelmed with their treatment and surrounding logistics. All patients in the pilot had insurance (25% had Medicaid; the rest had commercial or Medicare insurance), and a substantial proportion experienced debt during treatment, declines in income, some loans from family and friends and denials for coverage during the course of treatment. Close to 40% reported high financial burden, and almost half reported high anxiety about treatment costs. Shankaran said the program was timely and well received.

“There was high satisfaction with all components of the program and we’re looking right now at some of the costs recuperated for patients during the context of this program,” she said. “The most common interventions were help with budget planning, retirement planning, and questions around medical bills, and co-payment assistance, help with cost-of-living issues and help with disability applications and employment rights.”

Phase 3: Financial Navigation and Randomized Study

Shankaran explained that the next step of their work will be to perform a randomized study with the goal of showing that helping newly diagnosed cancer patients via proactive financial counseling and access to financial assistance resources will decrease financial hardship and improve clinical outcomes. She said, “We’ll be looking at various endpoints including financial hardship, quality of life, outcome and cost recovered by institutions.”



Additional Thoughts on Increasing Financial Literacy

“There are lots of interventions that can be done on both the physician and clinic side to improve patient financial burden,” said Shankaran. Along these lines, a Roundtable attendee suggested increased education about generic drug alternatives. He mentioned that an analysis of Medicare patients showed that switching from name-brand drugs to generics would have reduced the cost of the study medication from \$80 to \$6. Despite this finding, he said, “Only a very small percentage of these patients switch to generic drugs. A much larger proportion give up standard [drugs] totally instead of switching to generics. That’s really shocking.”

Using Electronic Medical Records to Increase Clarity around Treatment Alternatives, Add Value and Streamline Coverage

During the Q&A portion of the panel discussion entitled, *Addressing the Needs of Patients*, an attendee began by highlighting the value of having patients’ insurance information included in the medical record. “This would show what OOP costs are associated with different choices, making it much easier for patients to make an informed decision,” he said. Shankaran said that at the Fred Hutchinson Cancer Research Center, when physicians order prescriptions via their electronic medical record (EMR) system, the system will show whether drugs are formulary or non-formulary,⁴³ indicate the costs and suggest alternatives. “That’s been really helpful,” Shankaran said, “because when you’re sitting in the patient encounter ordering your prescription, patients are going to go by what you suggest, and they want the reassurance that if you’re going to suggest an alternative, it’s going to be similarly effective and that they’re still getting good treatment.” Without this type of support at the point of decision-making, patients find out the cost at the pharmacy and are less comfortable going with an alternative because they don’t know if it will be as effective as the option their physician prescribed.

Richards agreed, “I think that the electronic health records conversation is an important one here. Is there a way to empower patients, as well as their providers and everyone in the system, to have the right information about each other at the right time to make a significant difference?”

Fendrick concurred as well, “This multi-stakeholder group needs to get behind the fact that the investment we’ve made in EMRs has been woefully underutilized to take care of patients. Imagine your EMR telling your pharmacist that a patient’s HbA1c remains high despite the use of multiple generic medicines and the only alternative is a branded drug that I have to have a prior authorization for. Imagine the EMR removing that prior authorization when the drug is clinically indicated. The EMR is really key.”

⁴³Formularies list drugs preferred by insurers, and include both brand-name and generic drugs. Non-formulary drugs have higher patient OOP costs.

Use of Prior Authorization in the Value Decision

Doshi took the EMR discussion one step further toward prior authorization. “Once a patient qualifies through a prior authorization, at that point in time why couldn’t we waive or lower copayments for those patients?” She continued, “Right now for PCSK9 inhibitors, why does one have to fill out five pages’ worth of forms and fax in every medical record for these patients and jump through hoops? Once that’s taken care of, why can’t we have that FH [familial hypercholesterolemia] patient, [for example] access the drug for a low-cost or no-cost share?”

Presenting the other side of the prior authorization issue, Lawless put forth a reminder that medicine is not linear, that diseases don’t always follow a straight line. “There is a value in having prior authorization because the disease state may go into remission,” he said. “It may accelerate. It may go sideways. All of those kinds of things may happen. If you don’t have a touch point, every so often—it doesn’t have to be 15 pages of paperwork—but if you don’t have that built-in touch point for a number of diseases, you lose the opportunity to maybe change therapy, delay therapy, even increase therapy. It’s not always just about cost savings and managing money. Sometimes it’s about managing patient outcome also. It’s not all bad.”

