



Cost-Sharing Roundtable:

The Patient Assistance Safety Net: How Many Need Help? How Many Are Helped?

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

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1330 G Street, NW, Washington, D.C. 20005

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Hosts

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The Patient Access Network Foundation is an independent, national 501 (c)(3) organization dedicated to providing underinsured patients with financial assistance through more than 60 disease-specific funds that provide access to progressive therapies. Partnering with generous donors, healthcare providers and pharmacies, since 2004, PAN has provided more than 1 million underinsured patients with over \$3 billion dollars in financial assistance to cover out-of-pocket expenses for their prescribed treatments.

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.

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

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 Roundtable organization 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.

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Executive Summary

“More and more people are realizing they have no place to turn for assistance.”

— JULIE CARTER

The 2018 Cost-Sharing Roundtable, *The Patient Assistance Safety Net: How Many Need Help? How Many are Helped?*, hosted by the Patient Access Network (PAN) Foundation and *The American Journal of Managed Care*® (AJMC®) was attended by a diverse group of panelists and participants representing many perspectives. PAN’s Roundtable facilitated important conversations on illness-related financial toxicity and potential strategies to mitigate this challenging problem. This report synthesizes the daylong conference, which was held in Washington, D.C. on February 23, 2018.

Chapter 1 introduces the Roundtable, provides some background on prior years’ sessions, emphasizes the need to better understand how and why people seek financial assistance for illness-related out-of-pocket (OOP) costs, and stresses that the problem of cost sharing is still acute and in need of better solutions. The chapter also describes winners of the third annual PAN Challenge—a call for research to quantify the effectiveness of strategies to help patients ease the burden of OOP costs.

Chapter 2 explores the financial hardship associated with illness, including the increasing impact of financial toxicity associated with paying for treatment and medication. A major component of financial toxicity—prescription drugs—is discussed, along with the exponential rise in their costs, and increasing patient obligations to share in these costs. This chapter examines various types of hardship, i.e., the material condition of hardship, and its accompanying psychological response and coping behaviors, and uses these categories as a framework to discuss the impact of financial hardship (bankruptcy, nonadherence and poor outcomes) on patients, as well people who have completed their treatment. The

Now in its third year, the 2018 Cost-Sharing Roundtable provided a forum for presenters and panelists from health policy organizations, patient advocacy and provider organizations, health systems, charitable foundations, specialty pharmacies and the pharmaceutical industry to engage in thoughtful discussion on the financial hardships being faced by patients and how these might best be mitigated. The winning and runner-up PAN Challenge papers were presented, which addressed the safety net and the role of financial navigation. As in years past, the financial toxicity associated with high medical costs, and its corrosive effect on adherence and outcomes, were topics of central interest for stakeholders.

chapter concludes with a call for further research to provide a solid evidence base to assess the effects of financial hardship on various outcomes.

In **Chapter 3**, the issue of increasing OOP costs limiting access to treatment for Medicare beneficiaries is explored, including the relationship between cost and access, problems with understanding and navigating the Medicare system, and how patient assistance organizations are attempting to help. Systemic and short-term solutions are examined.

Chapter 4 gives the perspective of healthcare providers on the impact of costs on clinical practice and on patient outcomes. The importance of providing patients with financial navigation services is discussed, suggestions for optimizing this process are offered and a case study showing results of a financial navigation system are presented. The question of whether financial considerations have an impact on clinical decision-making is explored, as is the impact of cost on patients' adherence to treatment and clinical outcomes.

In **Chapter 5**, policy considerations that might mitigate patients' financial hardship are discussed, and several recommendations are made. The safety net, which includes charitable patient assistance organizations such as the PAN Foundation, is discussed, including how these organizations coordinate with each other to facilitate patient access to financial assistance for OOP prescription medication costs. The ability of another component of the safety net—federally qualified health centers (FQHCs)—to facilitate access to medications for underinsured patients is also discussed.

Chapter 6, summarizes strategies to address OOP cost-related challenges discussed throughout the Roundtable, emphasizes the need for proactive action on these issues, and reiterates the need to address high prescription drug costs (or OOP drug costs).

Several themes emerged from the 2018 Roundtable discussion, as follows:

Continued Importance and Vulnerability of the Safety Net

- » As costs of treatment continue to rise, the safety net is becoming increasingly important
- » Patient assistance organizations cannot keep up with the rising demand for help with OOP costs, leaving some patients with nowhere to turn
- » The current safety net is a patchwork of resources, many of which are dwindling, or in jeopardy

Relevance of the Emerging Study of Financial Hardship

- » Financial hardship continues to be a detrimental side effect of illness that may have a devastating impact on patient outcomes

- » Examination of the types and categories of financial hardship helps identify risk factors and possible intervention strategies
- » The importance of research on the impact of financial hardship is expected to increase in the future in parallel with decrements in the safety net and continued increases in prescription drug costs

The Immediate Impact of Policy Changes on Medication Access

- » Certain emerging policies, such as high-deductible health plans and co-pay accumulator adjustor programs by health insurers, increase OOP costs for patients
- » Policies that might have an immediate impact on reducing OOP costs include implementing caps on OOP expenditures; addressing high drug prices; and updating the Medicare payment structure, including closing the donut hole
- » Uncertainties in the current policy landscape leave large numbers of vulnerable patients without a clear-cut path to ensuring ongoing access to needed treatments

Continued Challenges for the Medicare Population

- » High OOP costs persist, including high coinsurance obligations, and costs are concentrated at the beginning of the year for many Medicare beneficiaries
- » The complexity of Medicare's benefit structure—especially for Part D drug plans—makes it hard for beneficiaries to choose the plan that best fits their needs, and it inhibits beneficiaries from changing plans to meet their needs
- » Scrutiny of patient assistance programs have made it challenging for organizations to assist a growing number of Medicare beneficiaries with their OOP costs for prescription medications

The Burden of OOP Health Costs Extends Far Beyond Medications

- » Nonmedical OOP costs and logistics, such as transportation and childcare, greatly contribute to financial hardship and have a large impact on adherence to treatment
- » High OOP costs have an impact on housing and food security (ability to pay rent or buy food)
- » Even when treatment is complete, the lingering effects of OOP healthcare costs have a far-reaching impact on patients' lives

The Growing Importance of Financial Navigation

- » Providing patients with financial navigation services is becoming increasingly important as OOP costs rise and resources provided by the safety net become more scarce
- » Financial navigation should begin early to manage patients' expectations and minimize financial toxicity as much as possible
- » Trained financial navigators can be effective in finding resources to help patients pay for their care, which helps both patients and hospitals

Providers Face Increasing Challenges

- » Financial hurdles associated with paying for OOP costs for medications often result in treatment delays
- » Financial considerations may be a factor in choice of treatment plan
- » High cost of treatment results in patients not adhering to their treatment plan, which affects the disease course and worsens clinical outcomes

Potential Policy Solutions

- » Several changes could be made to modernize Medicare to better meet the needs of patients:
 - Changing the Part D benefit structure to even out OOP expenses during the calendar year, eliminate the donut hole, and placing a hard cap on OOP costs
 - Eliminating the asset test for Medicare extra help programs
 - Improving patient education about plan choices
- » Trained financial navigation professionals should be used to help patients and their families with financial issues
- » Providing patients with the benefit of drug rebates at the point of sale
- » Placing zero co-pays on generic medications
- » Implementing value-based insurance design (VBID); limit co-pay amounts for high-value medications

Introduction

“We found that those living with cancer or other chronic illnesses like multiple sclerosis virtually could not afford any of the out-of-pocket costs for their medications...About 20% of individuals didn’t even look for financial assistance because they didn’t know assistance existed.” – AMY NILES

Continued Need for the Patient Safety Net

The February 2018 Cost-Sharing Roundtable hosted by the Patient Access Network (PAN) Foundation and *The American Journal of Managed Care*® (AJMC®) explored the problem of high out-of-pocket (OOP) costs for patients with life-threatening, chronic and rare diseases. For the third consecutive year, the Roundtable brought together a diverse group of stakeholders with a shared goal of continuing this conversation, and proposing potential short- and long-term solutions to mitigating the cost-sharing burden for patients. The Roundtable (see agenda in **Appendix A**) included a keynote address on financial hardship, four panel discussions, presentations of the winner and runner-up PAN Challenge papers and several question-and-answer (Q&A) sessions.

Amy Niles,¹ PAN’s Vice President of External Relations, began the day by welcoming attendees and introducing the theme of the day’s Roundtable discussion. “Today,” she said, “we’ll hear about the challenges associated with cost sharing for patients, for their providers, and for the healthcare system in general, and we’ll explore short- and long-term policy solutions that could mitigate the OOP burden for individuals.” The need for continued dialogue on the topic is vitally important in today’s uncertain political environment, in which: (1) it is unclear whether policy solutions such as placing a hard cap on OOP costs will move forward, (2) patient challenges in accessing

TED: OOP COSTS FOR PRESCRIPTION DRUGS

- » Ted has chronic myelogenous leukemia (CML), a rare blood cancer, as well as diabetes and high blood pressure
- » His income, although low/fixed, is above the cutoff for Medicare’s low-income subsidy (LIS)
- » CML guidelines call for treatment with tyrosine kinase inhibitors (TKIs), which have high coinsurance requirements for non-LIS patients
- » Of Ted’s \$6,322 yearly OOP drug expenses, he must pay 40% (\$2,456) in January²

— AMY NILES³

¹ Short biographies of all Roundtable participants are provided in *Appendix B*.

and affording needed medications are likely to continue, and (3) increasing numbers of patients will need financial assistance in the future. Referring to a hypothetical Medicare beneficiary named Ted who has a rare blood cancer and high OOP drug costs (see box on page 11), Niles said, “There will be more and more people like Ted, who is on a fixed income and cannot afford hundreds let alone thousands of dollars to cover the OOP costs for medications.” There was widespread agreement on the part of Roundtable participants that people like Ted will continue to bear the brunt of high OOP medication costs, and that there is no clear source of relief for these individuals in the near future.

“At the PAN Foundation, we get calls every day from people who can’t afford to get their medications without the assistance we provide. It can be as little \$50 dollars in OOP costs that prevents somebody from getting a critical medication.”

— DAN KLEIN

In response to the growing reliance on the patient safety net, PAN identified the need to better understand how and why people seek financial assistance for their OOP medication costs. In 2017, PAN, in collaboration with 21 patient advocacy groups, implemented a Patient Assistance Survey that examined multiple factors associated with patients’ OOP cost burdens [Figure 1].⁴ Of the 1,897 survey respondents, 37% could not cover the OOP costs for their prescription medications and 70% were extremely concerned about financial hardships. Niles explained, “Many people living with cancer and multiple sclerosis could not afford any of the costs.” Another result of the survey was that 22% of those who could not cover their OOP drug costs did not look for financial assistance. More than half of these patients were unaware that help was available. “So we all have a lot of work to do,” said Niles. “We need our collective voices to continue to advocate for improved access and affordability for patients.”

Niles then introduced Surabhi Dangi-Garimella, PhD, Associate Editorial Director, *AJMC*[®], who underscored the purpose of the meeting and challenged attendees to answer the question: “How can we improve patient access to much-needed care?” Dan Klein, President and CEO of the PAN Foundation, took the podium to welcome everyone and to emphasize the persistence of the problem of cost sharing. “Unfortunately,” he said, “even after three years of hosting the Roundtable, cost sharing remains a serious and growing problem, especially for people on Medicare who have life-threatening, chronic and rare diseases. It seems unlikely that the need for patient assistance will go away before next year’s Roundtable,” he continued. “High-deductible health plans and growing restrictions on the use of

²Doshi 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.” *Am J Manag Care*. <http://www.ajmc.com/journals/supplement/2017/beyond-charitable-assistance-sustainable-strategies-for-providing-access-to-critical-medications/reducing-out-of-pocket-cost-barriers-to-specialty-drug-use-under-medicare-part-d>. Accessed March 24, 2018.

(PAN Challenge #2 runner-up)

³PAN Foundation. Access to prescription medications under Medicare Part D. Issue Brief 2. June 2017. <https://panfoundation.org/files/PAN-Issue-Brief-2.pdf> Accessed March 24, 2018.

COST-SHARING ROUNDTABLE: A SHORT HISTORY

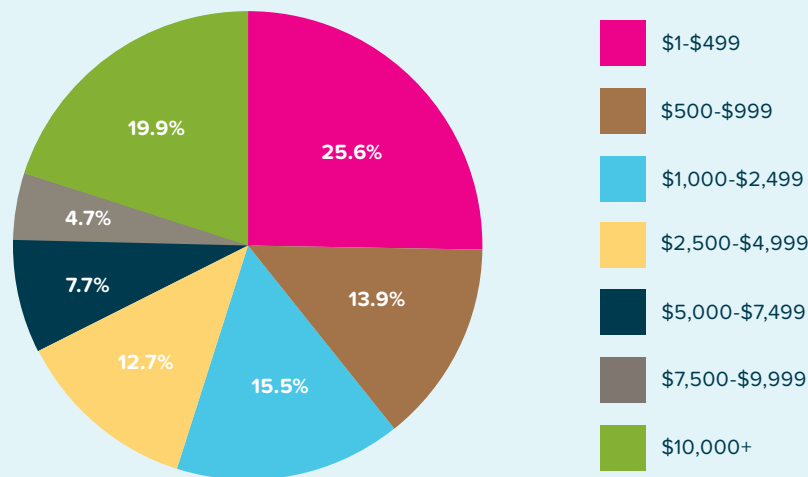
In fall 2014, the PAN Foundation hosted a patient advocacy roundtable that addressed the difficulty of meeting the growing need to help patients meet their OOP medication expenses. The desire to continue the conversation about cost sharing resulted in PAN and AJMC® co-hosting the first Cost-Sharing Roundtable in 2016, which laid the groundwork for the ones that followed.

- » *Improving Patient Access to Critical Therapies*, February 2016: Included focused discussions on the economic challenges associated with OOP costs faced by patients and caregivers
- » *Sustainable Strategies for Providing Access to Critical Medications*, February 2017: Explored the challenges of high-need patients and the uncertainty surrounding the future of the Affordable Care Act (ACA), as well as potential solutions to this growing problem
- » *The Patient Assistance Safety Net: How Many Need Help? How Many are Helped?*, February 2018: Continuation of the dialogue about the persistent burden of cost sharing and the increasing importance of the patient assistance safety net

These sessions featured representatives from patient advocacy organizations, the health insurance and pharmaceutical industries, professional/nonprofit groups, academia, clinical practice and individuals involved in public policy.

FIGURE 1. 4

Percentage distribution of the amount of OOP drug costs survey respondents reported being unable to cover in the past year



commercial co-pay cards and coupons are putting more pressure on commercially insured patients, who will begin to look to charitable foundations, such as PAN, for help with their OOP costs.”

As in previous years (see box on page 13), the 2018 Roundtable explored the issue of medication affordability from many angles. The agenda, which can be found in **Appendix A**, covered critical topics, including the financial hardship that accompanies illness, access to medications for Medicare beneficiaries, the effect of high OOP costs on clinical practice and patient outcomes, policy considerations to improve access and reduce financial hardship and the patient assistance safety net. The Roundtable also included presentations of the winning papers of the 2017 PAN Challenge, which solicited new research on the impact of cost sharing and the need for the patient safety net. A common thread that ran through the 2018 Roundtable was the uncertainty surrounding the future of the Affordable Care Act (ACA), and what changes to the program could mean for access and affordability of care.

The PAN Challenge

The third annual (2017) PAN Challenge, *The Patient Assistance Safety Net: How Many Need Help? How Many Are Helped?* solicited papers that quantified the following:

Need for patient assistance

- » For the underinsured population, how many people need financial assistance to pay for the OOP costs associated with their prescription medications?
- » What is the dollar amount of assistance that is needed?

⁴PAN Foundation. Patient experiences with out-of-pocket medication expenses. Issue Brief 3. December 2017. <https://panfoundation.org/files/PAN-Issue-Brief-3.pdf>. Accessed March 24, 2018.

2017 PAN CHALLENGE WINNING PAPERS

Winner

Ensuring Access to Prescription Medications in the Post-ACA Healthcare Access Landscape: The Essential Role of FQHCs in the Safety Net for the Underinsured⁵

Lizheng Shi, PhD, MsPharm, MA; M. Kristina Wharton, MPA, MPH; Alisha Monnette, MPH

Tulane University School of Public Health and Tropical Medicine

Runner-Up

Impact of Trained Oncology Financial Navigators on Patient Out-of-Pocket Spending⁶

Todd Yezefski, MD; Jordan Steelquist; Kate Watabayashi; Dan Sherman, MA; Rosie Cunningham, BA; Rebecca Lobb, ScD; Veena Shankaran, MD

Fred Hutchinson Cancer Research Center

Honorable Mention

A Descriptive Study of Patients Receiving Foundational Financial Assistance through Local Specialty Pharmacies⁷

Julia Zhu, MPH, MS; Randall Odebralski, MBA; Safia Boghani, MPH, Clorinda Walley; Frank Koen, RPh;

Chad Conley; Heather Kirkham, PhD, MPH

Walgreen Co. and Good Days Foundation

Size of the safety net

- » How large is the current safety net for people who need financial assistance to pay for the OOP costs associated with their prescription medications?
- » How many and what kinds of safety net programs are available?
- » What diseases and medications do they cover?
- » How much assistance do they provide?
- » How many people are unable to get the help they need?
- » Are there factors that limit the reach of safety net programs?

The papers were juried by an expert panel and the winners were announced in January 2018.

The winning paper evaluated the role of federally qualified health centers (FQHCs) in serving uninsured and underinsured patients and providing need-based, reduced-cost prescription medications in the post-ACA landscape. The runner-up paper demonstrated that hospitals that use trained financial navigators were able to facilitate access to care that would otherwise be unaffordable, and at the same time, reduce charity care and bad debt for the hospitals. In the paper that received an Honorable Mention, the authors described how local specialty pharmacies (Walgreens) collaborated with a charitable assistance organization (Good Days Foundation) to facilitate access to care for patients with chronic illnesses, thereby allowing them to focus on receiving and adhering to their treatment, rather than forgoing it because of financial hardship. The winning and runner-up papers were presented during the Roundtable and all three papers were published in the March 2018 supplement* of *AJMC*[®].

* <http://www.ajmc.com/journals/supplement/2018/the-patient-assistance-safety-net-how-many-need-help-how-many-are-helped>

⁵Shi L, Wharton MK, Monnette A. Ensuring access to prescription medications in the post-ACA healthcare access landscape: The essential role of FQHCs in the safety net for the underinsured. *Am J Manag Care*. March 6, 2018. <http://www.ajmc.com/journals/supplement/2018/the-patient-assistance-safety-net-how-many-need-help-how-many-are-helped/ensuring-access-to-prescription-medications-in-the-postaca-healthcare-access-landscape-the-essential-role-of-fqhcs-in-the-safety-net-for-the-underinsured>. Accessed March 24, 2018.

⁶Yezefski T, Steelquist J, Watabayashi K, Sherman D, Shankaran V. Impact of trained oncology financial navigators on patient out-of-pocket spending. *Am J Manag Care*. March 6, 2018. <http://www.ajmc.com/journals/supplement/2018/the-patient-assistance-safety-net-how-many-need-help-how-many-are-helped/impact-of-trained-oncology-financial-navigators-on-patient-outofpocket-spending>. Accessed March 24, 2018.

⁷Zhu J, Odebralski R, Boghani S, Walley C, Koen F, Conley C, Kirkham HS. A descriptive study of patients receiving foundational financial assistance through local specialty pharmacies. *Am J Manag Care*. March 6, 2018. <http://www.ajmc.com/journals/supplement/2018/the-patient-assistance-safety-net-how-many-need-help-how-many-are-helped/a-descriptive-study-of-patients-receiving-foundational-financial-assistance-through-local-specialty-pharmacies>. Accessed March 24, 2018.

Financial Hardship: An Emerging Consequence of Illness in the United States

“Cancer patients and survivors report being worried about being able to pay their rent or that they’ve spent a day or more in the past week skipping meals because they couldn’t afford to eat.” — ROBIN YABROFF

The Growing Impact of Financial Toxicity

Adverse economic impacts have become an inextricable part of the U.S. landscape of illness. In their runner-up PAN Challenge paper, *Impact of Trained Oncology Financial Navigators on Patient Out-of-Pocket Spending*⁸, the authors begin by noting the following:

“After a cancer diagnosis, patients and families face many stressors including the possibility of significant short-term and long-term financial consequences. Rising premiums, deductibles, coinsurance and co-payment for oral oncology drugs, many of which cost over \$10,000 per month, are exposing patients and families to significant out-of-pocket healthcare spending. These direct medical costs, in combination with the indirect costs related to patients’ and families’ decreased work hours or loss of employment, create a perfect storm for financial devastation.”

FINANCIAL EFFECTS OF A CANCER DIAGNOSIS

- » High monthly costs for cancer drugs
- » Increased risk of bankruptcy
- » Bankruptcy increases mortality risk in cancer survivors
- » Most (75%) cancer patients report stress and anxiety about the cost of cancer care⁹

⁸Yezeffski T, Steelquist J, Watabayashi K, Sherman D, Shankaran V. Impact of trained oncology financial navigators on patient out-of-pocket spending. *Am J Manag Care*. March 6, 2018. <http://www.ajmc.com/journals/supplement/2018/the-patient-assistance-safety-net-how-many-need-help-how-many-are-helped/impact-of-trained-oncology-financial-navigators-on-patient-outofpocket-spending>. Accessed March 24, 2018.

⁹Yezeffski T, Steelquist J, Watabayashi K, Sherman D, Shankaran V. Impact of trained oncology financial navigators on patient out-of-pocket spending. *Am J Manag Care*. March 6, 2018. <http://www.ajmc.com/journals/supplement/2018/the-patient-assistance-safety-net-how-many-need-help-how-many-are-helped/impact-of-trained-oncology-financial-navigators-on-patient-outofpocket-spending>. Accessed March 24, 2018.