Fendrick added the topic of rapidly evolving therapies, such as gene therapies and biologics, to the discussion. Previously, he said, unless a patient had a reason not to take first-line therapy, he [Fendrick] would not have approved patient assistance for a second-line therapy until the first line therapy failed. Now we know, for example, he said, that “this patient has a genetic marker indicating that methotrexate won’t work.”

The Value of Peer Support

Mended Hearts, Inc. Case Study

Baer opened her case study, *Reducing Barriers to Medication Access and Adherence: A Peer-to-Peer, Community-Based Approach*, with a personal story of bringing home a new baby with a congenital heart defect. She recalled. “They gave me this baby and they sent me home with some prescriptions, which I took down to my local pharmacist. They told me, ‘We don’t fill these here. You have to go to a compounding pharmacy⁴⁴ and I’m like, ‘What’s that?’” Baer had a sick newborn, had no information from the hospital or pharmacist, and ended up looking up information on the internet and asking friends. She finally figured out what a compounding pharmacy was and got the medication, but thought “how much easier it would have been if somebody [in the hospital had said] ‘You’re getting ready to take this baby home who’s critically ill and needs these medications. This is what a compounding pharmacy is, this is where you find it, these are the ones we have in town. Do you need any help?’”

⁴⁴Compounding pharmacies prepare personalized medications by mixing individual ingredients into prescribed strengths and dosages.

Baer and her family got much needed support from Mended Hearts and Mended Little Hearts, the largest peer-to-peer heart disease and congenital heart disease support networks in the world.⁴⁵ These became a lifeline as she realized that “these people have made it, [so] I might be able to [make it], too.” People who are going through significant health challenges alone often feel isolated, depressed and afraid of the unknown, and it helps to get support from people who have faced and overcome the same challenges. Empowered patients focus more on recovery and treatment options than on the hard time they are going through. Baer shared that the peer support helped her navigate medications, diet and other challenges, in addition to providing emotional support. She also noted that peer support has been shown to improve patient outcomes. A study of the Mended Hearts peer-support program sponsored by the Centers for Medicare & Medicaid Services (CMS) entitled, *Quantifying the Value of Peer-to-Peer Support Landmark Survey Results*⁴⁶ compared outcome data from 164 Mended Hearts hospitals and 4,641 other hospitals, and found that “hospitals with regular visits from Mended Hearts members are significantly more likely to have fewer patient readmissions for heart failure.” Results of this study indicated that peer support increased compliance with treatment regimens, improved outlook and increased active involvement in recovery. All of these are concrete, patient-centered outcomes that are valued by patients and their families.

Another benefit is the ability of peer supporters to step in and help when needed. “When you’re in a critical care situation,” said Baer, “who has the time or the energy or the emotional ability to make 17 phone calls? I was dealing with an insurance problem and I was ready to pull my hair out. I was like, ‘why can’t these people understand?!’ Why should you as a patient have to deal with that? I think that’s a huge piece of the peer support, not only giving emotional support, but saying, ‘Let’s call this place and they can do this for you, or they can do that for you, or this place can give this kind of support.’”

⁴⁵<http://www.mendedhearts.org>.

⁴⁶Mended Hearts. *Quantifying the Value of Peer-to-Peer Support Landmark Survey Results*. Centers for Medicare & Medicaid Services. 2014. <http://www.mendedhearts.org/Docs/2%20-%20QtV%20Fact%20Sheet.pdf>. Accessed April 4, 2017.

PEER SUPPORT IMPROVES ADHERENCE BY:

- » Reinforcing the power of habit
- » Providing social support systems
- » Helping with self-managed care
- » Instilling hope
- » Providing targeted educational resources
- » Role modeling
- » Providing connections to resources
- » Promoting emotional health
- » Improving outcomes

“We really want to encourage patients to advocate for their own healthcare, access to medications, etc. Sharing experiences with peers, patients and family members really does improve outcomes. . . Peer support is a powerful tool.”

— MARCIA BAKER

Richards added, “So here we are looking at multiple different chronic conditions, many people living with multiple conditions at the same time. One of the things that our groups [in the Partners for Better Care coalition] are doing is trying to develop qualitative data to explain the patient experience in a way that then can inform things like peer support and financial literacy programs. There’s an increased interest in not only having [these types of] programs for patients, but also for the specialists that treat them.”

Marcia Baker, MS, ED, Director, Corporate Development & Programs, Mended Hearts, described two Mended Hearts chapters, one in Hollywood, FL and one in Gastonia, NC, which hold discharge classes, meetings and peer-support activities. She related the story of one of their patient-members who, during a monthly gathering of the Mended Hearts group, found that there were several other patients who were taking the same blood-pressure medication. She mentioned that she took her medication in the morning, and was having side effects. When she found that some of the others took it at night, she checked with her doctor, switched to nighttime dosing, and the side effects diminished, which helped her to stay on the medication. This was an excellent example of how peer support can help optimize patient outcomes that are linked to medication usage.

Other Support

Physicians are not typically trained to discuss patients’ individual health coverage with them, and patients can rarely formulate all the necessary insurance coverage questions in the emotional aftermath of being diagnosed with a critical illness. Following up with peer support programs and call centers can help patients with unanswered questions. Partners for Better Care, said Richards has “a number of groups that are doing very specific case management and case work, so patients literally have a case worker who walks them through both their healthcare diagnosis as well as the financial element, and then connects them with things like patient support programs, grants, housing [assistance, and the like].”

To further tailor these types of patient support systems, patient advocacy groups need to identify and address the issues that are important to their own constituencies. For example, said Richards, “the Hemophilia Foundation of America is trying to ask the right questions of their population so that they can then develop the support programs that are needed.”

This exploration of the patient experience provided honest examples of the difficulties facing patients and how varied their experiences can be, cited research showing that certain interventions are effective in helping patients with some challenges, and illustrated that navigation of the financial aspects of critical illness, including access to medications, remains a significant challenge.

Summary

“We need to focus on making sure that insurance is truly about covering the sickest and that we aren’t essentially discriminating against patients who are very, very sick and need high-cost therapies. We don’t do that when they need an organ transplant; we shouldn’t do it when they need a specialty medicine.” — JENNY BRYANT

Meeting the Needs

As the Roundtable drew to a close, Goodman asked the panelists in the final session to provide “one kernel of golden advice” for PAN, and, by extension, other patient assistance groups. Anderson advised deciding whether to help a lot of patients with small amounts of money or fewer patients with larger amounts. Bryant suggested moving “in a value-based direction so that patients who need the medicine can afford it and that we don’t allow plans to be assessing cost sharing which will force people into the safety net for medicines that they absolutely need to be on.” Eyles counseled using data analytics to gain a greater understanding of the patient population being served. Fendrick advised maximum use of clinically nuanced payment and consumer incentives, and Lawless said, “Always listen to the wisdom of patients and patient organizations; they bring a lot of insight that we might otherwise miss.”

“This panel has been extraordinarily, but not surprisingly, full of candor,” Goodman concluded. “They have faced up to the toughest issues, answered some very difficult questions and all in a constructive way, which flowed into the best strategic planning advice you’re going to get for free in a long time from the top people.”

Klein noted that the safety net provided by PAN and other patient-support organizations is needed as much today as it has ever been. “There’s going to still be a group of people falling through the cracks who

“We want to encourage all of you today to really think about different strategies for helping us maintain the safety net while still looking to the future to get to a point in time where we maybe don’t need a safety net.”

— DAN KLEIN

are going to need assistance regardless of how intelligent the benefit design is,” he said. “We need to be pragmatic as well as compassionate, and we need to recognize that at least in the short term, the safety net is critical.” Niles agreed, “At PAN, we are very focused on medication access, but it’s clear that the safety net is much broader, and that patients need access to a whole range of services.”

Suggestions for preserving this vital resource included making changes to the structure of the system. “We have to change the conversation from how much we spend to how well we spend,” said Fendrick. “I want deductibles only to apply to services that don’t make Americans any healthier.”

Richards mentioned two recent initiatives that are positive examples of ways the safety net can be strengthened.

- 1 In November 2016, CMS finalized its decision to cover care planning services for Alzheimer’s disease patients.⁴⁷ “In these care planning episodes there are actual payments that go to a multidisciplinary team that walks a family through the different care treatment options, including utilization issues, co-therapies, allied health professionals and other options to maintain good outcomes over time,” she said.
- 2 Working with several drug companies, Aetna now offers *Leap Diabetes Plans*. These specialized plans for people living with Type 2 diabetes feature low co-pays for diabetes specialists (e.g., endocrinologists), free supplies, and a care management program to help manage their disease in such a way as to prevent negative outcomes.⁴⁸

“I think when you can get those multidisciplinary teams together,” Richards said, “whether it’s physicians, social workers, allied health professionals, or payers and manufacturers, along with the patients, that’s where we’re seeing the most promising and novel ideas.”