These observations were echoed by other Roundtable speakers. In her morning keynote, *Financial Hardship: An Emerging Consequence of Illness in the United States*, K. Robin Yabroff, PhD, Strategic Director, Surveillance & Health Services Research Program, American Cancer Society, described the magnitude of illness in the United States, in which a large proportion of the adult population has at least one chronic condition. The number of chronic conditions increases with age, and the effects of disease

ILLNESS IN THE UNITED STATES

- » Increased prevalence of chronic conditions
 - Half of U.S. adults have at least one chronic condition
 - One-third have more than one chronic condition
 - Number of chronic conditions increases with age
 - The U.S. population is aging
 - Public opinion surveys cite OOP healthcare costs as a major concern
- » Increasing healthcare expenditures, especially OOP costs
- » Lasting effects of disease and its treatment:
 - Increased risk of other chronic conditions
 - Limitations in amount or kind of work patients can perform, less income, less access to employer-sponsored health plans, job lock¹⁰
 - Forgone or delayed healthcare because of cost

and its treatment are long-lasting. Throughout Yabroff's presentation, it became clear that the enduring financial effects of disease treatment can become a chronic condition itself.

Illness-associated financial hardship are exacerbated by the fact that in 2017, 43.2% of U.S. health insurance plans are classified as high-deductible health plans (HDHPs),¹¹ which contribute, along with coinsurance and co-payments (co-pays), to increased cost sharing. Additional trends affecting healthcare-associated financial hardship in the United States include rising treatment costs, recent increases in the uninsured population (who are responsible for 100% of their healthcare bills), and cost-associated changes in treatment patterns.

¹⁰Yabroff defined job lock as people being restricted to certain jobs, or staying in lower-paying jobs, because of health insurance benefits.

¹¹HDHPs are defined by the National Center for Health Statistics as having an annual deductible of at least \$1300 for individual or \$2600 for family coverage. Cohen RA, Zammiti EP. High-deductible Health Plans and Financial Barriers to Medical Care: Early Release of Estimates From the National Health Interview Survey, 2016. June 2017. https://www.google.com/url?sa=t&rct=j&q=&resrc=s&source=web&cd=6&ved=0ahUKEwjIk7v6tdjZAhWCmeAKHQp-BRUQFghxMAU&url=https%3A%2F%2Fwww.cdc.gov%2Fncchs%2Fdata%2Fnhis%2Fearlyrelease%2FERHDHP_Access_0617.pdf&usg=AOvVaw0paYy-j1V_9QPkBNbYnLUZ. Accessed March 24, 2018.

Prescription Drug Costs

The high cost of oral prescription medications is a prime cause of financial hardship. “These drugs,” said Yabroff, “are commonly on formulary tiers [Table 1] Where you would have a generic tier under \$5 per drug, you might have a preferred brand tier a little bit more in terms of a fixed co-payment...then next would be branded drugs not necessarily preferred, and then the specialty tier, which generally has a coinsurance rate of 30%–40% of the listed drug price...If you think of a drug that costs \$100,000 a year, that OOP payment will be \$30,000–\$40,000 a year...To put this in perspective, the median household income in 2015 was \$56,000.”¹³

“A lot of people have no idea what you’re taking about when you say coinsurance. They think it’s a \$50 co-pay and they show up at the pharmacist’s counter and they are flabbergasted. It’s unimaginable how high the costs are.”
— PAUL BILLINGS

T A B L E 1 .¹²
Prescription Drug Tiers

DRUG TIER	DESCRIPTION	COST
Tier 1. Preferred Generic	Commonly prescribed generic drugs	\$
Tier 2. Generic	Generic drugs that cost a little more than Tier 1	\$\$
Tier 3. Preferred	Brand-name drugs with no generic equivalent. Lowest-cost brand-name drugs on drug list	\$\$\$
Tier 4. Nonpreferred	Higher-priced brand-name and generic drugs not in a preferred tier	\$\$\$\$
Tier 5. Specialty	Most expensive. Used to treat complex conditions like cancer and MS. Can be generic or brand-name	\$\$\$\$\$

Yabroff noted the exponential increase in the cost of cancer drugs after 2010 as a key driver of increased burden among cancer patients. Invariably, these costs impose financial hardships, and they have been found to increase the risk of bankruptcy. In a 2013 study published in *Health Affairs*,¹⁴

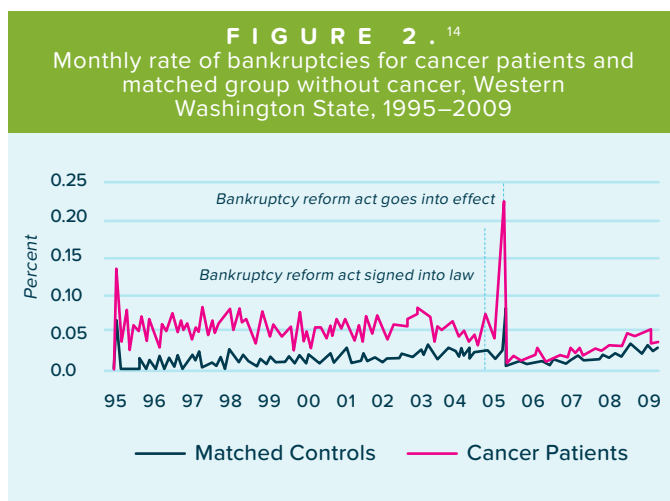
¹²Adapted from Blue Cross Blue Shield Blue Care Network. How do drug tiers work? <https://www.bcbsm.com/medicare/help/understanding-plans/pharmacy-prescription-drugs/tiers.html>. Updated October 2, 2017. Accessed March 24, 2018.

¹³In 2016, median household income rose to \$57,617. Source: Guzman GG. Household income: 2016. American Community Survey Briefs. September 2017. <https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=13&ved=0ahUKewjz2M7Vw9jZAhVIJt8KHeweWEAjkQFghjMAw&url=https%3A%2F%2Fwww.census.gov%2Fcontent%2Fdam%2FCensus%2Flibrary%2Fpublications%2F2017%2Facs%2Facs-br16-02.pdf&usq=AOvVaw3nUtMg4e13CXunZs5ZzEJl>. Accessed March 24, 2018.

¹⁴Ramsey S, Blough D, Kirchoff A, Kreizenbeck K, Fedorenko C, Snell K, et al. Washington state cancer patients found to be at greater risk for bankruptcy than people without a cancer diagnosis. *Health Aff* 2013;32(6):1143-1152. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4240626/>. Accessed March 24, 2018.



cancer patients in Washington State were 2.65 times more likely to go bankrupt than people without cancer [Figure 2]. In a subsequent study, the authors determined that filing for bankruptcy increases mortality risk in cancer survivors by nearly 80%.¹⁵ In trying to understand why the act of filing for bankruptcy could increase patients' risk of dying, the authors hypothesized that factors such as lower quality of life, reductions in overall well-being, increased food and housing insecurity, increased stress due to worry, decreased treatment adherence or lack of access to care could play a role.¹⁵ The idea that efforts to pay for lifesaving treatment may in themselves be life-threatening underscores the need for the patient safety net, a central theme of the 2018 PAN Roundtable.



Co-pay Accumulator Programs

Co-pay accumulator programs are a new type of cost-sharing tool that increases patients' OOP drug costs. These programs prevent manufacturer co-pay cards from being applied to a patient's deductible, thereby shifting more of the deductible back to the patient. Emily Harrison Gibb, Interim Vice President, Public Policy & Patient Assistance, GlaxoSmithKline (GSK), explained that co-pay accumulators are, "a utilization management tool...to keep patients in the deductible phase longer." A Q&A participant in the *Policy Considerations to Improve Access and Reduce Financial Hardship* panel asked about the short-term impact of these new policies, and what recourse patients have when they exhaust resources

"A lot of pharmacy benefit managers are using accumulator programs to prohibit manufacturer co-pay cards from being used through a patient's deductible. So, what happens if you're, say, a rheumatoid arthritis patient, you're on a biologic, you're using your co-pay card thinking that it's going toward your deductible like it always has and then all of a sudden, let's say April or May rolls around, and you get whacked with this \$3,000–\$4,000 bill at the pharmacy counter that you weren't expecting... So what do you do when you get a \$4,000 bill? You abandon your therapy."

— ANNA HYDE

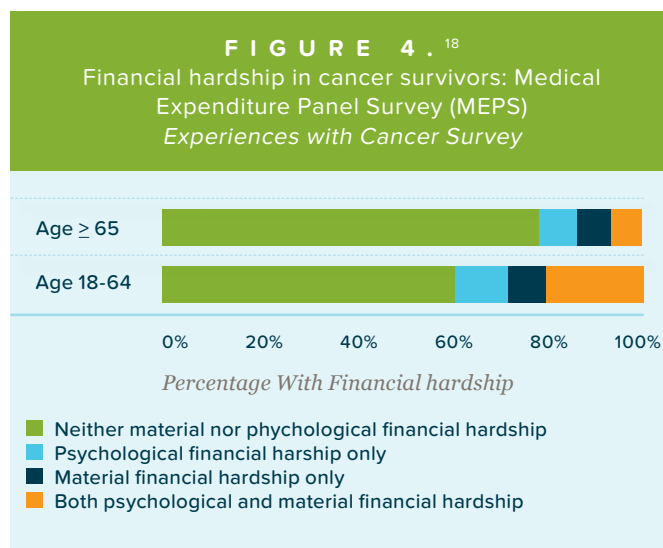
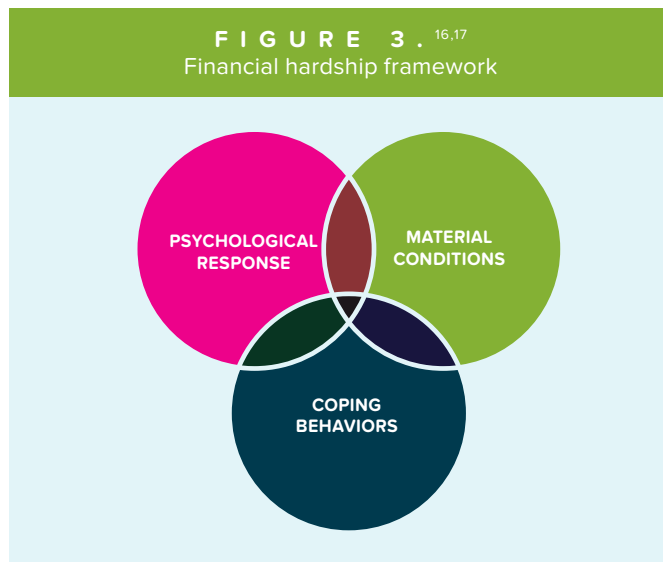
¹⁵Ramsey SD, Bansal A, Fedorenko CR, Blough DK, Overstreet KA, Shankaran V, Newcomb P. Financial insolvency as a risk factor for early mortality among patients with cancer. *J Clin Oncol* 2016;34(9):980-986. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4933128/>. Accessed March 24, 2018.

such as those provided by charitable foundations such as PAN. “Are there provisions to help these patients?” he asked. Anna Hyde, Vice President of Advocacy and Access, Arthritis Foundation, indicated that their research has confirmed that the short-term impact of not being able to pay for medications is non-adherence.

“My personal view,” said Gibb, “is that it shouldn’t matter whether co-pay assistance comes from a GoFundMe account or from a manufacturer, or from someone’s church. We have a patchwork of safety net resources in this country, and if patients are able to get assistance, then they should be able to use it in a way that moves them closer to using the insurance that they are actually paying premiums for.” Gibb said that co-pay accumulator programs present a “very big educational uphill battle” because they are new, and neither patients nor providers understand how they work. What is clear, however, is that many patients who were once accustomed to passing through the deductible phase of their prescription drug plans with the help of manufacturer coupons will no longer be able to rely on that resource in the same way in the future.

Categories of Hardship

Yabroff and colleagues recognized that the financial hardship that patients encounter when trying to secure access to needed care is complex and multi-faceted. To



¹⁶Tucker-Seeley R, Yabroff KR. Minimizing the “financial toxicity” associated with cancer care: Advancing the research agenda. *J Natl Cancer Inst* 2015;108(5).

¹⁷Altice CK, Banegas MP, Tucker-Seeley RD, Yabroff KR. Financial hardships experienced by cancer survivors: A systematic review. *J Natl Cancer Inst* 2017;109(2).

¹⁸Yabroff KR, Dowling EC, Guy Jr GP, Banegas M, 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.

parse out its components, they developed a financial hardship framework (*Figure 3*)^{16,17}, that includes several domains:

- » material conditions (e.g., problems paying medical bills);
- » psychological response (worrying about paying medical bills); and
- » coping behaviors (changing behavior as a result of medical bills, such as forgoing the care that they need because it is too expensive

Yabroff’s research on this framework confirmed the complexity of patients’ financial experiences. Her study, which used Medical Expenditure Panel Survey (MEPS) data, indicated that 40% of cancer survivors age 18–64 and 20% of those over the age of 65 experience material and/or psychological hardship [*Figure 4*].¹⁸ These findings were echoed by data from the 2012 LIVESTRONG Experiences with Cancer

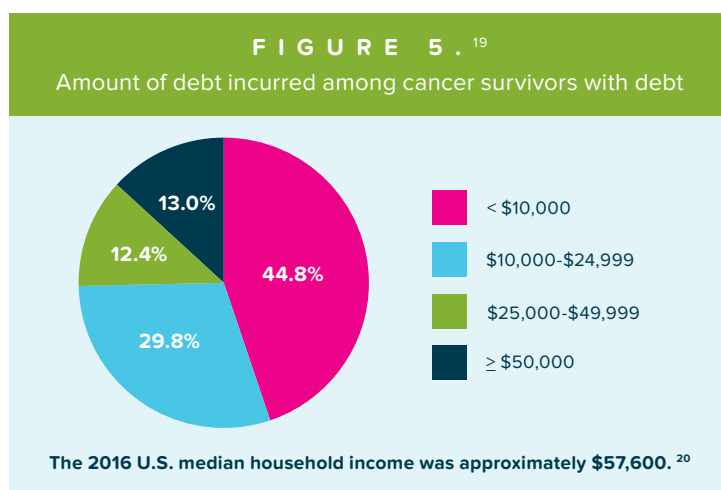
survey of financial hardship in cancer survivors ages 18–64 [*Table 2*],¹⁸ which indicated that one-third of all cancer survivors endure material hardships such as borrowing money, going into debt, filing for bankruptcy or making other sacrifices, and two-thirds endure the psychological hardship of worrying about their medical bills.

Among those with debt, more than two-thirds had material hardships (made sacrifices) and almost 90% suffered the psychological hardship of bill-related worry. Yabroff said that cancer patients and survivors report, “being worried about being able to pay their rent or report that they’ve spent a day or more in the past week skipping meals because they couldn’t afford to eat.” These data underscore the idea that illness-related financial hardship is not limited to the patient’s ability to access medications—it is linked to securing basic necessities for survival.

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TABLE 2 .¹⁸
Financial hardship in cancer survivors aged 18-64

FINANCIAL HARSHIP	FULL SAMPLE (%)	AMONG THOSE WITH DEBT (%)
Material hardship		
Borrowed money or went into debt	33.6	
Filed for bankruptcy	3.1	9.1
Other sacrifices	39.7	68.0
Psychological hardship		
Worried about medical bills	63.8	86.6

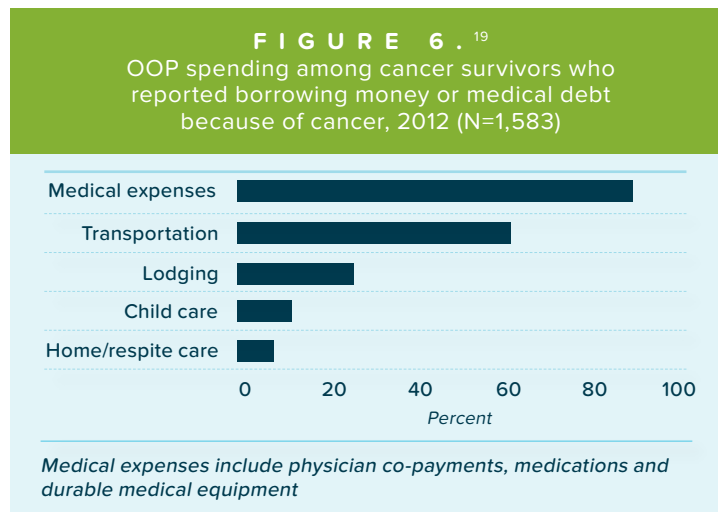


¹⁹Banegas M, Guy Jr GP, de Moor JS, Ekwueme DU, Virgo KS, Kent EE, et al. For working-age cancer survivors, medical debt and bankruptcy create financial hardships. *Health Aff* 2016;35(1):54-61

Importantly, it is common for financial hardship to persist even after cancer treatment has concluded and patients have been cured, or are in remission. As shown in *Figure 5*, among cancer survivors with debt, one-third owe \$10,000–\$24,999, with the remaining 25% almost evenly split between those who owe \$25,000–\$49,999 and those who are in debt in excess of \$50,000.

“Cancer survivors or individuals with illness,” continued Yabroff, “are spending for more than just medical care.” Although more than 90% have OOP costs for medical care, a large percentage spend money on transportation, lodging, childcare, hospice and respite care as well [*Figure 6*]. In addition to these types of expenses, people with cancer and other chronic illnesses may also have expenses related to hospital and emergency room visits, imaging (especially advanced imaging such as PET scans), and medical devices. It is not surprising that the financial burdens associated with securing appropriate healthcare—including prescription medications—can generate debt from which patients have great difficulty extracting themselves, even when their health is restored.

Although financial hardship is relatively common, especially in the working-age population, it disproportionately affects certain subsets of patients. Yabroff noted that MEPS data show that women are at higher risk of financial hardship than men, and that the highest risk of bankruptcy is among young women with certain cancers. These findings are supported by a larger body of literature indicating that being young, female, of a minority race or ethnicity, low-income, unemployed, uninsured or underinsured; having changed jobs because of cancer; having certain types of cancer; or being recently diagnosed/treated raise the risk of financial hardship.²¹⁻²⁸



²⁰In 2016, median household income rose to \$57,617. Source: Guzman GG. Household income: 2016. American Community Survey Briefs. September 2017. <https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=13&ved=0ahUKewjz2M7Vw9jZAhVIJt8KHeWEAjkQFghjMAw&url=https%3A%2F%2Fwww.census.gov%2Fcontent%2Fdam%2FCensus%2Flibrary%2Fpublications%2F2017%2Facs%2Facsbr16-02.pdf&usq=AOvVaw3nUtMg4e13CXunZs5ZzEJl>. Accessed March 6, 2018.

²¹Yabroff KR, Dowling EC, Guy Jr GP, Banegas M, 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.

²²Banegas M, Guy Jr GP, de Moor JS, Ekwueme DU, Virgo KS, Kent EE, et al. For working-age cancer survivors, medical debt and bankruptcy create financial hardships. *Health Aff* 2016;35(1):54-61

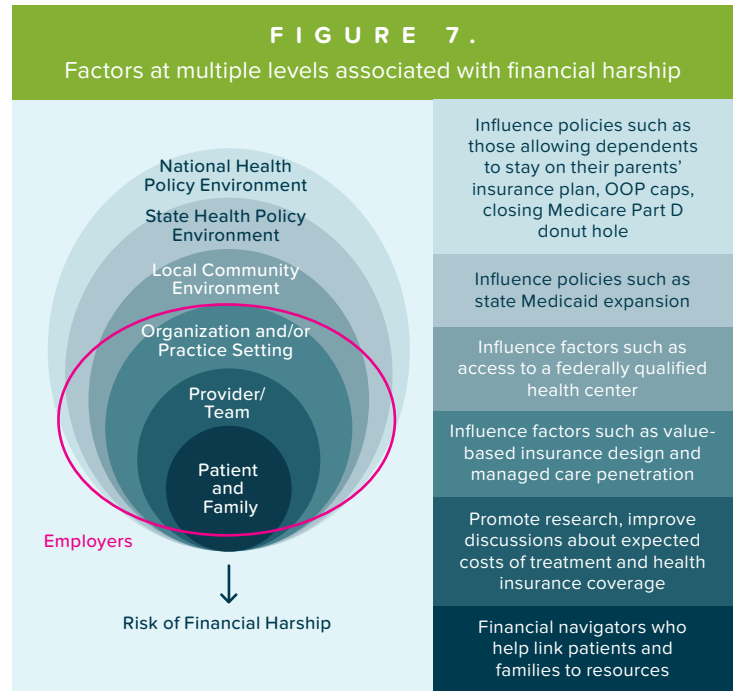
²³Zheng Z, Han X, Guy GP Jr, Davidoff AJ, Li C, Banegas MP, Ekwueme DU, et al. Do cancer survivors change their prescription drug use for financial reasons? Findings from a nationally representative sample in the United States. *Cancer* 2017;123(8):1453-1463.

²⁴Altice CK, Banegas MP, Tucker-Seeley RD, Yabroff KR. Financial hardships experienced by cancer survivors: A systematic review. *J Natl Cancer Inst* 2017;109(2)

These risk factors, concluded Yabroff, “are historically associated with poor health outcomes.” This point was also made by PAN Challenge Runner-Up author Todd Yezefski, MD, Senior Fellow, Clinical Research Division, Fred Hutchinson Cancer Research Center and Division of Medical Oncology, University of Washington, who noted that, “Financial distress and toxicity disproportionately affects younger, nonwhite and lower-income patients.” These forces manifest as financial setbacks such as accrual of debt, loss of savings and assets and personal bankruptcy.^{21,29-32}

Addressing the Issue

Yabroff provided a framework for examining and addressing illness-associated financial hardship and some example strategies for addressing them. The risk of financial hardship can be envisioned as being influenced by factors in a series of concentric circles [Figure 7]. These factors include the patient and family; the healthcare provider/team; and the local, state, and national policy environments. Employers also play a key role, with the choice of health insurance plans that they offer to their employees and policies such as paid sick leave. This framework is useful for identifying risk factors for financial hardship, and for examining the intervention strategies that may be used to mitigate it [Table 3].