Doshi agreed, “Every stakeholder in the system has a role to play in it. That includes providers. It includes pharma. It includes health insurance companies. It includes organizations like PAN.”

With input from advocacy organizations, academia and the insurance and pharmaceutical industries, the 2017 Cost-Sharing Roundtable continued to provide a forum for diverse stakeholders to discuss the widespread and evolving impact of cost sharing. This ongoing discussion places the issue of cost sharing in an historical context that began with the RAND Health Insurance Experiment and continues today

“The question I have is: why is it that we treat our older Americans so badly? I think we all should contribute to the solution because it’s for our parents, it’s for our grandparents and in fact it’s for all of us because we’re all coming down the pike.”

“It’s extremely clear that at this point in time we need every stakeholder in the system contributing to a solution.”

— JALPA DOSHI

with policy debates concerning the ACA and the future of our nation’s healthcare system and healthcare safety net. Case studies, panel discussions, as well as new research supported by the PAN Challenge, provided a rich context in which cost sharing could be examined against the backdrop of current policy debates that will impact the nation’s most vulnerable patients. Roundtable participants agreed about the importance of the safety net for this segment of the population. However, there was also widespread agreement that longer-term solutions are needed because the current safety net—including charitable organizations such as PAN—is ill-equipped to meet the needs of this population in the future.

⁴⁷Alz.org. Medicare. <http://www.alz.org/care/alzheimers-dementia-medicare.asp#cogassess>. Accessed March 15, 2017.

⁴⁸Andrews M. Now there’s a health plan that zeros in on diabetes care. NPR. November 17, 2015. <http://www.npr.org/sections/health-shots/2015/11/17/456255470/now-theres-an-aetna-health-plan-that-zeroes-in-on-diabetes-care>. Accessed March 15, 2017.

Appendix A. Roundtable Agenda

WELCOME (9:00 AM)	Amy Niles
INTRODUCTORY REMARKS	Amy Niles; Daniel Klein; Jeff Prescott
GUEST SPEAKER (9:15 AM)	Tricia Neumann
What's the Outlook for Medicare and High-Need Beneficiaries in 2017 and Beyond?	
A PATIENT'S PERSPECTIVE (9:45 AM)	Melissa Thompson
I am the Patient	
CASE STUDY PRESENTATIONS: INTRODUCTION (10:00 AM)	Amy Niles
» Fred Hutchinson Cancer Research Center	Veena Shankaran, MD, MS
» Mended Hearts, Inc.	Andrea Baer, MS; Marcia Baker, MS, Ed
CALL FOR PAPERS: INTRODUCTION (10:45 AM)	Amy Niles
» Presentation #1: PAN Challenge Winning Paper	Kai Yeung, PharmD, PhD
» Presentation #2: PAN Challenge Runner-Up Winning Paper	Jalpa Doshi, PhD
PANEL DISCUSSION (11:15 AM)	Amy Niles
Addressing the Needs of Patients	
Moderator	Clifford Goodman, PhD
Panelists	Andrea Baer; Jalpa Doshi, PhD; Mary Richards; Veena Shankaran, MD, MS; Kai Yeung, PharmD, PhD
Beyond Charitable Assistance: Sustainable Strategies for Providing Access to Medications	
Moderator	Clifford Goodman, PhD
Panelists	Gerard Anderson, PhD; Jenny Bryant; Matt Eyles; A. Mark Fendrick, MD; Dan Klein; Grant Lawless, RPh, MD, FACP
<i>Questions and Answers</i>	
CLOSING REMARKS/ADJOURN (3:00 PM)	Amy Niles

Appendix B. *Roundtable Participants*



« GERARD F. ANDERSON, PHD

Professor, Bloomberg School of Public Health, Johns Hopkins University

Gerard F. Anderson is a professor of health policy and management and Director of the Johns Hopkins Center for Hospital Finance and Management

From 1978 until 1983, when he joined Johns Hopkins, Dr. Anderson worked in the Office of the Secretary of the U.S. Department of Health and Human Services. While in the Office of the Secretary, he worked primarily on healthcare financing issues and was one of the principal architects of the Medicare Prospective Payment System. Dr. Anderson is currently conducting research on chronic conditions, drug pricing, comparative insurance systems, medical education, healthcare payment reform and technology diffusion. He has directed reviews of healthcare systems for the World Bank, World Health Organization and the U.S. Agency for International Development (USAID) in multiple countries and has directed more than 100 research projects. Dr. Anderson has written two books on healthcare payment policy, published more than 250 peer-reviewed articles, testified in Congress 50 times and serves on multiple editorial committees.

ANDREA BAER, MS »

Director of Patient Advocacy, Mended Hearts, Inc.

Before joining Mended Hearts/Mended Little Hearts (MLH), Ms. Baer was an accomplished volunteer who gave thousands of hours of service over the past seven years as a member of the Executive Committee and Board. Ms. Baer oversaw the creation and implementation of MLH's first strategic plan and provided vision and focus during the greatest period of growth MLH ever had. As the founder of MLH of Southwestern, PA, she led the group to win the MLH Group Excellence award in 2011. Ms. Baer is deeply involved in advocacy efforts and works to ensure that the patient voice is at the table. She is a member of the Congenital Heart Public Health Consortium Policy Committee and writers group, a member of the Person & Family Engagement Network, a peer reviewer for the Department of Defense's Congressionally Directed Medical Research Program and patient voice representative on the Transparency in Pediatric Public Reporting Consortium. Ms. Baer has an MS in nonprofit management and leadership.



« MARCIA BAKER, MS, ED

Director, Corporate Development & Programs, Mended Hearts, Inc.

At Mended Hearts, Inc. Ms. Baker is responsible for creating, implementing and managing educational programs planned with corporate partners on topics such as atrial fibrillation/stroke, cholesterol and heart failure. Ms. Baker also assists with business development and fundraising. A certified nonprofit professional, Ms. Baker joined Mended Hearts in 2010 as Director of Field Services, following 28 years of volunteer management positions at the American Heart Association at both the national and affiliate levels. In that role, Ms. Baker worked with Mended Hearts' volunteer national board of directors and committees to manage chapter policies and procedures and chapter and member training, and to develop and execute the annual member training conference. Ms. Baker has more than 30 years of experience in program and volunteer management. She holds an MS in health education from Southern Illinois University.

Appendix B. *Roundtable Participants (continued)*



« JENNY BRYANT

Senior Vice President, Policy and Research Pharmaceutical Research and Manufacturers of America (PhRMA)

At the Pharmaceutical Research and Manufacturers of America (PhRMA, the national association representing the country's leading pharmaceutical research and biotechnology companies), Ms. Bryant oversees development of public policy related to Medicare, Medicaid and healthcare reform, as well as analysis and policy development related to changes in the healthcare delivery system. She oversees a broad portfolio of economic and policy research, with a focus on better understanding how medicines are used and valued, and the impact of appropriate medication use on healthcare costs. Prior to joining PhRMA, Ms. Bryant was Vice President at The Lewin Group, a national healthcare consulting firm.

Previously, she held positions at Blue Cross Blue Shield Association, Blue Cross Blue Shield of Florida, New York Hospital-Cornell Medical Center and the State of New York. Ms. Bryant received her MBA from the Harvard Graduate School of Business Administration.

JALPA A. DOSHI, PHD »

Associate Professor, Perelman School 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. Joshi's research 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, including elderly, disabled, chronically ill and low-income patients. Her research has also focused on the prevalence, causes, outcomes, and costs of suboptimal medication use in chronic diseases, and the clinical and economic impact of innovative behavioral or policy interventions for improving medication adherence and management.

Other work concentrates on advancing methods in pharmaceutical outcomes and cost-effectiveness research. Dr. Doshi is coauthor of *Economic Evaluation in Clinical Trials* (Oxford University Press); has been principal investigator on numerous research grants from federal agencies, private organizations, and research foundations; has published widely in leading health policy and clinical journals; is currently co-editor of the *Value in Health* journal; and has received several awards and honors from national and international organizations. She and her team were first-prize winners of the inaugural PAN Challenge last year.



« MATT EYLES

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

At America's Health Insurance Plans (AHIP), the national trade association representing the health insurance industry, Mr. Eyles leads the Policy & Regulatory Affairs function, including the government programs (Medicare and Medicaid), state policy, and product policy departments. Mr. Eyles joined AHIP from Avalere Health in Washington, D.C., where he was Executive Vice President and was responsible for the health plans and providers business, strategic communications business and health reform team. Previously, Mr. Eyles 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. Mr. Eyles has a master's degree in public policy from the University of Rochester.