²⁵Kent EE, Forsythe LP, Yabroff KR, Weaver KE, de Moor JS, Rodriguez JL, Rowland JH. Are survivors who report cancer-related financial problems more likely to forgo or delay medical care? *Cancer* 2013;119(20):3710-3717.

²⁶Shankaran V, Jolly S, Blough D, Ramsey SD. Risk factors for financial hardship in patients receiving adjuvant chemotherapy for colon cancer: A population-based exploratory analysis. *J Clin Oncol* 2012;30(14):1608-1614;

²⁷Jagsi R, Pottow JA, Griffith KA, Bradley C, Hamilton AS, Graff J, Katz SJ, Hawley ST. Long-term financial burden of breast cancer: experiences of a diverse cohort of survivors identified through population-based registries. *J Clin Oncol* 2014;32(12):1269-1276.

²⁸Zafar SY, McNeil RB, Thomas CM, Lathan CS, Ayanian JZ, Provenzale D. Population-based assessment of cancer survivors' financial burden and quality of life: a prospective cohort study. *J Oncol Pract* 2015;11(2):145-150.

²⁹Nicolajje KAH, Ezendam NPM, Vos MC, et al. The state of cancer care in America, 2014: A Report by the American Society of Clinical Oncology. *J Clin Oncol*. 2014;33(31):119-142.

³⁰Ramsey S, Blough D, Kirchoff A, Kreizenbeck K, Fedorenko C, et al. Washington state cancer patients found to be at greater risk for bankruptcy than people without a cancer diagnosis. *Health Aff*. 2013;32(6):1143-1152.

³¹Banegas MP, Guy GP, de Moor JS, Ekwueme DU, Virgo KS, Kent EE, et al. For working-age cancer survivors, medical debt and bankruptcy create financial hardships. *Health Aff*. 2016;35(1):54-61.

Need for Further Research

At the end of her presentation, Yabroff noted that most data on financial hardship are from cross-sectional surveys and don't follow people longitudinally. Thus, she said, "We don't know exactly when financial hardship begins and we also don't know if, at some point, it lifts." Yabroff added that one of the best ways to measure financial hardship burden is the Comprehensive Score for financial Toxicity (COST) measure. She said that this tool, developed by de Souza et al.,³³ has "demonstrated reliability and validity in measuring financial toxicity. Its correlation with HRQOL [health-related quality of life] indicates that financial toxicity is a clinically relevant patient-centered outcome." Although much progress has been made on examining the relationship between financial hardship and various outcomes, more research is needed to develop a solid evidence base to assess its full effects. Yabroff noted that improved understanding of financial hardship could be gained via clinical trials, longitudinal data collection and expanded national surveys. Results of this research, she said, will be important in evaluating strategies, informing policy, and ultimately, in improving health outcomes.

LEVEL	EXAMPLE STRATEGIES
Patient and family	Financial navigators
Provider/team	Discussions about expected cost and benefits of treatment
Organization and practice setting	Value-based insurance benefit design
Employers	Workplace accommodations; paid sick leave
State policy environment	Medicaid expansion
National policy environment	OOP caps; closing Medicare Part D donut hole

³²Gordon LG, Merollini KMD, Lowe A, Chan RJ. A systematic review of financial toxicity among cancer survivors: We can't pay the co-pay. *Patient*. 2016:1-15.

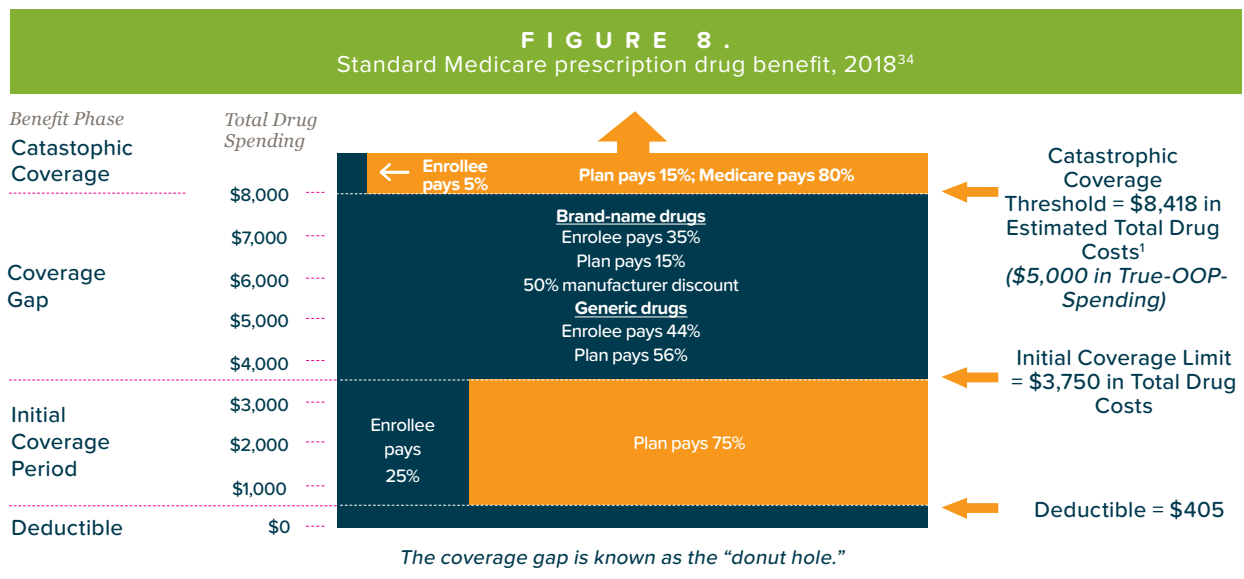
³³De Souza JA, Yap BJ, Wroblewski K, Blinder V, Araujo FS, Hlubocky FJ, et al. Measuring financial toxicity as a clinically relevant patient-reported outcome: The validation of the Comprehensive Score for financial Toxicity (COST). *Cancer* 2017;123(3):476-484. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5298039/>. Accessed March 24, 2018.

3 Access to Medications for the Medicare Population: Current and Future Need

“People don’t understand how the Medicare program works. They don’t understand how the various parts work. They don’t really understand what Part D is. If you start talking about Part D, they say, ‘What is that? I don’t get it.” – JULIE CARTER

Current Realities

In his introductory remarks, Klein noted that OOP costs are increasing for many Medicare beneficiaries, especially for those who have life-threatening, chronic and rare diseases, both in terms of the percentage who are paying large proportions of their income in OOP healthcare costs and in the numbers that are reaching the catastrophic threshold. “Given the complexity of the issue,” he



³⁴Fact sheet: The Medicare Part D prescription drug benefit. Kaiser Family Foundation. October 2017. <http://files.kff.org/attachment/Fact-Sheet-The-Medicare-Part-D-Prescription-Drug-Benefit>. Accessed March 24, 2018.

said, “it’s easy for policymakers to lose sight of the day-to-day challenges that face people with serious illness getting access to their critical medications.” He continued, “Many of the patients who we help can’t afford the annual deductible, they can’t afford the 25% cost-sharing during the initial coverage period and they can’t afford even the discounted cost that they pay during the coverage gap [shown in *Figure 8*].” He pointed out that more than one-third of Medicare patients spend in excess of 20% of their household income on health-related OOP costs. This number is projected to grow to over 40% in the next decade. “That’s a daunting number,” said Klein.

Cost and Access

Julie Carter, Federal Policy Associate, Medicare Rights Center, kicked off the panel discussion, *Access to Medications for the Medicare Population: Current and Future Need*, by describing Medicare beneficiaries’ current needs. Carter noted that not only has there been a large uptick in the number of calls into the Medicare Rights Center hotline, but many more questions are being raised that the Center can’t help with. “We are seeing more people who are falling through various cracks,” she said, “not eligible for Medicare savings programs or extra help because they’re making just a little bit too much money but can’t afford their physician services, hospital services or prescription drugs. More and more people are realizing they have no place to turn for assistance, something that we saw a lot of before the ACA.” As was

CATASTOPHIC THRESHOLD

“After paying their \$400 Medicare Part D deductible, beneficiaries typically pay 25% of their drug costs during the *Initial Coverage Period*. After their drug costs reach \$3,700, beneficiaries enter the *Coverage Gap* phase, often termed “the donut hole.” In this phase, beneficiaries can incur considerable OOP drug costs (up to approximately \$8,000) until they reach the *Catastrophic Coverage Threshold*, at which point they pay 5% coinsurance for their drugs until the end of the calendar year. There is no cap on OOP expenses. The cycle resets on January 1.”³⁵

“In 2015, 3.6 million Medicare beneficiaries with Part D coverage had OOP drug costs above the catastrophic threshold of \$6,680. Of these, more than 1 million did not have federal low-income subsidies to protect them from high OOP drug costs, and the number of these individuals more than doubled since 2007.³⁶ Thus, even with Part D coverage, increasing numbers of older adults are exposed to extremely high OOP costs for their medications.”³⁷

— DAN KLEIN

³⁵PAN Foundation. Access to prescription medications under Medicare Part D. Issue Brief 2. June 2017. <https://panfoundation.org/files/PAN-Issue-Brief-2.pdf>. Accessed March 24, 2018.

³⁶Kaiser Family Foundation. One million Medicare Part D enrollees had out-of-pocket drug costs above the catastrophic threshold in 2015. November 7, 2017. <https://www.kff.org/medicare/press-release/one-million-medicare-part-d-enrollees-had-out-of-pocket-drug-costs-above-the-catastrophic-threshold-in-2015/>. Accessed March 24, 2018.

³⁷PAN Foundation. Patient experiences with out-of-pocket medication expenses. Issue Brief 3. December 2017. <https://panfoundation.org/files/PAN-Issue-Brief-3.pdf>. Accessed March 24, 2018.

the case before the ACA, she continued, “people are in a panic. ‘What happens if my Medicaid goes away? I’m in an expansion Medicaid—what happens if my ACA plan goes away? Is there any way I can get on Medicare early?’” Worries about Medicare eligibility, prescription drug prices and OOP costs in general are prevalent, she said, noting that uncertainty surrounding the fate of the ACA has made the past year very disruptive and unsettling, especially for economically vulnerable seniors. “People don’t understand what all of this means for Medicare,” she continued, “A lot of people don’t necessarily understand the difference between Medicaid and Medicare.” The current trend, she summarized, is characterized by “a lot of confusion, panic, and alarm.”

Hyde said that the number one concern of people calling the Arthritis Foundation Helpline, especially among Medicare beneficiaries, is “their inability to afford their co-pays for their prescription drugs. Medicare beneficiaries don’t understand that drug manufacturers are unable to provide financial assistance to them. Cost sharing is a particular concern for those on Medicaid who are transitioning onto Medicare. Rheumatoid arthritis is one of the disease areas in which folks are more likely than a lot of other diseases to end up in the catastrophic phase.”

Similarly, Gibb noted that the most common type of call received by GSK’s Reimbursement Resource Center is from patients who are 65 or older and are looking for assistance with their OOP medication costs.” “Given the regulatory environment we’re in,” she said, “we are not able to offer manufacturer coupons to this particular population, and so they are often left without an option from us.”

Leslie Fried, Senior Director, Center For Benefits Access, National Council On Aging (NCOA) added that Medicare Part D plans have five tiers, in which many, if not most, have coinsurance payments, especially for the higher tiers. “With coinsurance tiers,” she said, “enrollees experience greater OOP costs as drugs increase in price.” Fried went on to say that the factors of costs rising significantly throughout the year, and increased use of plans with rebates that Medicare beneficiaries don’t get to use have contributed to a national trend in which Medicare beneficiaries are unable to afford their OOP costs at point of sale. Increasing coinsurance requirements under Medicare Part D mean that as drug prices increase, patients’ OOP costs increases as well. Plus, noted

“Many cancer patients, especially those taking specialty drugs, blow through the donut hole pretty quickly. For those who are receiving specialty drugs for serious illness, closing the donut hole may not be as much of a help as we might like.”

— ROBIN YABROFF

“At the Medicare Rights Center, we have a national hotline and we receive calls from about 20,000 people every year with questions about Medicare. Many of those revolve around affordability. Access and affordability are the two questions that we receive the most.”

— JULIE CARTER

Fried, “once they get into the catastrophic phase they still have a 5% coinsurance payment, which is a significant portion of a five- or six-figure drug.”

“There is a narrative out there,” said Leigh Purvis, Director, Health Services Research, AARP Public Policy Institute, “that Medicare beneficiaries can afford increases in healthcare costs. But the median income for Medicare beneficiaries is around \$26,000 a year; a quarter of them have incomes of less than \$15,000 a year, and a quarter of them have less than \$15,000 in savings.”³⁸ The source of these income data, a 2017 Kaiser Family Foundation report,³⁸ also indicated that being African-American or Hispanic, being ≤65 or >85, and being single, widowed or divorced dramatically affected the amount of savings among Medicare beneficiaries. In 2016, 24% of Medicare beneficiaries had no home equity and 25% had home equity below \$7,350.

“So when you’re talking about increasing healthcare costs,” Purvis continued, “you aren’t talking about a population that can really afford to absorb those costs easily, if at all, especially if they’re on a fixed income.” She related that many AARP members are taking prescription drugs to help control chronic conditions, and are now finding that they can no longer afford those drugs. These individuals are falling through cracks in the system, and Purvis said she is finding it increasingly difficult to be able to help them. “I’m desperate,” they tell her. “Please help me get access to this drug.” Not only is Purvis having difficulty finding help for these people, but their numbers are increasing rapidly. As a final emphasis on her larger point, Purvis said that AARP surveys its members regularly to ascertain what their concerns are, and prescription drug prices are always at the top of the list.

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

— DAN KLEIN

“It’s ‘pay me now or pay me later.’ Medicare is paying later in a big way for hundreds of dollars of medication that prevents tens of thousands of dollars of hospitalization.”

— PAUL BILLINGS

Problems Navigating the System

A fundamental problem that Medicare beneficiaries have is that they don’t understand how Medicare works and have difficulty choosing the plan that will best cover their OOP costs. “They don’t understand how the various parts work,” said Carter. “They don’t understand really what Part D is.” Paul Billings, National Senior Vice President, Advocacy, American Lung Association (ALA), concurred. “We have a cohort that is hitting the donut hole who didn’t know the donut hole existed,”

³⁸Jacobson G, Griffin S, Neuman T, Smith K. Income and assets of Medicare beneficiaries, 2016-2035. Kaiser Family Foundation. April 21, 2017. <https://www.kff.org/medicare/issue-brief/income-and-assets-of-medicare-beneficiaries-2016-2035/>. Accessed March 24, 2018.

he said. Carter expanded on this by saying that the plans are so complicated, and the choices so numerous, that Medicare beneficiaries are having a great deal of trouble identifying a plan that fits their needs. Many beneficiaries find the process so daunting that they just default to staying with their current plan, even if another plan would be more appropriate to meet their changing circumstances. “People get lost in this maze,” she said, “and a lot of people simply will not choose because it’s too hard.”

Edmund Haislmaier, Preston A. Wells Jr., Senior Research Fellow in Domestic Policy Studies, the Heritage Foundation, believes that people don’t change plans because they are satisfied with their current plan. However, Fried suggested that decision paralysis is responsible for the fact that only about 13% of people change their drug or Medicare Advantage plan each year. Carter said that when patients do not shop for the best plan and stick with the status quo, they may later discover “that the drug that they’ve been on for 10 years is not in the formulary or their provider is not in the network, which can start a serious cascade of problems.” Purvis reinforced this point, saying that among AARP members, Medicare enrollees tend to stick with their current plan. They don’t check the formulary to make sure their drugs will be covered for the following year, nor do they determine whether the plan has “utilization management,” which, like “prior authorization,” makes it more difficult for patients to access their medications.

Purvis concluded by saying, “I think it’s safe to say that Medicare patients are not coping so well, given the fact that more of them are contacting AARP. They are recognizing the limitations of their income in keeping up with the price trends for the drugs that they are taking. There is no way that things are going to improve until something changes. I don’t think this is a problem that is going away.”

Capacity to Respond

Carter briefly described the services her organization, the Medicare Rights Center, provides. These include a national helpline staffed with counselors, navigators and staff who handle certain complaints and appeals. The Center also has educational programming; publications; and a website, www.medicareinteractive.org (below), which provides information and answers to Medicare-related

“Every year, Medicare beneficiaries have to make more and more decisions to pinpoint exactly which plan they may need. These plans are so complicated for people when they are trying to fit their list of medications or their list of providers into a plan.”

— JULIE CARTER

“There is no way that things are going to improve until something changes.”

— LEIGH PURVIS

questions. The Center also advocates for policy that facilitates access to affordable healthcare for older adults and people with disabilities.

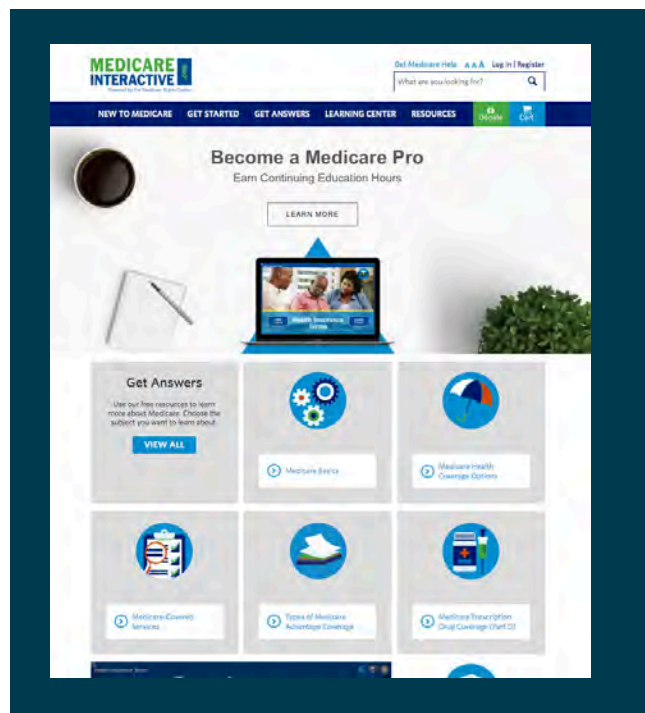
“Quite often,” said Carter, “we get calls to the helpline from people who...may not be eligible for certain state programs that can help people with Medicare, or they’re not eligible for national programs like the low-income subsidy or the Medicare savings program. In these situations, we just don’t have any mechanisms to be able to help.”

“Do you just tell them, ‘sorry, we can’t help you today?’” asked moderator Cliff Goodman, PhD, Senior Vice President, The Lewin Group. Carter replied that sometimes the best the Center can do is suggest that these patients work with their provider to make sure they are on the drugs that work best within the formulary of their drug plan. Carter added that the Center also helps patients with appeals because, “in a lot of cases they don’t realize, for example, that they could get a tiering exception for a certain drug.”

To cope with the increased needs of Medicare beneficiaries, Fried said that NCOA works with community-based organizations to provide a stream of funding to help enroll beneficiaries into low-income programs. She noted that there are Medicare state health insurance assistance programs (SHIPs)³⁹ in every state and county. NCOA refers people to SHIPs for help in filing formulary and tiering exceptions in an effort to try to lower OOP costs. However, Fried said, “Medicare SHIP funding is at risk. In the last couple years, it’s been slated for elimination and we’re very concerned about whether the SHIP funding will continue. Like other safety net resources, the continued vulnerability of programs like SHIP prevents older adults from securing long-term stability for their health needs.”

NCOA also helps patients with OOP costs that are not related to medication, such as transportation, lodging, lost income and other expenses that contribute to illness-related financial hardships. To help patients find programs they might

³⁹SHIPs can help with Medicare questions, complaints and appeals, and obtaining coverage by a Medicare plan (Advantage, Part D, LIS, MSP, etc.) Sources: www.medicare.gov and www.acl.gov/programs/connecting-people-services/state-health-insurance-assistance-program-ship. Accessed March 24, 2018.



“I would remind folks that some of the Tier 4 non-specialty drugs can have a 50% OOP cost for an individual, which is quite significant.”

“What we hear mostly is that folks cannot afford the OOP costs at the point of sale. That is where the stress is right now.”

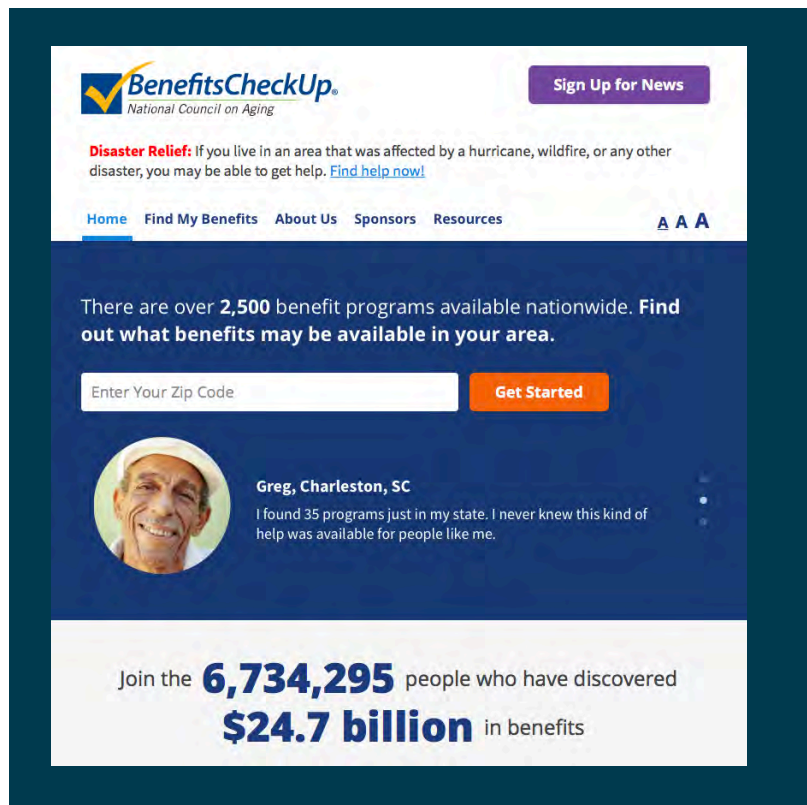
— LESLIE FRIED

be eligible for, NCOA has a free tool called Benefits CheckUp® (above), which is partially funded by the U.S. Department of Health and Human Services, Administration of Community Living. NCOA also provides some outreach and enrollment assistance for the Supplemental Nutrition Assistance Program (SNAP) to help mitigate food insecurity among Medicare beneficiaries.