Appendix B. *Roundtable Participants (continued)*



« A. MARK FENDRICK, MD

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

Mark Fendrick, MD, is a professor of internal medicine in the School of Medicine and a professor of health management and policy in the School of Public Health at the University of Michigan — the leading advocate for development, implementation, and evaluation of innovative health benefit plans. 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. His 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 U.S. Senate Committee on Health, Education, Labor and Pensions; the U.S. House of Representatives Ways and Means Subcommittee on Health; and the U.S. Senate Committee on Armed Services Subcommittee on Personnel. Dr. Fendrick has authored more than 250 articles and book chapters and has received numerous awards for the creation and implementation VBID. Dr. Fendrick received his medical degree from Harvard Medical School.

THE HONORABLE DR. PHIL GINGREY »

Senior Advisor, Drinker Biddle & Reath and District Policy Group and former U.S. Congressman (R-GA), 2003-2015

Dr. Gingrey is a former U.S. Congressman who served Georgia's 11th Congressional district from 2003 to 2015. Given his medical background and local, state and federal public policy careers, he is uniquely positioned to provide public policy and government relations counsel to clients on issues related to healthcare, energy and environment, education, communications and life sciences. Throughout his 12 years in Congress, Dr. Gingrey served on committees such as the House Committee on Energy & Commerce and its Health Subcommittee, the Committee on Education and the Workforce, and the Committee on Armed Services. In the 110th Congress, Dr. Gingrey was a ranking member of the Science Subcommittee on Technology and Innovation. During his Congressional tenure, Dr. Gingrey authored, sponsored, and won passage of several major initiatives including, the Protecting Access to Healthcare and the Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Acts. In 2009, Dr. Gingrey founded the GOP Doctors Caucus, which advises House Leadership on healthcare reform and offers solutions to critical health issues. Dr. Gingrey served as the co-chair of the Caucus (2009–2015) and promoted the importance of health information technology by writing and introducing the Assisting Doctors to Obtain Proficient and Transmissible Health Information Technology (ADOPT HIT). Prior to serving in Congress, Dr. Gingrey served two terms in the Georgia State Senate (1999–2003). He attended the Medical College of Georgia, and operated and managed a private OB-GYN practice for more than 27 years.



Appendix B. *Roundtable Participants (continued)*



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

Dr. Goodman has more than 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. Previously, he served as Chair of the Medicare Evidence Development & Coverage Advisory Committee for the Centers for Medicare and Medicaid Services and president of the professional society, Health Technology

Assessment International. A Fellow of the American Institute for Medical and Biological Engineering, Dr. Goodman holds a PhD from the Wharton School of the University of Pennsylvania and an MS from the Georgia Institute of Technology.

JEANNE IRELAND »

Advisory Board Member, District Policy Group and former Senior Advisor to the Commissioner and Associate Commissioner for Legislation at the Food and Drug Administration, Obama Administration

Ms. Ireland served as Senior Advisor to the Commissioner and Associate Commissioner for Legislation at the U.S. Food and Drug Administration (FDA) from 2009 to 2014, where she led high-priority policy and legislative initiatives, including negotiations on the FDA Safety and Innovation Act and legislation to reform the nation's food safety system. Prior to her time at the FDA, Ms. Ireland served as Chief Public Health Advisor to former Chairman John D. Dingell (former D-MI) on the House Energy and Commerce Committee, where she managed legislative efforts to grant the FDA new authority over tobacco products and improve the safety of imported food and medical products. She also spent time as Director of Public Policy at the Elizabeth Glaser Pediatric AIDS Foundation and as Minority Staff Director for the Senate Health, Education, Labor and Pensions Committee's Subcommittee on Children and Families. Ms. Ireland is currently Principal, Ireland Strategies, LLC. She received an MA from the University of Chicago.



« **DAN KLEIN**
President and CEO, PAN Foundation

Mr. Klein brings more than 35 years of experience in healthcare and information technology services to the PAN Foundation. Mr. Klein came to PAN from the Cystic Fibrosis (CF) Foundation, where he served as Senior Vice President for the CF Services pharmacy, and subsequently as Senior Vice President for Patient Access Programs. His leadership at the CF Foundation was exemplified by the steady growth and eventual sale of the CF Services pharmacy to Walgreens. During his tenure at the CF Foundation, Mr. Klein also was responsible for the development of the CF Patient Assistance Foundation, which provided financial assistance and case management services for people with cystic fibrosis. Mr. Klein has had numerous leadership roles in the healthcare and information technology sectors, including as Chairman and Chief Executive Officer of Panurgy

Corporation, a leading mid-market information technology services company, as well as a consultant on health planning and health promotion for the Pan American Health Organization and the U.S. Department of Health and Human Services, respectively.

Appendix B. *Roundtable Participants (continued)*



« GRANT D. LAWLESS, RPH, MD, FACP

Associate Professor of Clinical Pharmacy and Pharmaceutical Economics and Policy, University of Southern California; Vice Chair, Board of Directors, PAN Foundation

Dr. Lawless is Associate Professor of Pharmaceutical and Health Economics, and Program Director for the Master of Science Program in Healthcare Decision Analysis at the University of Southern California. Dr. Lawless served at Amgen, Inc. from 1999 to 2011, where he served as Director of Health Economics and Outcomes Research; Executive Director for Managed Care Marketing; and recently as Executive Director for National Accounts Managed Care. Prior to joining Amgen, he served 11 years as Vice President for Medical and Pharmacy Affairs for Highmark Blue Cross Blue Shield in Pittsburgh, PA, where he also served as Medical Director for the HMO Keystone West. Dr. Lawless's professional experience is focused on internal medicine and emergency medicine. He is Board Certified and a Fellow in Internal Medicine, Quality Assurance and Utilization Review, and Addiction Medicine. In addition, he is a registered pharmacist with specialty certification in nuclear medicine. Dr. Lawless is a graduate of the University of New Mexico and completed his residency in internal medicine at University of Pittsburgh and St. Francis Health System in Pittsburgh, PA.

TRICIA NEUMAN »

Director, Medicare Policy, Kaiser Family Foundation

As senior vice president of the Henry J. Kaiser Family Foundation and Director of the Foundation's Program on Medicare Policy, Tricia Neuman oversees the Foundation's policy analysis and research pertaining to Medicare, and health coverage and care for aging Americans and people with disabilities. A widely cited Medicare policy expert, Dr. Neuman focuses on topics such as the health and economic security of older adults, the role of Medicare Advantage plans, Medicare and out-of-pocket spending trends, prescription drug costs, payment and delivery system reforms and policy options to strengthen Medicare for the future. She has authored numerous papers pertaining to Medicare, has been invited several times to present expert testimony before Congressional committees, and has appeared and been quoted as an independent expert by major national media outlets. Before joining the Foundation in 1995, Dr. Neuman served on the professional staff of the Ways and Means Subcommittee on Health in the U.S. House of Representatives and on the staff of the U.S. Senate Special Committee on Aging, working on health and long-term care issues. Dr. Neuman received a Doctorate of Science degree in health policy and management and an MS in health finance and management from the Johns Hopkins Bloomberg School of Public Health.



« AMY NILES

Vice President of External Affairs, PAN Foundation

Ms. Niles oversees the PAN Foundation's collaborations and alliances with patient advocacy and professional associations, and its public policy initiatives. Before joining the PAN Foundation, 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. She began her career in hospital administration. Ms. Niles has an MBA from Baruch College, City University of New York.



« **ILISA HALPERN PAUL**

President, District Policy Group

Ilisa Halpern Paul leads the District Policy Group and has more than 25 years of experience in government relations, advocacy and policymaking in nonprofit, academic, federally funded and government settings. Ms. Halpern Paul’s practice centers on advising clients about advancing their federal legislative, regulatory and programmatic policy agendas. Her work has earned her the recognition as one of The Hill’s Top Lobbyists of 2015 and 2016, as well as a feature story in The Hill regarding her rise to success. She helps her clients by bringing traditional and nontraditional partners to the table in support of common goals, fostering relationships with members of Congress and their staffs and collaborating with the administration and federal agencies.

Ms. Halpern Paul frequently speaks at meetings and briefings providing political insight and analysis to help clients navigate the current policy environment. She previously served as Director of Federal Government Relations for the American Cancer Society and as Director of Federal Affairs with the American Public Health Association, and worked on the legislative staff for U.S. Senator Dianne Feinstein (D-CA). She earned a Master of Public Policy (MPP) from Georgetown University’s Public Policy Institute.