Another resource to help Medicare beneficiaries navigate Medicare is the Medicare Plan Finder tool,⁴⁰ which Carter characterized as “deeply flawed.” Fried concurred with this assessment, noting that when NCOA held focus groups at senior centers about the Plan Finder, they found widespread confusion with the tool and subsequent paralysis in decision making. Based on those findings, NCOA will be issuing a report with recommendations to improve this tool.

Billings said that several new lung cancer therapies have been approved in the past few years, but covering the cost of these drugs is a big concern both for the Medicare and non-Medicare populations. “It is terrifying to patients who are doing well on these therapies,” he said, “to think of losing coverage because they can cost tens of thousands of dollars a month.” To try to help patients afford their medications, Billings said that the ALA refers them to resources such as the PAN Foundation and offers to help identify available tools and support. However, ALA counselors report that “there are patients they can’t help, and it is really hard for the people who are answering those phone calls to run out of options for their patients,” he said. Not only is the system complex for counselors who have expertise and training, but it is even more challenging for patients who find it exceedingly difficult to navigate its complexities and yearly changes. It is often the case that “patients think they’ve got it solved,” said Billings, “and when the rules change, they find themselves almost back to

⁴⁰<https://www.medicare.gov/find-a-plan/>



The fact that AARP’s 38 million members rank prescription drug prices/costs as the top issue to be addressed “is an indicator that more needs to be done.”

— LEIGH PURVIS

American Lung Association counselors report that there are patients they can’t help. “It is really hard for the people who are answering those phone calls to run out of options for their patients.”

— PAUL BILLINGS

the beginning.” Roundtable participants repeatedly emphasized the unfavorable impact that the complexity of Medicare coverage places on beneficiaries, especially regarding the impact of Part D plan structures, and how they inhibit beneficiaries from engaging in periodic reviews of the suitability of their Part D plans.

Possible Solutions

Directly Reduce OOP Costs

Purvis suggested that “someone take a look at the big picture” to see if medication costs could be reduced. The bottom line, she said, is to “make sure you’re in the right plan for you.” The fact that AARP’s 38 million members rank prescription drug prices/costs as the top issue to be addressed, noted Purvis, “is an indicator that more needs to be done.”

To help minimize financial hardship for Medicare beneficiaries, Fried suggested liberalizing income eligibility for Medicare’s Low Income Subsidy (LIS) program, which “is for people who are at 150% of poverty level or less, a threshold met by a significant portion of the Medicare population....⁴¹ However, if somebody has resources (assets, not including a house) greater than a little over \$8,000 a year,” she explained, “such as maybe \$10,000 or \$15,000 in a bank account or 401(k) plan, they are not eligible for Medicare savings programs and extra help.” Fried pointed out this essentially penalizes people for saving. She also recommended eliminating the asset test,^{42,43} which would result in more people being eligible for the LIS program. Expanding LIS to a larger number of Medicare beneficiaries by increasing the means-tested threshold would help with OOP costs because with LIS, cost sharing for generic and brand medications is limited.

Other mechanisms that were discussed to potentially reduce OOP costs for Medicare beneficiaries included: (1) Medigap insurance, which helps pay some of the costs (such as co-pays, coinsurance and deductibles)

⁴¹In 2016, the Kaiser Family Foundation reported that 29% (12 million) Part D enrollees receive LIS assistance. Source: Hoadley J, Cubanski J, Neuman T. Medicare Part D in 2016 and trends over time. Kaiser Family Foundation. September 16, 2016. <https://www.kff.org/report-section/medicare-part-d-in-2016-and-trends-over-time-section-4-the-low-income-subsidy-program/>. Accessed March 24, 2018.

⁴²One of the findings in a report from the Kaiser Family Foundation was that “even moderate asset holdings can prevent beneficiaries from qualifying for low-income assistances.” Source: Moon M, Friedland R, Shirey L. Medicare beneficiaries and their assets: Implications for low-income programs. Kaiser Family Foundation. June 2002. <https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&cad=rja&uact=8&ved=0ahUKewjItv7AuYbaAhVFVd8KHYA3CSwQFggxMAE&url=https%3A%2F%2Fwww.urban.org%2Fsites%2Fdefault%2Ffiles%2Fpublication%2F59826%2F1000249-Medicare-Beneficiaries-and-Their-Assets.PDF&usg=AOvVaw1QyoQ8IHjgAJqtTmht-n9I>. Accessed March 24, 2018.

“We’re really kind of at the tip of the iceberg of what we’re going to be facing in terms of costs, and that makes it very difficult...A lot of the drugs that are coming won’t necessarily face competition anytime soon, so we’re going to have more people taking drugs that don’t have any price competition with these incredibly high prices that grow every year and that’s a really daunting thing to try to address.”

— LEIGH PURVIS

“Saving for a rainy day doesn’t help you with a hurricane.”

— CLIFF GOODMAN

that might not be covered under a Medicare plan, and (2) eliminating the 5% coinsurance during the catastrophic phase.⁴⁴ Although the latter appears as though it would reduce OOP costs, Fried clarified that we need to be careful in terms of how true OOP (TrOOP) costs are calculated. If there is an increase in the time it takes people to make it through the coverage gap and into the catastrophic phase, OOP costs may not reduce at all.

Placing a cap on catastrophic costs was also discussed by several Roundtable participants. Klein remarked that “policymakers may think that a cap on catastrophic costs is a silver bullet, but the numbers indicate that many seriously ill Medicare patients will still need help paying for their critical medications. It will certainly be a huge help for some people but it is absolutely not enough.” Purvis reiterated her assertion that eliminating costs in one place merely shifts them to another. “Any time you have a cap, there could potentially be a tradeoff. Where you cap costs for people who have incredibly, incredibly expensive drugs,” she said, “there could be implications for the larger population.”

“Part D...protects plans...by accepting a lot of the risk, but then these costs get shifted onto beneficiaries in the form of premiums and cost sharing.”

— JULIE CARTER

Two policy recommendations that have long been supported by PAN speak to many of the complex issues raised by Roundtable participants. These are: (1) spreading OOP costs more evenly throughout the year, and (2) ensuring that every clinical indication has at least one highly effective drug that is not on the specialty tier.

Reduce Confusion

Fried expressed optimism that improving the Medicare Plan Finder tool will greatly help beneficiaries find the right Part D drug plan. At present, it is not only difficult to use but is restricted to one point in time. “Someone might be fine in the fall,” explained Fried, “before they get diagnosed with lung cancer or some other disease, and then realize they are in a plan that doesn’t cover the drugs that their oncologist said would save their lives. Even though they can file for a formulary exception, they can jump through lots of hoops, and it’s difficult.” Fried characterized improving the Medicare Plan Finder as “low-hanging fruit,” reiterating that NCOA will soon be issuing a report containing numerous recommendations for improving this tool.

⁴³Primary house, car, personal possessions, burial spaces, life insurance, and Social Security Insurance (SSI) cannot be counted as assets. Some states may exclude other assets as well. Partial Extra Help is available for individuals with incomes above the Full LIS limit. Full Extra Help has very low generic and brand-name co-pays and a \$5000 OOP maximum, but Partial Extra Help has 15% coinsurance or plan co-pay, whichever is less, and then very low co-pays after \$5000 OOP. Source: Medicare Rights Center, Extra Help Program. Income and Asset Limits 2018. www.medicarerights.org/fliers/Help-With-Drug-Costs/Extra-Help-Chart.pdf. Accessed March 24, 2018.

⁴⁴Cubanski J. Summary of recent and proposed changes to Medicare prescription drug coverage and reimbursement. Kaiser Family Foundation. February 15, 2018. <https://www.kff.org/medicare/issue-brief/summary-of-recent-and-proposed-changes-to-medicare-prescription-drug-coverage-and-reimbursement/>. Accessed March 24, 2018.

Fried also recommended requiring that drug prices be frozen on January 1 so that people who are shopping for the right plan can see what they can expect their OOP costs to be for the year. “What we hear the most complaints about,” she reported, “is the coinsurance situation, in which when they are shopping in the fall, the prices are X, but in February when they are refilling their prescriptions, the price is X times three.”

Address Systemic Problems

In an attempt to improve the Medicare decision making process, Fried described NCOA’s launch of an Improving Medicare Markets Initiative⁴⁵ several years ago. She said that NCOA is studying ways to optimize plan shopping because the small proportion of people who currently shop for the best plan is a disincentive for making changes. “This is a good Econ 101 point,” clarified Goodman, “If people aren’t shopping for a better deal, why offer a better deal?” Carter speculated that the situation is likely to get worse before it gets better, noting that the Centers for Medicare and Medicaid Services’ (CMS’s) current trend toward even higher levels of complexity will further reduce plan shopping. There was widespread agreement that this was not a favorable direction because there is a clear need for the process to be simplified.

Solutions were also discussed that address key issues such as drug discounts not filtering down to patients and disincentives in the system for lowering drug costs. Fried explained, “Plans can build in price protection rebates, so if a drug price goes above a certain dollar amount, the manufacturers give an additional rebate to the plan....but beneficiaries don’t have price protection until they get to the catastrophic phase.” She continued, “The reinsurance after the catastrophic phase has significantly increased the Part D cost for Medicare, and I think that’s something we all have to be concerned about.” Fried considered whether application of some of the rebates applied toward reducing patients’ OOP costs at point of sale might come at the cost of increased premiums for everyone. Carter said, “There are these weird incentives in the plan’s benefits from pushing people through and out the other side of the donut hole because then the plan’s liability goes way down. This is not really what you think of as insurance. The lack of transparency makes it extremely difficult to understand Part D.” Carter continued, “Part D protects plans by accepting a lot of the risk, but then these costs get shifted onto beneficiaries in the form of premiums and cost sharing.”

“Someone might be fine in the fall,” explained Fried, “before they get diagnosed with lung cancer or some other disease, and then realize they are in a plan that doesn’t cover the drugs that their oncologist said would save their lives.”

— LESLIE FRIED

⁴⁵The Medicare Markets Initiative was created to “craft pragmatic, bipartisan solutions to the following problems: (1) Beneficiaries not shopping around for prescription drug plans and struggling to evaluate complex options, (2) Lack of knowledge of and access to consumer-friendly tools and unbiased assistance for comparing and choosing among plan options, and (3) Unaffordable insurance coverage for many lower-income beneficiaries, who also do not have access to or do not take advantage of assistance with out-of-pocket costs.” Source: NCOA Annual Report, FY 2014. https://www.ncoa.org/wp-content/uploads/NCOA_AnnualReport_FY14_Proof5.pdf. Accessed March 24, 2018.

“We need to keep talking about what these OOP costs are for patients,” said Billings, “and what it means for the system when a drug has a very high list price. Transparency is really key here.” Billings hypothesized that improved transparency leading to improved understanding of the cost-related forces at work in the system such as list prices, OOP costs and rebates would provide incentives to reduce costs. He also speculated that improved clarity about the yearly cost of plans would help patients make more informed plan choices. “Better education,” summarized Goodman, “can lead to better decision making, on principle.”

Update Needed to Medicare Payment Structure

Despite its systemic problems, Goodman remarked, “policymakers are pointing to the ‘success’ of Part D as a reason to potentially consider price negotiation for Part B.” Carter replied that she did not view Part D as the ideal model, but supports the idea of drug price negotiation. “I don’t think we’re looking at this as a magic bullet,” she cautioned. “It’s just another potential arrow in the quiver.”

Purvis noted that MedPAC is interested in changing the Medicare Part D benefit structure to try to “stem the bleeding.” However, she cautioned, “the challenge with messing with Part D and changing the way things are is that you’re really just shifting the costs around. Unfortunately, the weakest player is the beneficiary, so those costs...most likely will end up back with them. Purvis said, “I don’t think anyone was anticipating the trends in cost of prescription drugs that we have seen lately and the way that they are projected to go going forward.” Goodman concurred, saying that today’s astronomically high drug costs were not anticipated when the current Medicare system was designed, and that, “the Medicare payment structure is not able to accommodate today’s market.” Ilisa Halpern Paul, President, District Policy Group, noted that the world of prescription drug therapy has changed significantly between 2003, when the Part D structure was designed, and today. “The Part D benefit structure is probably showing its age,” she said.

“Sunshine is a great disinfectant. if we could get a better understanding of not just list prices and OOP costs, but the nature of the rebates, then the whole system might serve as a mechanism to provide downward pressure on the overall cost to the system. It would also help improve patients’ ability to navigate and to select plans if they really understood what it was going to cost them...throughout the full year.”

— PAUL BILLINGS

“It’s hard to look at Part D as being a roaring success for beneficiaries. It has been successful in a lot of ways but it hasn’t really done a great job of containing costs for beneficiaries... who are trying to afford prescription medications.”

— JULIE CARTER

“I think if we were creating Medicare today, we wouldn’t have a B, C and D. It’s crazy-making, but it is an artifact of the history of the policymaking.”

— ILISA HALPERN PAUL

Provider Perspective: How do High Out-of-Pocket Costs Impact Clinical Practice and Patient Outcomes?

“Every decision I made around my treatment was based on money. I didn’t have reconstruction because I couldn’t afford the co-pay. I also couldn’t afford the risk of infection in hospitalization. When the doctor recommended tamoxifen, I couldn’t afford \$300 a month for the pills.”

— BREAST CANCER SURVIVOR

Provider Identification of Those in Need⁴⁶

Goodman kicked off the panel discussion, *Provider Perspective: How do High Out-of-Pocket Costs Affect Clinical Practice and Patient Outcomes*, by asking the panelists how they identify patients who might need extra help. Erin Hughes, Financial Advocate, Abington Cancer Care Specialists, Abington-Jefferson Health (AJH), said that AJH tries to be proactive in verifying patients’ insurance, and then reviews benefits and OOP expenses with them. When she meets with patients, if they indicate they need help with finances or logistical issues such as childcare, AJH has a social worker on staff who tracks down the appropriate resources so that patients will not have to forgo treatment at any point. She said, “We’re finding that about 90% of our patients have no idea about their medical benefits. It’s very rare when I ask a patient, ‘how much do you know about your

“As of 2010, we’re starting to see more cancer drugs at a list price of \$25,000/month. Most recently, the FDA approved a new CAR-T-cell therapy for a rare condition that has a list price of \$450,000 for one treatment. That most certainly will be a specialty drug with a 30%–40% (\$135,000–\$180,000) coinsurance rate.”

— ROBIN YABROFF

⁴⁶Although the majority of the discussion of provider perspectives on OOP costs focused on cancer, all of the themes apply to other chronic illnesses as well.

insurance coverage?,' that they say, 'I know I have a \$6,700 OOP maximum.' They usually say, 'I have insurance; it's taken care of.'" Hughes said that AJH staff members often have to explain to patients that they have coinsurance obligations and co-pays. "These are patients who clearly are struggling," she said. "Some of them say, 'I don't even want to hear about it.'" She estimated that 80% of the patients she sees have financial issues that require her help.

"About 90% of our patients have no idea about their medical benefits. They usually say, 'I have insurance; it's taken care of.'"

— ERIN HUGHES

The Importance and Growing Role of Proactive Financial Navigation

Hughes said that if patients are ready for the conversation, AJH has found it beneficial to meet with them at the very beginning to try to "eliminate the complete shock" later on. The issue of being proactive—starting the conversation about costs and how to manage them as early as possible, was a common theme throughout the discussion. Goodman noted that all four panelists "seem to have their antennae out for coping with this issue as early as possible."

"Be honest, be proactive, preserve privacy, offer informed choices, be a detective/resource finder, learn about best practices more broadly, yet remain rooted in one's community."

— CLIFF GOODMAN

There was broad agreement that providing information proactively is important because it lets patients know that there are resources they can tap into and it allows patients and families to begin working through the process of identifying and securing needed resources. Margaret O'Grady, RN,

Administrative Director, Oncology Service Line, AJH, said that the AJH Cancer Center's proactivity on the clinical side facilitates early detection of patients' financial/logistical problems. This is accomplished by working closely with AJH's primary care group, including using a connected medical record. She emphasized, "Primary care and cancer have to go hand-in-hand in order to get a population benefit and in order to make sure that we're taking care of patients at an earlier stage of disease integration."

During the Q&A after the discussion, an attendee noted that clinically, pain is dealt with proactively, so the same should be true of financial navigation "so the patient isn't harmed in the world of financial toxicity and distress." He stressed that proactive, expert financial navigators are needed to help patch the hole by optimizing insurance, finding co-pay assistance, etc.

Financial Navigation

During the Q&A after Yabroff's presentation, an attendee asked if it might be possible for physicians to be compensated for including the conversation about cost at the time of diagnosis, or when the treatment plan is presented. She pointed out that, "This would at least provide patients with some

kind of menu or range of costs upon which they could make informed decisions.” In responding, Yabroff raised the question as to whether the physician or oncologist would be the best person to have cost-related conversations, or whether it should be another member of the care team, or perhaps a social worker. She said that oncologists are often uncomfortable discussing costs with patients, and that patients frequently do not want to distract their oncologist from discussing treatment. Concerning non-clinical personnel taking on the financial navigator role, a participant emphasized the importance of education and certification requirements for professionals involved with financial navigation. Although the absence of clear-cut education and certification requirements for financial navigation is not surprising because of the relatively recent arrival of these professionals, if financial navigators are to be fully leveraged in the future, it is almost certain that there will need to be greater emphasis on better defining professional competencies.

Use of Financial Navigation Professionals

O’Grady, who, like Hughes, helps patients living with cancer understand the financial implications of their treatment, said that AJH uses several tools to assist in the financial navigation process. One of these is Carevive,⁴⁷ a “technology-enabled care planning tool” that provides, among other services, treatment planning that includes cost of care. Because patients’ top concerns, fears and anxieties always include finances, O’Grady said that the right people, such as social workers and financial counselors, should be on board early to assist. She strongly recommended that those conversations take place early on, instead of, “when a patient gets a \$90,000 bill and decides not to come back for care.” O’Grady explained that the principle behind AJH’s financial counseling resources is to use existing staff with social work or preauthorization/precertification expertise to provide assistance and support from the beginning. She said, “you see patients’ shoulders just relax, and see them think ‘okay, now I can breathe.’ That is our goal,” she concluded, “That is what we really should be doing.”

Eileen R. Peng, PharmD, Director of Pharmaceutical Services, Regional Cancer Care Associates (RCCA), said that when patients enter a treatment plan, a financial counselor will discuss their benefits and OOP costs with them. When patients can’t afford treatment, RCCA finds money for them. “We try not

⁴⁷www.carevive.com

“We have patients who are so completely overwhelmed with ‘psychosocial/financial/how do I tell my kids?/can I ever work?’ that it’s just completely numbing to them and then we have to try to retrieve that patient appropriately.”

— MARGARET O’GRADY

“What’s covered, what’s not, what’s in network, where’s the deductible, have we hit the in-network and out-of-network cap? There’s a lot to unpack and it takes a team of people to manage not just the care but the financial piece.”

— ILISA HALPERN PAUL

to have them pay more than \$200, \$400, even \$50,” she said. Peng indicated that RCCA automatically searches for patient assistance when a co-pay exceeds \$10. She explained that financial counseling is a necessary service for patients in RCCA’s community oncology office. “We don’t get any reimbursement for social workers to go over costs,” she said, “but we need to spend this money to make sure our patients get taken care of.” Peng reiterated how complicated the financial navigation process is for patients who have just received a cancer diagnosis. “They get very anxious,” she said, “with everything—job, family and financial status.” After the physician gives the patient the diagnosis, Peng said that the patient then gets a “chemo teach,”⁴⁸ and then a meeting with a financial counselor. Peng said that RCCA views financial navigation as an aspect of care that should be separate from physician interaction. “We tell our physicians, ‘please do not talk to your patients about cost because you are not trained to do so.’”

Cesar Santa-Maria, MD, MSCI, Assistant Professor, Breast and Ovarian Cancer Program, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University, concurred. He emphasized that because there are so many factors that can affect a patient’s ability to receive treatment, he relies on his social work and financial care teams to help patients navigate the financial aspects of treatment. He said, “It’s important to understand that multiple variables play into patients being able to receive their care in a timely and effective manner.” Santa-Maria agreed with other Roundtable participants who emphasized the importance of clinicians working together with staff to ensure that the totality of patients’ needs are covered in the care delivery process.

Optimizing the Financial Navigation Process

Hughes remarked that two of the most important things about helping patients deal with the financial realities of their illness are honesty and the expectation of privacy. “People are so private about their finances,” she said, “and we need them to be honest with us so that we can then provide additional supports for them...We try to begin the conversation with our patients by telling

“The fact that a patient is going to be undergoing chemotherapy may change his or her financial status, even before they have paid anything. It’s going to be time off of work and other things. They are in a different financial place now as a result.”

— CLIFF GOODMAN

“When a physician tells you that you have cancer, that’s one of the most difficult things to hear and it’s really something that affects your life at multiple levels—not just yourself but your family, friends or social network and job. There are many, many factors that can affect your ability to receive treatment (e.g., transportation and childcare), so being able to get your drugs is one aspect of it, certainly an important one, but definitely not the only one.”