JEFF PRESCOTT, PHARM.D. »

Senior Vice President, Managed Markets, Michael J. Hennessy Associates

Dr. Prescott is responsible for day-to-day oversight and operation of the managed care franchise within the Michael J. Hennessy Associates (MJH) portfolio, which is anchored by the flagship publication, The American Journal of Managed Care (AJMC). He joined MJH in May 2008 to lead the clinical communications team, and was responsible for overseeing content development and delivery for non-accredited (non-CME) educational projects and programs. Prior to joining MJH, Dr. Prescott worked as a consultant, evaluating and developing health economic data and data models across a number of therapeutic areas, was director and clinical practice leader for the Health Informatics division at Practice Patterns Science, a wholly owned subsidiary of Express Scripts, Inc., and was the clinical pharmacy director for a self-funded pharmacy benefit program for a Teamsters Union. Dr. Prescott has more than 20 years of practical experience in community pharmacy and practice management, managed care formulary development, drug utilization review (DUR), and disease management programs and continues to practice community pharmacy. He holds a Doctor of Pharmacy degree from the University of Illinois and is a licensed pharmacist in Illinois and Pennsylvania.



« **MARY RICHARDS**

Executive Director, Partners for Better Care

Partners for Better Care is a coalition of patient advocacy organizations and their allies, which advocates for the next generation of healthcare based on key principles of patient-centered quality care, availability, transparency and affordability. Ms. Richards has 20 years of patient advocacy, policy, lobbying and Congressional experience. Prior to joining Partners for Better Care, Ms. Richards led the Alzheimer’s Association’s federal policy agenda and was the founding executive director of the Alzheimer’s Impact Movement (AIM) and AIMPAC, an independent political organization working in partnership with the Alzheimer’s Association. She has also

served as Deputy Chief Executive Officer, Parkinson’s Action Network (now the Michael J. Fox Foundation), where she directed the government relations activities of the Parkinson’s community and advocated for regenerative medicine. Ms. Richards has worked on Capitol Hill for two members of the House of Representatives, served as a board member of the Alliance for a Stronger FDA and the Partnership to Fight Chronic Disease, and held leadership positions with the National Health Council. She has a BS in interdisciplinary social sciences from James Madison University.



« **VEENA SHANKARAN, MD, MS**

Associate Professor, Division of Medical Oncology, University of Washington and Associate Member, Clinical Research Division, Fred Hutchinson Cancer Research Center

Dr. Shankaran is a medical oncologist who specializes in caring for patients with gastrointestinal malignancies, with a particular focus on cancers of the esophagus and stomach. Her research expertise includes health economics and comparative effectiveness, with an emphasis on patterns of care and risk factors for financial hardship among cancer patients. She received a master’s degree in pharmacy at the University of Washington’s Pharmaceutical Outcomes Research and Policy Program. Dr. Shankaran is the recipient of a 2013 Career Development Award from the American Society of Clinical Oncology Conquer Cancer Foundation. She is the principal investigator of a Southwest Oncology Group (SWOG)-funded national multicenter study, investigating the financial impact of colorectal cancer treatment on patients and caregivers.

MELISSA THOMPSON, MBA »

Healthcare Strategist and Cancer Patient

Melissa Thompson is a healthcare technology strategist, entrepreneur, cancer patient and advocate for patient-centered innovation. She is on the patient and family advisory council for quality at Memorial Sloan Kettering, is a patient advisor to the Innovative Molecular Analysis Technologies program at the National Institutes of Health/National Cancer Institute, and sits on the Patient-Centered Outcomes Research Institute Merit Review Board. Referred to in WIRED Magazine as a “game changer” by Bill Gates, Ms. Thompson works with organizations to highlight, address, and solve problems in healthcare.



« **KAI YEUNG, PHARMD, PHD**

Scientific Investigator I, Group Health Research Institute (GHRI)

Kai Yeung is a pharmacist and scientist with expertise in pharmaceutical economics and outcomes research. He is interested in optimal incentives to encourage value in healthcare. In particular, Dr. Yeung does research in applied econometrics, health insurance design, and cost-effectiveness analysis. Before joining GHRI in 2016, Dr. Yeung was a postdoctoral fellow at the University of Washington, where he sought to understand payer acceptability of alternative payment models for high-priced curative therapies. Dr. Yeung’s dissertation assessed the impact of a novel prescription drug benefit, the Value-Based Formulary (VBF), which used cost-effectiveness analysis to inform drug co-pay tiers. He utilized econometric methods to quantify the impact of the VBF on beneficiary medication utilization behavior, health outcomes, and healthcare expenditures from beneficiary and payer perspectives. For this work, he received a multidisciplinary research training grant from the National Center for Advancing Translational Sciences of the National Institutes of Health and a health services research dissertation grant from the Agency for Healthcare Research and Quality. Dr. Yeung received his PharmD from the University of Southern California and his PhD in pharmaceutical economics from the Pharmaceutical Outcomes Research & Policy Program at the University of Washington.