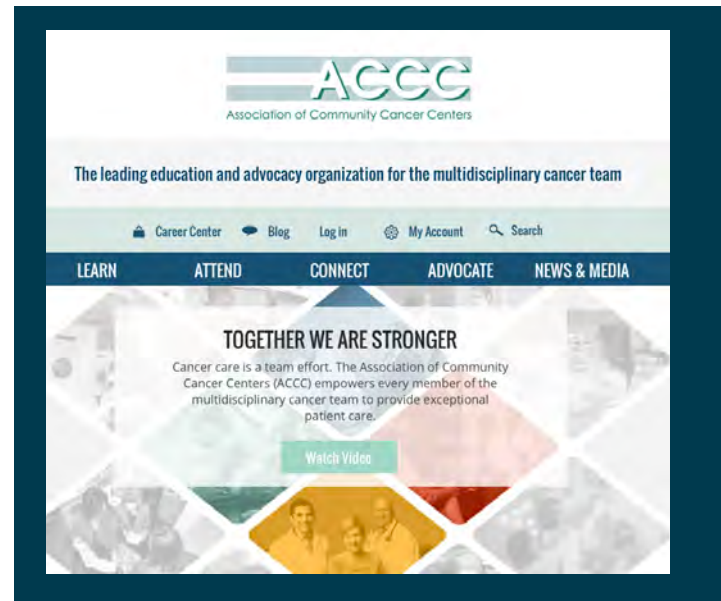
— CESAR SANTA-MARIA

⁴⁸ A chemo teach is a consult in which a healthcare professional speaks with patients regarding their chemotherapy treatment plan.

them that nothing they will tell us will shock us, we don't judge, we're here to listen, and we want to find a solution for them financially to the best of our ability—to find options to help pay for their care.”

O'Grady mentioned that there is a network of best-practice sites for information exchange on how to provide effective financial counseling that AJH has tapped into, including the following:

- » The Association of Community Cancer Centers (ACCC),⁴⁹ which is a free boot camp for financial counselors that not only provide AJH counselors with training, but that serves as an ongoing resource that staff can access for answers to questions
- » Healthcare analytics and intelligence company, Sg2,⁵⁰ provided AJH with a 10-year strategic plan, including financial counseling
- » Oncology Roundtable⁵¹ provided best-practice sites that AJH could access via videoconference to discuss program barriers as well as “what worked, what didn't and why.”



“You can go to a 60-bed hospital,” said O'Grady, “you can go to a full-blown health system with 70 or 80 institutions—they all do financial navigation differently. You do a great community needs assessment... and then you backfill with the resources to meet those needs. That's how you take care of your patients in your community and, quite frankly, that's how they stay.”

A Roundtable attendee noted that pharmacy technicians and coding specialists are often underutilized resources in financial navigation. He said that these professionals have prescription/ insurance backgrounds and specific expertise in resolving incorrect claim denials. O'Grady agreed that pharmacy technicians are invaluable in providing patient education and preauthorization review as well.

⁴⁹The ACCC is “the leading education and advocacy organization for the multidisciplinary cancer team.” <https://www.accc-cancer.org/>. Accessed March 24, 2018.

⁵⁰According to Bloomberg, “Sg2, LLC offers analytics, intelligence, consulting, and educational solutions to the healthcare industry.” 2017. <https://www.bloomberg.com/research/stocks/private/snapshot.asp?privcapid=31021977>. Accessed March 24, 2018.

⁵¹The Advisory Board's Oncology Roundtable provides “oncology program leaders with forecasting tools and best practice insights.” <https://www.advisory.com/research/oncology-roundtable>. Accessed March 24, 2018.

To help walk patients through the complicated process of getting assistance, Peng said that in her practice, staff members meet with patients to discuss more than just finances. They provide lists of resources to help with transportation, housecleaning, companions and others. Goodman noted that being a resource for these nonmedical needs dovetails with Yabroff's elucidation of "all the things nonmedical that impact patient risk and distress." Peng's and Yabroff's discussions of the need for patients to cover numerous nonmedical expenses underscores the varied nature of OOP healthcare costs, and the importance of the diversity of safety net organizations and supports that help vulnerable patients handle these burdens.

"I think we need to spend more time educating patients. They are really lost. Even providers need to be educated because they often don't understand financial toxicity."

— EILEEN PENG

Impact of Trained Financial Navigators on Costs: PAN Challenge Runner-Up Paper

The Runner-Up paper, *Impact of Trained Oncology Financial Navigators on Patient Out-of-Pocket Spending*, was presented by lead author Yezefski. Although it focused on financial navigation in the setting of cancer, the research and its findings are potentially generalizable to other chronic diseases as well.

Yezefski framed his research by explaining that nearly one-third of physicians feel uncomfortable discussing costs with patients, although they agree that it is necessary, and 20% of doctors do not think that costs should be factored into treatment decisions.⁵² "Improving cost communication between patient and oncologist," the authors write in the published paper, "is therefore not sufficient in order to truly address patients' and families' financial issues."^{53,54} Yezefski noted that financial navigation is not standardized, is inconsistent, often falls to poorly-trained staff and has no centralized database of assistance programs upon which to rely. Further, sources of assistance have varied eligibility criteria and limited resources.

Yezefski and his colleagues teamed with The Navectis Group,⁵⁵ which helps medical practices develop and implement financial navigation services such as staffing recommendations, on-site training in insurance optimization and external assistance programs, post-training supervision and support, and

⁵²Schrag D, Hanger M. Medical oncologists' views on communicating with patients about chemotherapy costs: A pilot survey. *J Clin Oncol.* 2007;25(2):233-237.

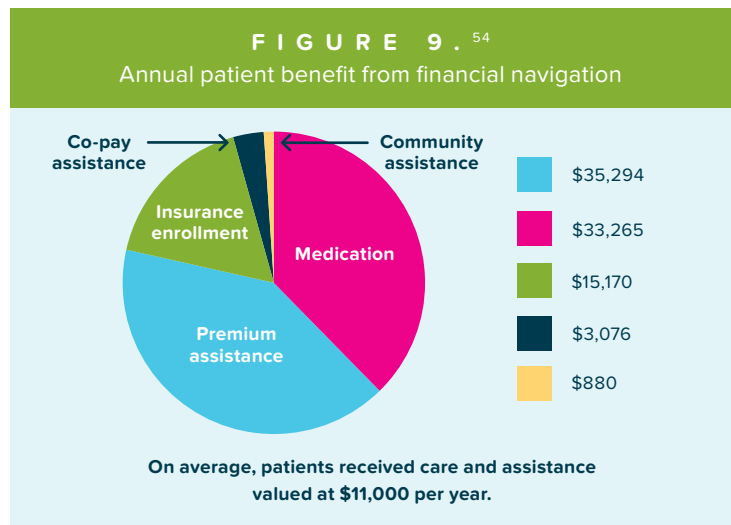
⁵³Sherman DE. Transforming Practices Through the Oncology Care Model: Financial Toxicity and Counseling. *J Oncol Pract.* 2017;13(8):519-522.

⁵⁴Yezefski T, Steelquist J, Watabayashi K, Sherman D, Shankaran V. Impact of trained oncology financial navigators on patient out-of-pocket spending. *Am J Manag Care.* March 6, 2018. <http://www.ajmc.com/journals/supplement/2018/the-patient-assistance-safety-net-how-many-need-help-how-many-are-helped/impact-of-trained-oncology-financial-navigators-on-patient-outofpocket-spending>. Accessed March 24, 2018.

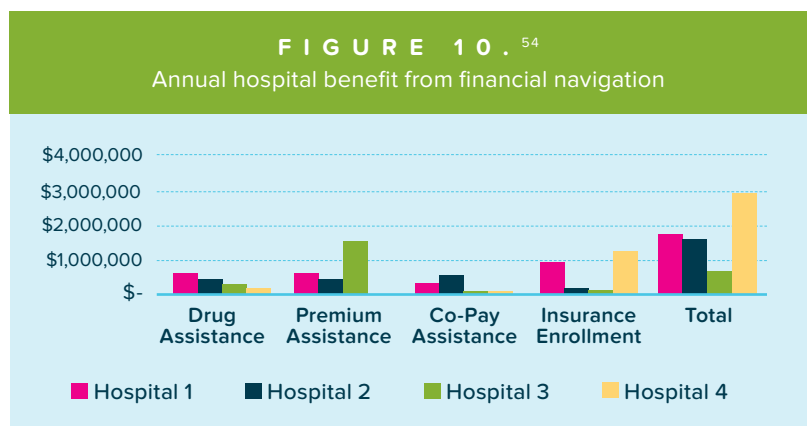
⁵⁵www.navectis.com

tracking/reporting software. The research team collected data on services provided and cost savings to both patients and providers during an 11-year period in four hospitals that employed NaVectis-trained financial navigators. The paper describes a training program that included implementing systematic processes for identifying patients in need, obtaining or improving insurance coverage for patients and using tracking software to quantify benefits.

Results of the paper indicated that the trained financial navigators were able to facilitate access to free medication; health insurance education; and premium, co-pay, and community assistance such as transportation and childcare. In aggregate, the hospitals were able to provide financial assistance to approximately 32% of patients (although this varied by hospital, e.g., in 2016 ranging from 17% in one hospital to 87% in another), and patients received an average of \$11,000 in assistance per year (Figure 9). “Medication and premium assistance,” emphasized Yezefski, “brought the biggest net benefit, with about \$33,000 in free medication for each patient and more than \$35,000 in premium assistance. This included not just the cost of the premium, but the cost of the care that the hospital provides. Without the premium assistance, the patient would not be able to get any care, most likely.”



In addition, the study showed that hospitals also benefited from the program (Figure 10). “If they treated some of these patients who couldn’t pay for their care...,” clarified Yezefski, “they essentially lost money, with costs going to either charity care or bad debt.” By enabling patients to pay for their care, the program enabled hospitals able to increase their revenues by about \$1 million per year.



Yezefski noted that the study likely underestimated the actual benefits of using trained financial navigators because patients were only tracked during the year in which they enrolled. Other limitations included: (1) benefits to patients from insurance enrollment and premium assistance were estimated

from insurance payments to hospitals, (2) utilization of assistance programs before formally trained navigators is not known and (3) no comparison with other hospitals was done.

The study concluded that trained financial navigators can:

- » provide significant financial assistance to cancer patients
- » allow for access to previously unaffordable medical care
- » enable hospitals to reduce reliance on charity care and write-offs
- » help reduce financial stress related to cancer
- » potentially improve patient outcomes

Impact of Financial Considerations on Clinical Decision Making

During the panel discussion, Santa-Maria stated that he does not consider cost when he recommends a treatment plan, but chooses what he thinks is best for the patient and then puts pressure on his social work and financial teams to help him carry out the plan. “I can’t say to a patient, ‘Oh well, I’m not sure you’ll be able to afford this drug,’” he said. “I’m just going to recommend what I feel is the right treatment medically and then work the best I can with my team members to ensure access to treatment...” He and other Roundtable participants

said that financial hurdles such as needing to write letters, helping with preauthorization, and communicating with insurance companies, often result in treatment delays.

Santa-Maria said that it was rare for financial considerations to result in him changing a patient’s treatment plan, although it could result in him changing the method of delivery. In the case of metastatic breast cancer, he said, “getting the oral drugs is challenging” and subject to the kinds of delays such as those mentioned above, which may influence him to choose an intravenous (IV) option instead. “So you start off,” Goodman clarified, “from best clinical practices—this is the right therapy for you—as your point of departure, but then pushback on the insurance side causes a delay, and then... you may be forced to make a choice between... oral and IV, for example.” Santa-Maria replied, “At some point, you have to treat the patient in front of you, with the tools that you have. Whether I would have

“By instituting a financial navigation program using trained counselors, hospitals can save money that would typically have gone to bad debt, and patients can gain access to care that would otherwise have been unaffordable.”

“While this study did not specifically look at the financial toxicity that these patients faced, we expect that the financial navigation services helped to decrease some of the economic stresses associated with their care. As financial toxicity is associated with non-compliance and poorer outcomes, these patient navigation services would have the ultimate effect of improving outcomes for cancer patients.”⁵⁴

— TODD YEZEFSKI

liked to pursue one line of treatment is one thing, but if I can't get it, I still have to treat the patient who's in front of me." In answer to a participant's question during the Q&A about cost-benefit analysis, Santa-Maria said that treatment decisions need to balance the possible risks and benefits of treatment given patients' clinical realities and wishes, not cost. An elderly patient who has several co-existing conditions, for example, may not be the best candidate for aggressive treatment. "It's not necessarily the finances that drive that recommendation," he said, "but the ultimate net benefit for the patient. It's not, 'you're 89, I don't think you'll be able to afford it.' It's, 'you're 89, I don't think you're going to have a benefit.'"

"I don't have access to patients' financial records...I evaluate them and give the recommendation as to what I feel is best for them."

— CESAR SANTA-MARIA

Peng remarked that she could think of many instances in which cost was a factor in choice of treatment plan, and critical choices are sometimes initiated by the patient. She described one example in which an RCCA physician recommended an injectable drug for an immune thrombocytopenia patient. When the patient discovered that she had a \$250 co-pay per treatment (after co-pay assistance had been applied), she did some independent research and discovered that there was an oral daily medication that had a \$50 co-pay after assistance was applied. The physician concluded, however, that the injection was preferable because of better adherence and a lower toxicity profile than the oral drug, and a long delay ensued while the patient made her decision. Peng noted that, like different diseases, different types of treatments (infusions, oral, home- or hospital-based, etc.) are subject to different levels of coverage and types/levels of potential assistance. Clinicians at the Roundtable all pointed to the complexities that occur at the intersection of potential treatment benefits, side effects, cost, convenience and clinical judgement.

"At some point, you have to treat the patient in front of you, with the tools that you have. Whether I would have liked to pursue one line of treatment is one thing, but if I can't get it, I still have to treat the patient who's in front of me."

— CESAR SANTA-MARIA

Goodman wondered if patients ever turn down a suggested treatment plan or decide to go with another therapeutic option because of cost. "Patients need to have the right information," said O'Grady. They need to know whether the suggested treatment would have a curative or merely a palliative intent. In the best-case scenario, a clinic should be able to help patients get where they need to go therapeutically, to help them in any way possible." At AJH, she said, patients are given written estimates so they can review their options at home, and are given the assurance that AJH will find a way to work with them. "Whether it's a sliding scale payment," she said, "or other assistance or support, we are unbelievably generous... and if we are really in need, we use philanthropic resources to be able to benefit the patients who live in our community."

Impact on Adherence and Outcomes

Santa-Maria discussed the impact of both cost and logistics on outcomes of breast cancer patients. He noted that in his experience, problems not only with the price of drugs, but with logistics including transportation, childcare, limited support/social networks and other factors often prevent patients from showing up for or otherwise being compliant with treatment. Santa-Maria conceded that many of the issues surrounding illness, including logistics, can translate into suboptimal patient outcomes— affecting mortality, morbidity, and quality of life.

“Financial toxicity is one of the top reasons for adherence issues,” agreed Peng. “We have patients who don’t take their pills according to instructions just to save their co-pay.” At RCCA, when patients are due to refill their next prescription, they are asked how many pills they have left to make sure they are following their treatment regime. “Adherence leads to good outcomes,” she reiterated, “otherwise it’s a waste of money because the treatment is not going to work.”

For individuals with a history of cancer, Yabroff quantified the impact of financial hardship on behavior, specifically prescription drug adherence. As shown in *Figure 11*, these individuals were much more likely than those with no cancer history to delay filling a prescription, to take less medication or to skip doses. “The main point here,” said Yabroff, “is that we continue to see problems with delaying or foregoing care long after a cancer diagnosis.” Yezefski cited recent studies showing that patients living with cancer who experience financial hardship have decreased treatment adherence, poorer quality of life and higher mortality rate than their counterparts without financial hardship.^{57,58,59}

The result of high OOP costs, concurred Billings, “is that patients are skipping doses, not picking up prescriptions, and exploring importing their drugs from abroad.” He gave an example of how this might play out for patients with chronic obstructive pulmonary disease (COPD), for whom skipping their medicine can exacerbate their condition and put them in the emergency room or the critical care unit. “This

“Financial status, financial toxicity, can have an impact on access and adherence. Sometimes patients drop out.”

— CLIFF GOODMAN

“If you look solely at cancer, I think you’re missing the boat. It’s a trickle-down effect. If you’re not feeding the community well, they will get chronic disease; it’s just a hands-down fact. If you’re not able to appropriately educate the community on what screenings are appropriate and vital to them based on family history or community benefit, then you haven’t done the service to the community.”

— MARGARET O’GRADY

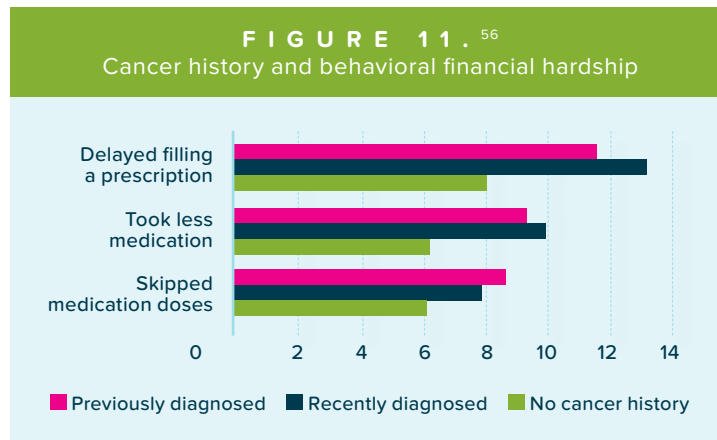
“If you can’t get to the clinic for an infusion but you can’t afford the pill alternative, what does that mean for your outcome?”

— ILISA HALPERN PAUL

can cost hundreds or thousands or tens of thousands in hospitalization costs,” he said, “simply because they could not afford a few hundred bucks for prescriptions.”

During the Q&A, participant Molly MacDonald introduced the Pink Fund,⁶⁰ a national organization she founded that makes 90 days of nonmedical bill payments for breast cancer patients in active treatment for housing and transportation. She relayed her personal story of how costs influenced her treatment plan and adherence during her fight against breast cancer, including not being able to afford her medication. At the Pink Fund, she said, “we have met with women who stopped treatment because they can’t stop working. One of them was an elementary school bus driver. She stopped treatment because she could not take the time off from work and she subsequently died.” Goodman asked, “The wage loss or the potential for wage loss steered her away from care?” MacDonald responded, “Yes, it’s that lost income that really catapults you into that financial toxicity chasm.”

Halpern Paul opened the panel discussion on policy considerations to improve access and reduce financial hardship by exploring the effect of OOP costs on patients with polypharmacy⁶¹, multiple chronic, but non-life-threatening diseases such as diabetes, in which adherence to treatment is vital to keeping them out of the hospital. Kavita Patel, MD, Nonresident Fellow, Economic Studies, Center for Health Policy, Brookings Institution, and a practicing primary care physician, remarked that



“Patients who don’t adhere to their recommended treatment regimens are more likely to have hospitalizations, emergency room visits and other chronic conditions and in addition they’re probably not treating their disease very well.”

— ROBIN YABROFF

⁵⁶Zheng Z, Han X, Guy GP Jr, Davidoff AJ, Li C, Banegas MP, Ekwueme DU, et al. Do cancer survivors change their prescription drug use for financial reasons? Findings from a nationally representative sample in the United States. *Cancer* 2017;123(8):1453-1463.

⁵⁷Dusetzina 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.

⁵⁸Narang AK, Nicholas LH. Out-of-pocket spending and financial burden among Medicare beneficiaries with cancer. *JAMA Oncol.* 2017;3(6):757-765.

⁵⁸Ramsey SD, Bansal A, Fedorenko CR, Blough DK, Overstreet KA, Shankaran V, Newcomb P. Financial insolvency as a risk factor for early mortality among patients with cancer. *J Clin Oncol.* 2016;34(9):980-986.

⁶⁰<https://www.pinkfund.org/>

⁶¹Polypharmacy is defined as “the simultaneous use of multiple drugs to treat a single ailment or condition” [https://www.google.com/search?q=Dictionary+mortality+among+patients+with+cancer.+J+Clin+Oncol.+2016;34\(9\):980-986.](https://www.google.com/search?q=Dictionary+mortality+among+patients+with+cancer.+J+Clin+Oncol.+2016;34(9):980-986.)

“even in oncology, patients’ oral chemotherapeutics have lower adherence the higher their OOP costs. You would think that patients would take their oral chemotherapy drugs but they’re not because of OOP costs. With chronic conditions, especially conditions such as mental illness, we know adherence dramatically drops with increased OOP costs.” She

described medication adherence as the “holy grail,” and explained that it is influenced not only by OOP costs, but by the presence of chronic conditions and the need to take multiple medications, which become increasingly common as people age. She indicated that complex insurance benefit design and increasingly complex care (i.e., the more specialists being seen and the more medications a patient is on) correlate with lower adherence. These trends hold true even in the relatively stable employer-sponsored insurance market and Medicare. Patel also mentioned that physicians often do not realize a patient is not taking his/her medication. “It’s only when [the insurance company] sends me a letter,” she stated, “saying ‘by the way, your patient on this congestive heart failure drug actually hasn’t filled their medication for nine months’—that’s generally the only time we know that someone is not taking their medication. And we have absolutely zero insight into why.”

“It’s so overwhelming for these patients and your heart breaks for them. I always try to put myself in the situation: This could be my mother, my father, my sister, my cousin, my friend.”

— ERIN HUGHES

Policy Considerations to Improve Access and Reduce Financial Hardship

“We’re scrambling. We’re patching a sinking boat, and we need a new boat.”

— CESAR SANTA-MARIA

Awareness and Understanding

Moderator Ilisa Halpern Paul explained that the focus of the afternoon panel, *Policy Considerations to Improve Access and Reduce Financial Hardship*, would be on the underinsured—those whose insurance does not give them full access to the therapies that their physicians have prescribed for them.⁶² Before launching the session, she emphasized the “significantly and growing problem,” discussed earlier by Yabroff, that 33%–44% of Medicare beneficiaries face some sort of financial hardship (material, psychological or behavioral) associated with their OOP costs. It is the growing problem of these costs that fuels an even greater need for sustainable policies to address these issues.

Halpern Paul opened the discussion by asking the panel, “What percentage of the people who can actually change policy and programs really understand the challenge of OOP expenses and cost sharing?” Hyde (Arthritis Foundation) estimated that only 15%–20% really understand the issue. She stressed that understanding and appreciating the effect of OOP costs on access, increasingly within employer-sponsored health plans, is critical, as is the ability to empathize with patients. Patel replied that although there is awareness of the problem, stakeholders have their own constituencies and unique obligations. She also noted

⁶²Issues facing the uninsured were not included in the discussion.

“Our hope is that together we can continue to educate the policymakers and the thought leaders about the importance of the safety net and the challenges that so many Americans are facing today in affording their OOP costs.”

— AMY NILES

“If you are living with a chronic disease, and you are on a medication that you need to stay on in order to remain stable in your disease, not having access to that medication, even if you’re fully insured means that you’re underinsured.”

— ANNA HYDE

that the healthcare policy landscape is so complicated that most of the subtle differences are lost when policies are crafted and implemented. Gibb concurred, emphasizing the difference between awareness and ability to understand the issue and take action.

Policy Recommendations

Gibb said that one policy area that should be addressed relates to adult immunizations, which improve health, prevent disease and reduce overall healthcare costs. For Medicare, however, the ACA did not include immunization coverage at zero-dollar cost sharing, as it does in commercial plans. “So if you have Medicare and you need an immunization,” she said, “you are often paying OOP sometimes as much as \$95 or \$100 for an immunization that is already approved by the Advisory Committee on Immunization Practices (ACIP) and proven to be beneficial for your care. That’s a real concern for us and from a policy standpoint; we would like to see a fix there.” She added that the 2019 draft Medicare Call Letter, which sets forth proposed rules, guidelines and clarifications for Part C and Part D plans,⁶³ includes language to encourage plans to offer immunizations at low or reduced cost sharing, which GSK supports.

Haislmaier said that the latest Kaiser Family Foundation employer survey reported that “85% of covered workers are in a plan that does not have a separate drug deductible. In other words, it’s an integrated deductible now.”

“Part B vs. Part D is an artifact of the old system,” said Halpern Paul, “but while we still have A, B, C and D, what are some suggestions for ways that the Congress could take action to help patients?” Hyde said, “Medicare is a little tougher. On the legislative side, most of the Arthritis Foundation’s efforts tend to be more in the commercial space, e.g., bills to cap OOP costs at the federal and state level.” She observed that high-deductible health plans and health savings accounts are popular among Arthritis Foundation members. “We’ve polled our population,” she said, “thinking that a health savings account for the high utilizer, chronic disease patient, isn’t going to be an effective tool but they actually really like them.” Hyde added that patients wish that (1) these accounts were easier to use; (2) there were fewer administrative barriers; and (3) the dollars were more front-loaded, available and matched their maximum OOP costs. She said, “So we’re very supportive of those types of proposals. In Medicare, we look to rulemaking a lot.” Patel said that people are extremely interested in seeing changes that will lower OOP drug costs. “Passing on some of the rebate to the consumer at point of sale is probably the only one that I can see that has the desired immediacy,” she said, but expressed doubts about the ability to implement this. “We are still seeing an interest in value-based payment models of different

⁶³Centers for Medicare & Medicaid Services. 2019 Medicare Advantage and Part D Advance Notice Part II and Draft Call Letter. February 1, 2018. <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-02-01.html>. Accessed March 24, 2018.

kinds... but there has not been enough integration of Part D in those discussions, and there is no reason they can't go after part D in those models.”

Gibb recommended that alternative payment models receive additional emphasis and vetting, and that the tie back to quality is critical. She said there have been “a lot of proposals around Medicare Part B to change the average sales price (ASP) structure, to move away from $\geq 6\%$ to some percentage lower than that, or even eliminate it altogether and go to a flat fee.” She noted that MedPAC has been working on a phased approach away from “ASP +6” to one that builds in more of a value-based system over time, and that she believes this is a move in the right direction although more policy research is needed. Haislmaier said that the science is moving in the direction of biologics and personalized medicine. “Of the 46 drugs approved by the FDA last year,” he said, “16 would be classified by the Personalized Medicine Coalition⁶⁴ as personalized medicine, and... for the first time, they approved new genetic therapies last year. We are going to get better and better at targeting therapies, which means we will get rid of a lot of waste in the system. It's better for patients, but the unit cost becomes higher, so that is a challenge to thinking through your benefit design for the patient because if the patient is not really a decisionmaker, then co-pays aren't going to move the patient.” He added, “I have vanishingly little faith that you can change benefit design from the top down at CMS—I believe that [this type of change can happen] like I believe in little green men three galaxies over—and the concern that I have is that we may inadvertently wind up having everybody paying zero in co-pays but behind the scenes we're paying doctors the wrong way and people aren't getting the right treatment.”

Patel made the point that no alternative payment model (Medicare or commercial), with the exception of oncology, gets timely Part D data. “The private-sector alternative payment models have even fewer, and poorer, data flows,” she said. “To get a physician like me to understand who's doing what and who's not, I at least need the data. Knowing things in real time is what I need, and that's just not happening in most of these models.” Gibb agreed about the need for data, emphasizing that data must be tied to outcome measures. She cited the new adult Immunization Composite Measure⁶⁵ as a good example that will pave the way toward more alternative payment models. However, she added the caveat that there are regulatory hurdles among plans, manufacturers, providers and the government, and that well-intentioned regulations sometimes inhibit innovation.

“The ACA is great for people who need a social welfare program to pay for their medical care and it's terrible for people who want a financial service product to protect their assets. Middle class people who are self-employed are not interested in getting somebody else to pay for their medical care and paying a high premium for it. They want a low premium for insurance that protects their assets. There are two different customer bases.”

— EDMUND HAISLMAIER

⁶⁴“The Personalized Medicine Coalition (PMC), representing innovators, scientists, patients, providers and payers, promotes the understanding and adoption of personalized medicine concepts, services and products to benefit patients and the health system.” Source: http://www.personalizedmedicinecoalition.org/About_Us/About_PMC. Accessed March 24, 2018.

Simplifying the Process

“Healthcare delivery is very complicated,” summarized Haislmaier, “and then the financing of it is by extension horribly complicated.” He suggested the following reforms:

- » A structure in which patients rely on the following two resources:
 - Medical (primary care physician), who can help guide them with complicated matters such as using other providers in the system
 - Financial (insurance agent). Insurance agents not only help people determine which policy would be the best fit, but they are also paid to service the policy when there is a problem or issue (coverage question, need for precertification, etc.).

- » Movement toward a medical home/direct primary care⁶⁶ structure

Klein remarked that efforts to educate patients to improve their ability to select among health plans have not been successful, and asked for ideas that would help seriously ill patients in the short term. “How can we help them get through the next 2 years,” he asked, “and simplify their chore rather than add to the complexity—and unfortunately everybody else is adding to the complexity?” Hyde said that arthritis patients and stakeholders have indicated a need for aggregated resources for dealing with administrative complexity, including digital tracking tools. “Sort of like FedEx where you can go in and see where your appeal is in the process instead of picking up the phone and waiting for hours.” She noted that some traction is being gained on this, as the American Medical Association (AMA), along with some trade associations, has created a set of common principles for preauthorization and streamlining.

“I think you have to leverage the existing infrastructure,” said Patel, “to activate them to become health advocates.” She suggested that the PAN Foundation could work closely with organizations such as the American Society of Clinical Oncology (ASCO), the Community Oncology Alliance (COA), or the AMA to make their financial counselors into patient advocates. She gave the example of the Brookings Institution, which has a third-party health advocate that is offered as an employee benefit. Patel also suggested that organizations can help current providers, who have existing infrastructure and resources that are generally focused very narrowly (e.g., paying for an in-office IV infusion), to do more to help patients. “Leveraging community-based services is the way to go,” said Gibb. “If we can simplify and aggregate information while the patient is sitting in the provider’s office, I think that’s really the best way to simplify things for patients in the short term.”

⁶⁵This measure was developed using the Healthcare Effectiveness Data and Information Set (HEDIS) tool, which “measures performance on important dimensions of care and service.” Source: <http://www.ncqa.org/hedis-quality-measurement>. Accessed March 24, 2018.

⁶⁶“Direct Primary Care (DPC) is an innovative alternative payment model improving access to high functioning healthcare with a simple, flat, affordable membership fee. No fee-for-service payments. No third party billing.” Source: www.dpcare.org. Accessed March 24, 2018.

The Safety Net

Patient Assistance Organizations

Klein indicated that PAN provides financial assistance to 150,000–250,000 people per year, depending on funding. PAN is one of the 7–9 charitable foundations and programs and represents about 50% of the assistance given over the past 5 years. He estimated that 500,000–1 million people request assistance from safety net programs such as PAN, Good Days or CancerCare each year. Michele McCourt, Senior Director, CancerCare Co-Payment Assistance Foundation (an oncology safety net organization) reported that CancerCare provided more than \$26.4 million in financial assistance (co-pay, transportation, etc.) to approximately 25,000 individuals in 2017. Noting that CancerCare is one of the smaller foundations, McCourt said that in 2017, they received approximately 14,000 requests, were able to approve 9600 (68%), denied less than 7%, and had to turn away more than 20% because of lack of funding. “Our mission is to help patients,” she said, “but without donations, we can’t fulfill our mission.”

McCourt said that when they turn people away due to lack of funding, CancerCare tries to refer them to other foundations or to the drug manufacturer’s program if they are taking a brand-name medication (see section on collaboration, below). She indicated that Medicare patients are a particular challenge because the manufacturer’s program may or may not be able to assist them. Clorinda Walley, President, Good Days (an independent charitable foundation) and a coauthor of the PAN Challenge Honorable Mention paper, said that Good Days uses a similar approach. “Quite honestly,” she said, “If I’m looking for funding for a multiple myeloma or prostate cancer patient, we’re all closed. The next option for this patient is the manufacturer’s free drug program, and the likelihood of the patient getting into that is not very large.” Goodman summarized this situation by saying, “So, they basically fall off the grid.”

Roundtable participants agreed that holes in the safety net are growing, and disparities are increasing. “We’re overwhelmed,” said an attendee from the Colorectal Cancer Alliance. “The help that can be provided does not make much of a dent...”

Walley reported that, “The amount of people collectively that we’re all able to help year after year is decreasing, but the need is increasing. In 2016, Good Days had

“In 2017, CancerCare received approximately 14,000 requests for assistance, we were able to approve 9600 (68%), and had to turn away more than 20% because of lack of funding.”

— MICHELE MCCOURT

“Quite honestly, if I’m looking for funding for a multiple myeloma or prostate cancer patient, we’re all closed. The next option for this patient is the manufacturer’s free drug program, and the likelihood of the patient getting into that is not very large.”

— CLORINDA WALLEY

35 programs. In 2018, of those 35 programs (of which 12 are in the oncology space), we are only assisting in 11 due to lack of funding.” She said that in June 2017, she approached the seven large charities Klein referenced above to determine how many programs are open. She found that 51% of the assistance programs were closed due to lack of funding.

Klein pointed out that the problem has to do with both the timing and availability of funds. Between 2012 and 2015, the amount of annual funding that went into the charitable assistance space increased from approximately \$0.5 billion to about \$1.4 billion. “What has changed,” he said, “is that the demand has outstripped the availability of funding. Across the 7–9 charities that we track, there are about 125 different disease-specific programs, and at any one time 50%–60% of these programs have funding. So, for example, a patient might come to PAN in January and be able to get a grant for assistance with prostate cancer, but if they come in April, they might not be able to.” “The big change is in demand,” he said. “Cost sharing is increasing among people with serious illnesses, and that is where the disconnect is. It is probably a little harder to be confident about keeping a disease fund open 12 months a year than it used to be” In addition to the growing demand, Klein indicated that “more people on Medicare are reaching the catastrophic threshold and... spending more than they can afford on OOP costs. As a result, we are having to turn more people away.”

A Roundtable participant asked whether the co-pay assistance programs would be able to accommodate the influx of patients who would need help because of new co-pay accumulator policies. Klein made the important point that although manufacturer coupons will no longer be applied toward patient deductibles in these programs, charitable assistance is not subject to that restriction. “With Good Days,” said Walley, “we’ve moved more and more of our programs to Medicare-only programs because Medicare patients have no other option: they can’t go to a coupon card and they can’t get commercial assistance. So, if I can send three commercial patients to a pharmaceutical company, then I can put three Medicare patients in a program in which otherwise there wouldn’t be a spot.” These and other insights into the operational challenges that are faced

“[The ability to provide funding] is very dynamic.... The funds in the past few years have tended to open and close, whereas 8, 9, 10 years ago, they tended to stay open. Even though the total funding 8, 9, 10 years ago was less, there was more continuity.”

— DAN KLEIN

“Good Days also provides premium assistance, which is generally for people in the ACA exchanges. Now in 42 states, these insurance plans are rejecting our premium assistance so my biggest concern today is, ‘How are those the patients who have the most need—are critically ill, don’t qualify for Medicaid, aren’t disabled, don’t qualify for the silver plan because their disease is rare or orphaned and the medication or the treatment or the doctors don’t fall under that tier—going to get to a physician when they can’t even get insurance?’”

— CLORINDA WALLEY

by charitable foundations highlight how these organizations need to respond to changing policies in order to continue fulfilling their missions.

Collaboration

Roundtable attendees were impressed with the cooperation among charitable foundations like PAN, Good Days and CancerCare, and their leaders attributed this to the need to optimize safety net resources for the benefit of vulnerable patients, regardless of where they seek support.

“Our fundamental value is in helping people,” said Walley. She said that if her organization can’t help, patients will be referred to one that can, including one that may have additional services such as psychosocial assistance. “If a patient needs a counselor, for example,” she said, “I can transfer them to CancerCare’s cancer support community to get them engaged with a social worker. There are 40,000 cancer patients that I’m no longer helping financially,” she added, “but I can leave them a pathway to fulfill other needs within their care.” McCourt gave the example that last year, CancerCare’s multiple myeloma fund closed just before a multiple myeloma patient contacted them for assistance. They found that another organization had an open fund, and sent to the patient to that organization. The emphasis on collaboration among the organizations represented on the panel was clear, and a solid reflection of the shared missions of many safety net organizations.

“In the end, we have one mission, and it’s to help the person on the telephone, whether it’s me doing it directly, or referring them to another organization.... I don’t care if it’s Good Days [my organization] you choose, but choose someone, so at least I have an avenue in which I can provide support.”

— CLORINDA WALLEY

Facilitating Access to Assistance

All three panelists indicated that their organizations were taking active steps to facilitate access to their services. Klein indicated that PAN has put in place the following initiatives:

- » Automating enrollment by patients, healthcare providers and pharmacies
- » Implementing a “fund reopen notification” system, whereby patients can sign up to receive an email when a closed fund reopens
- » Updating website portals so providers and pharmacies can see claims information in one place

“Collaborating means that at least I have somewhere to send these patients because it’s horrible when you have nothing for them to turn to.”

— MICHELE MCCOURT

McCourt said that CancerCare is doing many of the same things as Good Days and PAN, e.g., providing electronic income verification, making it easier for patients to get assistance, etc. “We continue to do what

we've been doing for over 74 years," she said, "we provide free psychosocial support to anyone affected by cancer..., determine other needs such as transportation assistance, home care, childcare, and all of the other nonmedical things that go along with treatment."

During the Q&A, a participant from the Pulmonary Hypertension Association said that their organization received about 400 calls this spring from people looking for financial assistance. "About 25% of these people don't have computers in the home and they don't have reliable access to the internet, and many are elderly and disabled," she said. "In my experience, folks without internet access are at a profound disadvantage through the first-come, first-served process for access to patient-assistance funds." Klein acknowledged the growing role of online enrollment in relation to accessing OOP assistance, and responded by saying that PAN has a toll-free number for people who prefer to use that means of communication. But, he added, "In January, as soon as the benefits renew for Medicare, we get 5000 calls a day so we bring on seasonal staff. We had 125 staff answering the phones at our call center in January and we were still pressed to keep up with the volume." Walley said that when someone calls Good Days, the Good Days representative enters the patient's information into portal for them, and tries to make the process as easy as possible.

"Once again, it's not just about the medical costs and if you just focus on the medical cost you're not serving your communities. You've got to find out about transportation, food, childcare, and all the rest."

— CLIFF GOODMAN

Hopes for the Future

Goodman posed a hypothetical scenario to the panelists: *It's New Year's Eve, December 31, 2019, and you have to identify one policy change that, if implemented, would make your organization better able to address the needs of more patients and families. What would it be?* "If the donut hole closed," said McCourt. "If OOP costs for specialty medications were limited to no more than \$100/month," said Klein, noting that California has set a limit of \$250/month. The clear need for policy-driven changes that address OOP costs underscored the importance of ensuring the adequacy of the safety net until these changes are fully in place.

"Your organizations are all in great need. We need you for the safety net now more than ever. Otherwise too many people are lost."

— CLIFF GOODMAN

FQHC's and the Safety Net

The winning PAN Challenge paper was presented by M. Kristina Wharton, MPA, MPH, doctoral student, Department of Global Health Management and Policy, Tulane University School of Public Health and Tropical Medicine, on behalf of her co-authors, Lizheng Shi, PhD, MsPharm, MA and

Alisha Monnette, MPH. The paper, entitled *Ensuring Access to Prescription Medications in the Post-ACA Healthcare Access Landscape: The Essential Role of FQHCs in the Safety Net for the Underinsured*,⁶⁷ evaluated the role of federally qualified health centers (FQHCs) as a safety net for access to prescription medications for underinsured individuals. FQHCs are primary care safety net providers for uninsured/underinsured patients regardless of their ability to pay and insurance status. FQHCs provide reduced-cost medications via the following programs:

» Health Resources and Services Administration (HRSA) 340B Drug Pricing Program (340B)

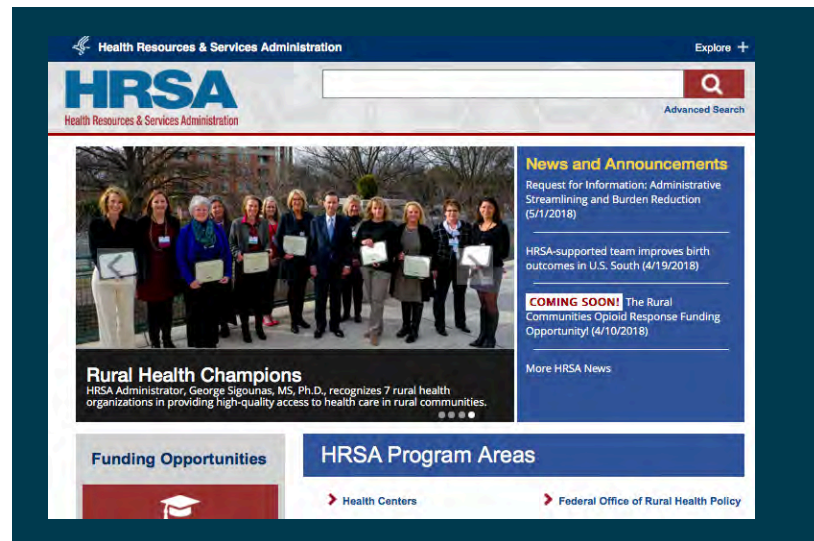
- Set price ceilings for prescription and over-the-counter (OTC) drugs
- Allows FQHCs to provide their patients with affordable medications based on income (generic drugs can cost as little as \$4)⁶⁸

» Prescription assistance programs (PAPs)

- FQHC-organized programs offered to uninsured patients
- Discounted medications provided by pharmaceutical manufacturer donations
- Study showed average cost per drug was \$25 in an FQHC setting⁶⁹
- Average staff time of 6 minutes per submission per prescription⁶⁹

FQHCs: PRIMARY CARE SAFETY NET

- » Federally qualified health centers (FQHCs) are primary care safety-net providers
 - Located in medically underserved areas (MUAs)
 - Serve patients regardless of ability to pay (including uninsured, underinsured and some Medicaid patients)
 - Must be 51% patient-governed
- » FQHC methods to close the prescription access gap for underinsured populations
 - The HRSA 340B Program
 - Prescription assistance programs



⁶⁷Shi L, Wharton MK, Monnette A. Ensuring access to prescription medications in the post-ACA healthcare access landscape: The essential role of FQHCs in the safety net for the underinsured. *Am J Manag Care*. March 6, 2018. <http://www.ajmc.com/journals/supplement/2018/the-patient-assistance-safety-net-how-many-need-help-how-many-are-helped/ensuring-access-to-prescription-medications-in-the-postaca-healthcare-access-landscape-the-essential-role-of-fqhc-in-the-safety-net-for-the-underinsured>. Accessed March 24, 2018.

The winning paper used a two-pronged approach to (1) assess the need for patient assistance (by age, insurance status, disease diagnosis) and (2) evaluate the FQHC safety net system for prescription medications. Results showed that the number of FQHCs grew from 20.7 million in 2012 to 25.4 million in 2016. Attributes of FQHC patients in 2016 are summarized at right. Wharton said, “Medicaid expansion can be seen to decrease the uninsured rate in FQHC patients by 7.9% and to increase by 4.4% non-medical services utilization like mental health and dental coverage.”

Next, the authors attempted to determine how well FQHCs provided access to prescription medications. Regarding FQHC pharmaceutical costs, per-patient spending for pharmacy services varied widely by state (e.g., \$6.07 in Delaware to \$33.42 in California in 2016). A state-by-state analysis of FQHC 340B programs also showed wide variations by state. For example, there were 3 FQHCs with 340B programs in Nevada, but 129 in California. Similarly, there were big differences in the ratio of 340B programs to FQHC patients, with a ratio of 1:263 in South Dakota, and 1:2098 in Washington, D.C.

“These are incredible differences between the states and level of resources for the FQHCs,” she said. “The evidence shows that the FQHCs play a really important role in serving this unmet need for prescription medication access as well as other services on the 340B program, and PAs

ATTRIBUTES OF FQHC PATIENTS: 2016

- » 25.4 million patients were served by 1337 FQHCs
- » Number of FQHCs per state ranged from 4 (ND) to 176 (CA)
- » 90.6% had incomes at or below 200% of the FPL
- » 66.7% had incomes at or below 100% of the FPL
- » Uninsured patient rates ranged from 9% (VT) to 59% (WY)
- » Uninsured rates decreased from 40.4% in 2012 to 28.7% in 2016
- » FQHC Section 330 grants increased by -\$1.2 million in annual grant funding from -\$1.9 million in 2012 to -\$3.2 million in 2016
- » Average annual per-patient FQHC cost increased from \$688 in 2012 to \$960 in 2016
- » Most prevalent FQHC patient diagnoses (highest listed first)
 - Chronic diseases: hypertension, overweight/obesity, diabetes, asthma, heart disease
 - Mental health and substance abuse: depression, anxiety disorders, alcohol use
 - Infectious disease: HIV, Hepatitis C, STDs*, Hepatitis B

*STDs, sexually transmitted diseases, excluding HIV

⁶⁸Bright DR, Adams AJ, Akala FO, Lengel AJ, Martin SJ, Powers MF. Implementation of a \$4 generic drug program in a 340B pharmacy. *Am J Health Syst Pharm.* 2010;67(11):929-931.

⁶⁹Clay P, Vaught E, Glaros A., Mangum S., Hansen D, Lindsey C. Costs to physician offices of providing medications to medically indigent patients via pharmaceutical manufacturer prescription assistance programs. *J Manag Care Pharm* 2007;13(6):506-514.

are incredibly important—really the only ways that FQHCs have to gain access for patients who may not get insurance or if they aren't eligible for Medicaid or in a state that expanded.”

She said that policy implications of the FQHC research included highlighting the vital role of FQHCs in the safety net for prescription drugs, and showing the efficacy of 340B and PAPs in making prescriptions affordable. Areas for opportunity include expanding these services and addressing the disparities in FQHC resources and access between states. “The FQHC tool is a vital resource,” she said, “It’s something we should keep funding, keep prioritizing, and think about how its role might continue to change.”

Wharton’s published report concluded, “Despite changes in the healthcare access landscape due to the ACA, underinsured populations remain prevalent and the need for financial assistance with medications persists. FQHCs are uniquely situated to provide access to these essential services. Further policy and funding efforts, such as expansion of 340B programs, is evidenced to assist FQHCs in fulfilling the role of prescription safety net providers.”

“Despite changes in the healthcare access landscape due to the ACA, underinsured populations remain prevalent and the need for financial assistance with medications persists. FQHCs are uniquely situated to provide access to these essential services. Further policy and funding efforts, such as expansion of 340B programs, is evidenced to assist FQHCs in fulfilling the role of prescription safety net providers.”⁷⁰

⁷⁰Shi L, Wharton MK, Monnette A. Ensuring access to prescription medications in the post-ACA healthcare access landscape: The essential role of FQHCs in the safety net for the underinsured. Am J Manag Care. March 6, 2018. <http://www.ajmc.com/journals/supplement/2018/the-patient-assistance-safety-net-how-many-need-help-how-many-are-helped/ensuring-access-to-prescription-medications-in-the-postaca-healthcare-access-landscape-the-essential-role-of-fqhcs-in-the-safety-net-for-the-underinsured>. Accessed March 24, 2018.

RECOMMENDATIONS

Funding Considerations

- » The ACA Community Health Center Fund has increased FQHC funding (62.3% increase from 2012 to 2016)
- » Medicaid expansion’s financial impact on FQHCs

Potential Priority Areas

- » FQHCs in states that did not expand Medicaid (18)
 - VA, NC, SC, GA, FL, TN, AL, MS, WI, MO, SD, NE, OK, KS, TX, ID, WY, UT
- » FQHCs in states with less access to 340B programs
 - States where <80% FQHCs operated 340B programs
 - i. NV, DC, VT, CA, LA, IN and ID (ranked in order from least to greatest percentage of FQHC 340B programs)
- » Focus resources on FQHCs in states that have low 340B program-to-FQHC patient ratios
 - i. One 340B program per 1000 or more FQHC patients: DC, AK, MT, MO, NM, NV, HI, WI, CO, and AL (ranked in order of lowest ratios)

Summary

“It’s only fitting that at the end of the day, you are left with a safety net.

Absent a safety net, patients and families are going to be lost.” – CLIFF GOODMAN

Meeting Critical Needs

The third annual cost-sharing Roundtable provided an in-depth exploration of financial hardship associated with OOP costs of illness; a discussion of medication access for Medicare recipients; a deep dive into the provider perspective, including the discipline of financial navigation and effects of OOP costs on clinical practice and patient outcomes; and a discussion of policy considerations in the continuing conversation about improving access to care.

“Is anybody rethinking the whole way we deliver healthcare, so instead of trying to patch a sinking boat, we get a different boat?” asked an attendee. Billings said, “We have spent the better part of the past 15 months trying to put patches on the boat that we have, to protect the ACA and the key patient protections and coverage that it provided. We shouldn’t give up on finding that solution, but we should also fight to protect what we’ve got.”

Strategies discussed throughout the Roundtable included the following:

- » Changing the OOP calculation to reflect TrOOP costs
- » Changing the Medicare Part D structure
- » Eliminating the asset test for some of the Medicare extra help programs
- » Providing transparency in the prescription drug supply chain
- » Training navigators to help with financial assistance
- » Having specific, trained, financial navigation professionals help patients and their families with financial issues
- » Providing rebates at the point of sale
- » Building in flexibility to allow people to change plans mid-year

- » Helping patients better understand their choices so they will be better able to use the plan finder tool to shop for the plan that will be the best fit
- » Educating and supporting patients in the process of understanding/choosing their benefits
- » Evening out OOP expenses over the course of the year so most of the expenses are not concentrated at the beginning of the year
- » Placing a hard cap on OOP expenses
- » Making generics zero co-pay
- » Implementing value-based insurance design (VBID)s

“What’s missing in this set of solutions is incentives to keep people well, and to help people minimize cost sharing when they’re in the deductible phase, to go get a preventative treatment, to take advantage of their well visits, or even to get prescriptions filled that will keep them adherent.”

— EMILY HARRISON GIBB

During the *Policy Considerations to Improve Access and Reduce Financial Hardship* panel discussion, moderator Halpern Paul asked panelists to comment on these strategies – what they liked or didn’t like. Gibb responded, “What’s missing in this set of solutions are incentives to keep people well, and to help people minimize cost sharing when they’re in the deductible phase, to go get a preventative treatment, to take advantage of their well visits, or even to get prescriptions filled that will keep them adherent.” She added, “There is a lot of good work coming out of the VBID center.

“We need proactive, not just reactive strategies,” said Patel. “Our society needs better financial literacy. We’re doing these little cosmetic marginal things when there’s an elephant in the room.” Hyde agreed, “This is a financial literacy issue that is compounded with the realities of dealing with chronic disease. We know that patients need to be educated about what’s in their health plans, about how coinsurance works, about these new accumulator adjustment programs, but how do we do that in a digestible way that they can absorb easily and then empower them to take action?”

Haislmaier said that insurance agents have real expertise in financial navigation, and can help people choose the best plan. Haislmaier thought that the idea of being able to switch plans midyear was unfavorable from an insurance perspective. However, he agreed that spreading co-pays over the calendar year might be a good solution for those on a fixed income.

“All roads lead to ‘patients need to choose the right health plan.’ There are many reasons why that isn’t happening. Part of it is a health literacy issue..., but it’s difficult when you’re dealing with someone from the chronic disease community who has a difficult time just managing their disease, getting through the day, [and dealing with] the administrative burden from their health insurance.”

— ANNA HYDE

Implementation of value-based insurance design (VBID) was mentioned several times throughout the Roundtable, and participants generally agreed that it could be a valuable tool in incorporating financial incentives to use treatments that work, with the downstream implications of reducing financial hardship.

The problem of high prescription drug costs was woven into most of the discussions, and at one point, the question was raised about how to encourage pharmaceutical companies to produce innovative, promising therapies yet keep costs affordable for patients. “How do you align your enthusiasm for innovation, which can be pricey, and your role and responsibility to look after your patient population?” posited Goodman. “Can you do both at the same time?” Focusing on lung disease, Billings replied, “I think we have to because we want the breakthroughs. We want to achieve that world free of lung disease. We want to defeat lung cancer. And pharmaceutical interventions are key to that. At the same time, we also understand that if patients can’t afford the therapies, then it’s something that’s unattainable, so we have to strike that balance.”

He continued, “The list price is important for the overall system, but patients don’t call us about list prices. What they’re calling us about is their OOP costs, coinsurance, and co-payments.” Yabroff noted that there has been a substantial increase of generic drugs over the past 5 years, as well as some expansions in health insurance coverage. However, she cautioned that current changes to the ACA, as well as the increasing cost of specialty drugs for patients with chronic, serious conditions could increase distress and exacerbate problems paying medical bills. In this and other discussions, there were many examples of trade-offs, and the need to balance benefits and harms as various policy options are considered in the future.

In the case of lung disease,” asked Goodman, “which has benefitted recently by truly breakthrough products...., Is there a stopgap for the patient financial hardship that may arise from these wonderful therapies?” Billings replied, “I don’t have the secret sauce or the magic solution. I think that we’re going to struggle for awhile until we figure out how we solve this enormous challenge.”

Billings’ observation that “we’re going to struggle for awhile,” is an accurate, but troubling summary of PAN’s 2018 Roundtable. Ongoing confusion about Medicare coverage, continued threats to the fragile safety

“We need proactive, not just reactive strategies. Our society needs better financial literacy.”

— KAVITA PATEL

“A number of organizations and practice settings are implementing value-based insurance benefit designs. This is also something that may help address financial hardship if those treatments that are most effective also have lower co-payment to incentivize patients to use those effective treatments.”

— ROBIN YABROFF

“Patients don’t call us about list prices. What they’re calling us about is their OOP costs, coinsurance, and co-payments ”

— PAUL BILLINGS

net, and growing evidence of the extent and impact of financial hardship all suggest that challenges associated with securing access to needed treatments will remain a persistent problem into the foreseeable future. Although PAN and other stakeholders will continue to respond to these challenges to the greatest extent possible, only long-term, sustainable, policy-driven solutions will be able to address these problems over the long term.

“How do you align your enthusiasm for innovation, which can be pricey, and your role and responsibility to look after your patient population? Can you do both at the same time?”

— CLIFF GOODMAN

Glossary of Terms

A

ACA exchanges	Affordable Care Act exchanges: State entities through which health insurance can be purchased; also known as health exchanges or health insurance marketplaces
Access	Ability to pay for needed health-related goods and services, such as treatments and prescription medications
Accumulator adjustor programs	Programs adopted by some health insurance plans, in which co-pay assistance such as manufacturer coupons for specialty drugs is not applied to deductible and OOP maximums <i>See Co-pay accumulator</i>
Adjusted Gross Income (AGI)	Gross income minus specific deductions <i>See Modified Adjusted Gross Income (MAGI)</i>
Advocate	A person who acts on behalf of another person in the interest of protecting the rights of the latter <i>See Patient advocate</i>
Affiliated provider	A healthcare provider or facility that is part of a health plan's network <i>See In-network care, In-network provider</i>
Affordable Care Act (ACA)	Comprehensive health insurance reform put in place by President Obama in 2010 that aims to make affordable health insurance available to more people, expand Medicaid and lower healthcare costs <i>See Obamacare, Patient Protection and Affordable Care Act</i>
Allowed charge	The maximum amount a health insurance plan will pay for a covered service
Annual election period (AEP) Medicare	The period in which an individual can sign up for, change or cancel enrollment in Medicare Part C and Part D <i>See Medicare Part C, Medicare Part D</i>

B

Beneficiary	A person who is eligible to receive benefits (e.g., being enrolled in Medicare makes one a Medicare beneficiary)
Benefits	The items or services covered under an insurance policy (e.g., office visits, prescription drugs)
Biosimilar	A biologic medical product which is almost identical to, and has no clinically meaningful differences from another product
Brand-name drug	Drug approved by the U.S. Food and Drug Administration (FDA) that is marketed with a specific brand name

C

Catastrophic Coverage Phase Medicare	The final phase in the Medicare Part D plan, in which OOP medication costs are typically ~5% of retail. This phase kicks in after a patient reaches the OOP maximum in the Coverage Gap Phase
Case manager	A healthcare professional who helps coordinate patient care
Catastrophic limit	In Medicare Part D drug plans, the maximum OOP drug costs paid by a beneficiary before the beneficiary is required to pay 5% co-insurance for the rest of the calendar year
Centers for Medicare and Medicaid Services (CMS)	The federal agency that administers Medicare and works with states to administer Medicaid, CHIP and HIPAA
Charitable foundation patient assistance program	A program run by an independent nonprofit organization that helps patients meet their co-pay and/or other medical expenses based on financial need
Children's Health Insurance Program (CHIP)	A U.S. Department of Health and Human Services program that provides matching funds to states for uninsured low-income children not covered by Medicaid

Claim	An invoice sent by a healthcare provider to a health insurance company detailing the services received
Clinical nuance	A tenet of value-based insurance design (VBID), which recognizes that different medical services provide different benefits and that clinical benefit is dependent on patient, disease/ stage, provider/ facility, and type of service <i>See Value-Based Insurance Design</i>
Coinsurance	Requirement for patients to pay a percentage of costs of covered services
Coordination of benefit	A process used by insurers to determine which plan has responsibility for which charges; used when a patient has more than one policy or type of coverage
Commercial insurance	Health insurance provided by a private (non-government) company (not Medicare) <i>See Exchange/Marketplace/Commercial insurance</i>
Community pharmacy	<i>See Retail pharmacy</i>
Comprehensive Score for financial Toxicity (COST)	A tool used to quantify financial toxicity
Co-payment (co-pay)	A fixed amount paid by patients for services or prescriptions covered by health insurance
Co-pay accumulator	<i>See Accumulator adjustment programs</i>
Co-pay coupon	A discount coupon issued by a drug manufacturer that can be used to offset the cost of the drug <i>See Drug coupon program</i>
Co-pay foundation	A program run by an independent nonprofit organization that helps patients meet their co-pay expenses based on financial need
Cost sharing	Expenses that are not covered by health insurance and must be paid by patients; these OOP costs can include deductibles, coinsurance, and/or co-pays
Coverage	The benefits included as part of a health insurance plan

**Coverage Gap
Medicare**

When Medicare Part D beneficiaries hit the Initial Coverage Phase limit (~\$3700), they enter the Coverage Gap Phase, where they remain until they have spent ~\$5000 and can enter the Catastrophic Coverage phase (during which they pay 5% coinsurance for their drugs until the end of the calendar year) *See Donut hole*

Creditable coverage

Insurance that is comparable to that provided by Medicare Part D (e.g., TRICARE)

D

Deductible / Initial deductible

OOP payments before a health insurer covers any costs

Donut hole

A nickname for the Medicare Part D Coverage Gap
See Coverage Gap

Drug coupon program

See Co-pay coupon

Drug formulary

A list of specific prescription drugs that are covered by a health insurance plan, which includes drugs that are preferred because of efficacy and cost
See Formulary, Preferred drug list

Dual eligible

Eligible for both Medicare and Medicaid

E

Employer Sponsored Commercial Insurance

Health insurance that is provided through the workplace

Exchange/Marketplace

See Commercial insurance

Exclusion or limitation

A provision within a health insurance plan that denies coverage for certain conditions or services

Explanation of Benefits (EOB)

Health insurance company's explanation of which costs were covered

F

Fail first	Insurance policies that mandate that the cheapest drug must be tried first, regardless of which drug the physician prescribed <i>See Step therapy</i>
FDA	U.S. Food and Drug Administration: federal agency that approves drugs before they can be marketed/sold in the United States
Federal Poverty Level (FPL)	An annual HHS-issued measure of income that is used to determine patient eligibility for programs and benefits
Federally Qualified Health Centers (FQHCs)	Primary care safety net providers for uninsured/underinsured patients
Financial navigator	An individual who helps patients with health insurance coverage and with locating financial assistance when needed <i>See Patient navigator</i>
Financial toxicity	Unmanageable OOP costs related to medical treatment, that cause stress, may impact adherence with therapy and impact patient outcomes
Formulary	<i>See Drug formulary, Preferred drug list</i>
Formulary transparency	A clear and easily understood listing of all drugs in a health plan formulary, along with their costs

G

Gatekeeper	The person in charge of a patient's treatment, who decides which specialists and other medical resources a patient can utilize <i>See HMO, Managed Care</i>
Generic drug	An exact copy of a brand-name prescription drug, i.e., with the same active ingredients, which usually costs less than the brand-name version

H

Health insurance marketplace (exchanges)	Organizations in each state where health insurance meeting certain benefits and cost criteria can be purchased
Health insurance network	<i>See Affiliated provider, In-network care, In-network provider</i>
HHS	U.S. Department of Health and Human Services: The federal agency that regulates and administers health and human service programs, and promotes advances in medicine, public health and social services. The U.S. Food and Drug Administration, Office of the Inspector General, National Institutes of Health, the Centers for Disease Control and Prevention, and the Centers for Medicare & Medicaid Services are administered by the HHS
Health Insurance Portability Accountability Act (HIPAA)	A federal law that provides data privacy and security for individuals' medical information
Health-Related Quality of Life (HRQOL)	A measurement used to quantify health status
HMO	Health Maintenance Organization: A healthcare system comprising a network of providers and facilities, in which costs are managed centrally and gatekeepers are used <i>See Managed care, Gatekeeper</i>
Health savings account	A type of account for setting aside pre-tax income to pay for medical expenses
High Deductible Health Plan (HDHP)	A health insurance plan with higher deductibles and lower premiums than traditional plans

I

In-network (preferred) care	Care provided by an HMO or PPO healthcare plan's approved list of providers or facilities <i>See Affiliated provider, In-network provider</i>
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In-network provider	A healthcare provider who is contracted with a health insurance plan to provide services to policy holders at pre-negotiated rates <i>See Affiliated Provider, In-network care</i>
Initial Coverage Phase Medicare	In Medicare Part D, the period after the deductible is met, in which the patient pays the prescribed share of cost for medications; when the maximum is reached, the patient enters the Coverage Gap Phase
Initial deductible	<i>See Deductible</i>
Insurance cap	The maximum amount a health insurance plan will pay in total benefits

L

Legend drug	A drug approved by the U.S. Food and Drug Administration that can only be obtained with a prescription
Low Income Subsidy (LIS) Medicare	A program that provides assistance with drug costs for Medicare Part D beneficiaries who are below a certain income level

M

Mail order pharmacy	A pharmacy that ships prescription medications to customers
Managed care	<i>See HMO</i>
Manufacturer-sponsored patient assistance programs (PAP)	Programs in which drug companies provide low-income individuals with access to medications at reduced, or no cost
Medicaid	A federal/state program for low-income individuals that helps with medical costs; eligibility and benefits vary by state
Medicaid HMO	Managed care plan within Medicaid

MediCal	California’s medical assistance program for low-income individuals
Medical Expenditure Panel Survey (MEPS)	An ongoing, HHS-administered database of healthcare costs, usage, and insurance
Medically necessary	Required to diagnose, prevent, or treat a condition, illness, or injury
Medicare	Federal health insurance program for U.S. citizens \geq 65 years old, certain younger people with disabilities and individuals who have end-stage renal disease
Medicare Advantage	<i>See Medicare Part C</i>
Medicare Low-Income Subsidy (LIS)	<i>See Low-Income Subsidy</i>
Medicare Part A	Medicare hospital insurance: coverage for inpatient hospital/skilled nursing facility, hospice and some home healthcare
Medicare Part B	Medicare medical insurance: coverage for physician services, outpatient/preventative care, lab services, screenings, surgical supplies/feels and occupational/physical therapy
Medicare Part C/Medicare Advantage	Insurance plans that combine Part A (hospital insurance) and Part B (medical insurance) into a single plan. Can also be combined with Part D prescription coverage. <i>See Medicare Advantage</i>
Medicare Part D	Medicare prescription drug insurance
Medicare Payment Advisory Commission (MedPAC)	A Congressional agency established to advise Congress on Medicare-related issues
Medicare Savings Program (MSP)	A federal program that assists eligible low-income individuals with medical expenses such as premiums, deductibles, co-pays and coinsurance; administered by the states
Medicare Supplemental Plan / Insurance	An insurance policy that covers costs that Medicare does not cover <i>See Medigap policy</i>

Medigap policy

See Medicare Supplemental Plan/Insurance

Modified Adjusted Gross Income (MAGI)

Adjusted Gross Income plus tax-exempt interest income
See Adjusted Gross Income (AGI)

N

Narrow network

Health plans with lower premiums but a more limited choice of providers than typical plans

Non-formulary drugs

Drugs that are not on a healthcare plan's approved list
See Drug formulary, Formulary, Preferred drug list

Non-preferred medication

High-cost medications with higher co-pay amounts and co-insurance obligations; often not on a formulary, and require prior authorization

Non-prescription drug

A drug that can be purchased without a prescription
See Over-the-counter (OTC)

O

Obamacare

See Affordable Care Act, Patient Protection and Affordable Care Act

Office of the Inspector General (OIG)

One of 57 entities that provide independent oversight to federal agencies and departments; the Health and Human Services OIG oversees Medicare and Medicaid

Ombudsman

A person who helps resolve problems between an individual and an institution

Open Enrollment

A specific period of time during which people can add, drop or change their health insurance coverage

Original Fee-for-Service Medicare (Parts A, B, or D)	The traditional federal fee-for-service program in which the government pays directly for healthcare services; includes Part A (inpatient/hospital) and Part B (outpatient/medical services). Part D (prescription coverage) typically needs to be purchased separately <i>See Traditional Medicare</i>
Out-of-network care	Care that is provided by a provider or facility that is not on an insurance plan's pre-approved provider list <i>See Out-of-network provider</i>
Out-of-network provider	A healthcare provider that is not contracted with the health insurance plan, and whose services are covered by the insurance plan minimally, if at all <i>See Out-of-network care</i>
Out-of-pocket (OOP) costs	Costs for medical care that are not covered by insurance
Out-of-pocket maximum	A cap on OOP costs within a defined coverage period; when the OOP maximum is met, the health insurance plan begins paying for covered services
Over-the-counter (OTC)	<i>See Non-prescription drug</i>

P

Patient advocate	An individual who acts in the patient's best interest and helps direct patients to needed information and services <i>See Advocate</i>
Patient assistance program (PAP)	A program offered by a drug manufacturer to help low-income patients obtain free or reduced-cost medication <i>See Pharmaceutical patient assistance program</i>
Patient consent	Patient permission for disclosure of personal information
Patient navigator	An individual who helps guide patients through the healthcare system, often assisting with locating financial and logistical (e.g., transportation, childcare) assistance during treatment <i>See Financial navigator</i>
Patient Protection and Affordable Care Act	The formal name of the Affordable Care Act <i>See Affordable Care Act (ACA), Obamacare</i>

Payer of last resort	The insurer who is responsible for paying costs of care for Medicaid beneficiaries, either Medicaid or another insurer
Pharmacy Benefit Manager (PBM)	A third-party administrator of health insurance plans' prescription drug programs
Part D Plan (PDP)	Prescription drug plans obtainable through private companies that provide Medicare Part D insurance <i>See Medicare Part D</i>
Pharmaceutical patient assistance program	<i>See Patient assistance program</i>
Plan	Package of health insurance benefits
Preauthorization	Determination by a health insurance plan that a medication or service is medically necessary prior to approving it for payment <i>See Prior authorization/approval, Reauthorization</i>
Precision medicine	Medical care that is tailored to genetic, environmental and lifestyle factors
Preferred drug list/preferred medication	<i>See Drug formulary, Formulary</i>
Premium	The amount paid to purchase health insurance coverage, typically in monthly installments
Prescriber	A healthcare professional (e.g., physician, dentist, physician assistant, nurse practitioner) who is licensed to prescribe drugs
Primary payer/primary insurance	When an individual has more than one insurance policy, the policy that is responsible for paying first on a medical claim
Prior authorization/approval	<i>See Preauthorization, Reauthorization</i>
Private insurance	<i>See Exchange insurance, Marketplace insurance, Commercial insurance</i>
Provider	Any professional or facility that provides healthcare services

R

Reauthorization	Renewal of prior authorization approval for delivery of healthcare services <i>See Preauthorization, Prior authorization/approval</i>
Refill	A new installment or cycle of a prescription medication <i>See Renewal</i>
Renewal	A new prescription for medication when all refills have been used <i>See Refill</i>
Retail pharmacy	A pharmacy (e.g., CVS, Walgreens) that sells drugs to patients <i>See Community pharmacy</i>

S

Safety net	A conglomeration of organizations and programs that assist patients with OOP healthcare costs
Second opinion	An additional medical opinion on diagnosis or treatment options that may confirm or contradict the original opinion
Secondary payer/secondary insurance	An additional insurance plan that may cover gaps in the primary plan
Service area	The area in which health insurance plan beneficiaries can utilize services
Social Security Disability Insurance (SSDI)	A Social Security program that pays monthly benefits to people under the age of 65 if they become disabled and are unable to work
Special enrollment period <i>Medicare</i>	A specific period of time during which people can add, drop or change their health insurance coverage if special circumstances caused them to miss the open enrollment period <i>See Open enrollment period</i>

Specialty medication	High-cost prescription drug used to treat complex, chronic or rare conditions
Specialty pharmacy	A pharmacy that handles high-cost, specialty pharmaceuticals that may have particular storage and handling requirements and are not available at a regular pharmacy
Specialty tiers	Insurance plans' categorization of drugs based on cost, with higher tiers having higher associated cost sharing
Spend down	Spending of excess income on medical bills to lower income to meet eligibility requirements for programs such as Medicaid
Standard Medicare Prescription Drug Benefit	Dollar-amount thresholds for each phase of the Medicare Part D prescription drug benefit (e.g., the 2018 Part D standard benefit has a deductible of \$405 and an initial coverage limit of \$3750 in total drug costs)
State Health Insurance Assistance program (SHIP) Medicare	A program that provides Medicare beneficiaries with Medicare-related support, including providing answers to questions about coverage, premiums, deductibles, etc.
Step therapy	<i>See Fail first</i>
Stop loss	Agreed-upon point beyond which a managed care organization is no longer liable for costs
Subscriber	The primary enrollee in a health insurance plan (e.g., the employee in an employer-provided plan)
Subsidy	Federal money used to help contain costs to individuals, such as the Medicare Part D Low Income Subsidy (LIS) for eligible Medicare beneficiaries <i>See Low Income Subsidy</i>
Supplemental Nutrition Assistance Program (SNAP)	Federal nutrition assistance given to low-income individuals in the form of a debit card to use to purchase food
Supplemental Security Income (SSI)	Benefits paid monthly to people with low incomes who are age 65+, blind, or disabled; the program is administered by the U.S. Social Security Administration

T

Temporary Assistance to Needy Families (TANF)	A federal program for low-income families that replaces the Aid to Families with Dependent Children program
Third party payer	An entity that pays medical expenses on behalf of its beneficiaries
340B Drug Discount Program	A federal program administered by the U.S. Health Resources & Services Administration (HRSA) that requires pharmaceutical companies to provide discounted drugs to certain entities and organizations
Traditional Medicare	<i>See Original Fee-for-Service Medicare (Parts A, B, or D)</i>
TRICARE	U.S. Department of Defense Military Health System healthcare program for U.S. service members, reservists and dependents
True out-of-pocket costs (TrOOP) Medicare	OOP costs (co-pays, deductibles, etc.) that count toward a Medicare beneficiary's OOP threshold and determine when the beneficiary will enter the Catastrophic Coverage Phase

U

Underinsured	Having health insurance that does not cover enough medical expenses, resulting in high OOP costs
Uninsured	A person who does not have health insurance

V

Value-Based Insurance Design (VBID)	Insurance designed to align OOP costs with the value of services, encouraging use of high-value care and disincentivizing use of low-value care
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Veterans Administration (VA)

U.S. Department of Veterans Affairs: A federal agency that provides healthcare and other services to U.S. veterans

Voucher

A certificate, typically for those with low/moderate income, that assists with the cost of prescription drugs or services

W

Waiting period

Period of time before coverage begins

Workers' Compensation

Mandatory employer-purchased insurance, which provides wage replacement and medical benefits to employees who get sick or injured on the job

Y

Yearly resets

Amounts paid toward annual deductibles reset back to zero

Appendix A. Roundtable Agenda

WELCOME (9:00 AM) *Amy Niles; Dan Klein; Surabhi Dangi-Garimella, PhD*

GUEST SPEAKER (9:15 AM) *K. Robin Yabroff, PhD*
Financial Hardship: An Emerging Consequence of Illness in the United States

Questions and Answers

PANEL DISCUSSION: (10:00 AM)

Access to Medications for the Medicare Population: Current and Future Need

Moderator *Clifford Goodman, PhD*

Panelists *Leigh Purvis; Julie Carter; Leslie Fried, JD; Paul Billings*

Questions and Answers

PANEL DISCUSSION: (11:15 AM)

Provider Perspective: How do High Out-of-Pocket Costs Affect Clinical Practice and Patient

Outcomes

Moderator *Clifford Goodman, PhD*

Panelists *Cesar Santa-Maria, MD, MSCI; Eileen Peng, PharmD; Margaret O'Grady, RN; Erin Hughes*

Questions and Answers

PAN CHALLENGE PRESENTATIONS (1:00 PM)

» Presentation #1: PAN Challenge Winning Paper *Lizheng Shi, PhD, MsPharm, MA; Mary Kristina Wharton, MPH*

» Presentation #2: PAN Challenge Runner-Up Winning Paper *Todd Yezefski, MD*

PANEL DISCUSSION: (1:30 PM)

Policy Considerations to Improve Access and Reduce Financial Hardship

Moderator *Ilisa Halpern Paul*

Panelists *Emily Harrison Gibb; Anna Hyde; Kavita Patel, MD; Edmund Haislmaier*

Questions and Answers

PANEL DISCUSSION: (2:30 PM)

The Patient Assistance Safety Net: How Many Need Help? How Many are Helped?

Moderator *Clifford Goodman, PhD*

Panelists *Dan Klein; Clorinda Walley; Michele McCourt*

Questions and Answers

CLOSING REMARKS/THANK YOU (3:25 PM) *Amy Niles*

Appendix B. *Roundtable Participants*



« PAUL BILLINGS

National Senior Vice President, Advocacy, American Lung Association

As Senior Vice President, Advocacy, Paul Billings oversees the American Lung Association's asthma, lung cancer, chronic obstructive pulmonary disease, healthy air and tobacco control advocacy program. During his 25+-year tenure at the American Lung Association, Mr. Billings has led federal advocacy campaigns that resulted in stricter regulations on tobacco products, growth in research funding, improved patient access to preventive services, and cleanup of air pollution from motor vehicles and power plants. Previously, Mr. Billings directed grassroots activities for the National Clean Air Coalition, and he was an associate with the FMR Group in Washington, D.C.

JULIE CARTER »

Federal Policy Associate, Medicare Rights Center

Julie Carter is an attorney and Federal Policy Associate in the Washington, D.C. office of the Medicare Rights Center. Medicare Rights Center is a national, nonprofit consumer service organization that works to ensure access to affordable healthcare for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Before joining Medicare Rights Center, Ms. Carter was a Health and Aging Policy Fellow in the Administration for Community Living's (ACL) National Institute on Disability, Independent Living and Rehabilitation Research and the Center for Policy and Evaluation. Prior to her time at ACL, Ms. Carter was an Irmis Fellow with Justice in Aging, focused on person-centered planning and Medicaid Long-Term Services and Supports.



« SURABHI DANGI-GARIMELLA, PHD

Associate Director, The American Journal of Managed Care®

Surabhi Dangi-Garimella, PhD, is Associate Editorial Director with the AJMC® Managed Markets Network, responsible for four print publications within the managed care space, including *The American Journal of Managed Care®* as well as two digital platforms: AJMC.com and CenterforBiosimilars.com. Dr. Dangi-Garimella earned her doctorate in pharmaceutical sciences at the University of Maryland, Baltimore. She did her post-doctoral work at the University of Chicago, where she studied the mechanism of breast cancer metastases. Subsequently, as a research associate at Northwestern University, she studied the mechanisms of matrix metalloproteinase-mediated drug resistance in pancreatic cancer.

Appendix B. *Roundtable Participants (continued)*



« LESLIE FRIED

Senior Director, Center for Benefits Access, National Council on Aging (NCOA)

In her role at NCOA, Ms. Fried directs the Center's activities to support community-based organization outreach and enrollment activities of low-income older adults, and advocates for improved access to Medicare and other public benefits for seniors and adults with disabilities of limited means. Prior to joining the NCOA, Ms. Fried was a senior attorney with the American Bar Association (ABA) Commission on Law and Aging. She joined the ABA as the Medicare Advocacy Project attorney, and was subsequently selected to be a member of the National Academy of Social Insurance. Ms. Fried has served as a patient advocate member of the Centers for Medicare and Medicaid Services Medicare Evidence Development and Coverage Advisory Committee; a member of the Continuing Care Advisory Committee for the Maryland Department of Aging; and staff attorney/managing attorney of Legal Services for Senior Citizens of Montgomery County, MD. Ms. Fried received her BA from the University of Michigan and her JD from the University of Maryland. She is a member of the Maryland, District of Columbia and Supreme Court bars.

EMILY HARRISON GIBB, MA »»

Interim Vice President, Public Policy & Patient Assistance, GlaxoSmithKline

Emily Harrison Gibb serves as Executive Director of the GlaxoSmithKline (GSK) Patient Assistance Foundation and oversees GSK's U.S. patient assistance programs across all therapeutic areas. She also leads public policy and advocacy strategies to educate state and federal officials on the role that innovative pharmaceuticals and vaccines play in reducing healthcare costs and improving health in communities. Ms. Harrison Gibb has worked on efforts to address some of today's most dynamic public policy issues including healthcare reform legislation, deficit/debt reduction, access to medicines in the Medicare Part D program, healthcare quality improvement, and patient safety. Prior to joining GSK, she worked at Eastern Maine Medical Center, at Novartis Pharmaceuticals, and on several political campaigns in her home state of Virginia. Ms. Harrison Gibb is passionate about improving access to high quality healthcare for vulnerable populations and people with chronic conditions in the United States and abroad, and periodically speaks at policy conferences in Washington, D.C.



« CLIFFORD GOODMAN, PHD

Senior Vice President, The Lewin Group

Clifford Goodman, PhD, has 30 years of experience in health technology assessment, evidence-based healthcare, comparative effectiveness research, health economics, and studies pertaining to healthcare innovation, regulation, and payment. He directs studies and projects for an international range of government agencies; pharmaceutical, biotechnology, and medical device companies; healthcare provider institutions; and professional, industry, and patient advocacy groups. Dr. Goodman's recent work has involved oncology, cardiovascular disease, diabetes, blood disorders, obesity, end-stage renal disease, HIV/AIDS, follow-on biologics, diagnostic testing, pharmacogenomics, personalized medicine, and organ donation and transplantation. He is an internationally recognized health policy issues moderator and facilitator of expert panels, health industry advisory boards, workshops, and focus groups, and served as Chair of the Medicare Evidence Development & Coverage Advisory Committee for the Centers for Medicare and Medicaid Services. Dr. Goodman served as president of Health Technology Assessment International and is a Fellow of the American Institute for Medical and Biological Engineering. He received a PhD from the Wharton School, University of Pennsylvania, an MS from Georgia Institute of Technology, and a BA from Cornell University.

Appendix B. *Roundtable Participants (continued)*



« EDMUND F. HAISLMAIER

Preston A. Wells Jr., Senior Research Fellow in Domestic Policy Studies, The Heritage Foundation

Edmund F. Haislmaier has 30 years' experience analyzing healthcare markets and public policies. He has particular expertise in the structure and regulation of health insurance markets, tax treatment of health benefits, and pharmaceutical policy issues. He has published extensively on those and other healthcare policy topics. During the past several years, his work has focused primarily on measuring the effects of the Affordable Care Act on health insurance enrollment, the Medicaid program, insurer competition, insurer profitability, and the law's risk-mitigation programs. Mr. Haislmaier is often asked to assist federal and state lawmakers in designing health reform proposals and legislation. He has testified on numerous occasions before congressional and state legislative committees, and is frequently interviewed by the media.

ERIN HUGHES »

Financial Advocate, Abington Cancer Care Specialists, Abington-Jefferson Health

In her role as Financial Advocate, Erin Hughes focuses on insurance verification and researching of secondary entitlements through foundation and drug reimbursement programs for hematology, medical, gynecological, and radiation oncology practices. Ms. Hughes and her team counsel patients and their families on the OOP expenses of their treatment, helping them to maximize their insurance benefits and tap into vital financial resources internal and external to the organization. It was essential to Ms. Hughes and her team to help establish the Oncology Financial Assistance Program so that patients and their family members would experience compassionate guidance and financial stability throughout their treatment. Ms. Hughes serves as a member of the Patient and Family Advisory Committee at Abington Jefferson Health Oncology Department.



« ANNA HYDE

Vice President of Advocacy and Access, Arthritis Foundation

Anna Hyde oversees the Arthritis Foundation's federal and state legislative programs, in addition to grassroots engagement. Her focus is to raise the visibility of arthritis as a public-health priority, build support for federal and state legislation that ensures access to affordable, high-quality healthcare, and enhance patient engagement in the policymaking process. Ms. Hyde previously served as Senior Director of Advocacy and Access, managing the federal affairs portfolio and overseeing the state advocacy team. Prior to joining the Arthritis Foundation, she managed a portfolio of issues including appropriations, physician workforce, and health IT at the American Congress of Obstetricians and Gynecologists. She began her health policy career as a Congressional Fellow for Energy and Commerce Committee members, where she drafted legislation and staffed Committee activities. Ms. Hyde received a BA in history from Southern Methodist University, and taught junior high and high school history before moving to Washington D.C. in 2007 to pursue an MA in political science from American University.

Appendix B. *Roundtable Participants (continued)*



« DAN KLEIN

President & CEO, PAN Foundation

Dan Klein brings over 35 years of experience in healthcare and information technology services to the PAN Foundation. As President and CEO of the PAN Foundation, Mr. Klein is committed to ensuring that people living with life-threatening, chronic, and rare diseases have access to their critical medical treatment by helping pay for their OOP costs and by advocating on their behalf. He leads ongoing efforts to raise awareness about escalating OOP costs and about the safety net provided by PAN and other charitable patient assistance organizations. Since joining PAN in 2014, Mr. Klein has increased PAN's capacity to meet the growing needs of patients as efficiently and compliantly as possible. 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 that 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 CEO of Panurgy Corporation, 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.

MICHELE MCCOURT »

Senior Director, CancerCare® Co-Payment Assistance Foundation

Michele McCourt has more than 28 years of experience developing and implementing patient-assistance programs for both uninsured and underinsured patients. In her current role, she is responsible for overseeing the daily operations of the CancerCare® Co-Payment Assistance Foundation. She also has overall responsibility for the Foundation's growth and development working closely with CancerCare's Chief Business Development Officer to maintain and establish new funding resources. Prior to joining CancerCare, Ms. McCourt was Director of Patient Services for the National Organization for Rare Disorders.



« AMY NILES

Amy Niles, Vice President of External Relations, PAN Foundation

Amy Niles oversees relationships with patient advocacy organizations and directs the PAN Foundation's public advocacy initiatives. Before joining PAN, Ms. Niles served for 8 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. Ms. Niles is a member of the Board of Directors of NeedyMeds and the Community Access National Network. She has an MBA from Baruch College, City University of New York, and an undergraduate degree in Biology from the University of Rochester.

Appendix B. *Roundtable Participants (continued)*



« MARGARET O'GRADY, RN

Administrative Director, Oncology Service Line, Abington-Jefferson Health System

Margaret (Peg) O'Grady is the Administrative Director of the Abington-Jefferson Health System's Rosenfeld Cancer Center. She oversees inpatient and outpatient oncology service, including a robust research relationship with the Sydney Kimmel Cancer Center. Ms. O'Grady was previously the Director of Nursing for the Sydney Kimmel Cancer Center Medical Oncology division. She has significant expertise in oncology care coordination, also having worked at Fox Chase Cancer Center as the Senior Director of the first cancer center network in the United States—The Fox Chase Partners Program, supporting development of more than 30 institutions' cancer centers. She is past President of the Pennsylvania Society of Oncology and Hematology, the statewide

American Society of Clinical Oncology group, and is the past president of the American Academy of Medical Administrators. Her research interests are health outcomes, transition of care and navigation, and breast and colorectal navigation processes.

KAVITA PATEL, MD »

Nonresident Fellow, Economic Studies, Center for Health Policy, Brookings Institution

Kavita Patel, MD is a nonresident senior fellow at the Brookings Institution, and a practicing primary care physician at Johns Hopkins Medicine. In her role at the Brookings Institution, Dr. Patel was instrumental in the development of several specialty payment models that have been adopted by Medicare. Dr. Patel was previously a Director of Policy for The White House under President Obama and a senior advisor to the late Senator Edward Kennedy. Her prior research in healthcare quality and community approaches to mental illness has earned national recognition, and she has published numerous papers and book chapters on healthcare reform and health policy. She has testified before Congress several times; she is a frequent guest expert on NPR, CBS, NBC, and MSNBC; and she has served on the editorial board of the journal, *Health Affairs*.



« ILISA HALPERN PAUL, MPP

President, District Policy Group

Ilisa Halpern Paul leads the District Policy Group, a boutique public policy, government relations, and lobbying practice within Drinker Biddle & Reath LLP, a prominent national law firm. Ms. Paul has 25 years of experience in federal healthcare issues, lobbying and advocacy, and legislative and regulatory policymaking. She advises and represents healthcare clients with respect to understanding, navigating, surviving, and thriving in today's dynamic policy environment. Her work has earned her recognition as one of The Hill's Top Lobbyists of 2015, 2016 and 2017, as well as a feature story in The Hill regarding her rise to success. Ms. Paul works with patient advocacy groups, health and hospital systems, healthcare provider organizations, health professional societies, medical device and technology companies, healthcare coalitions, and other organizations to advance their public policy

priorities before the legislative and executive branches, with a focus on establishing strong relationships with elected and federal agency officials. Ms. Paul previously served as Director of Federal Government Relations for the American Cancer Society and Director of Federal Affairs with the American Public Health Association. She began her public policy career in Washington, D.C. working on the legislative staff for U.S. Senator Dianne Feinstein (D-CA). Ms. Paul earned a master's of public policy degree from Georgetown University's Public Policy Institute.





« EILEEN PENG, PHARM D

Director of Pharmaceutical Services, Regional Cancer Care Associates, LLC

In addition to her role as Director of Pharmaceutical Services for Regional Cancer Care Associates (RCCA), LLC, Dr. Eileen Peng also serves as manager of the RCCA Pharmacy and Practice Administrator of the Central Jersey Division of Regional Cancer Care Associates LLC. Prior to joining RCCA, she worked as an oncology pharmacist at Robert Wood Johnson University Hospital, St. Peter's University Hospital, Memorial Sloan-Kettering Cancer Center, and Mt. Sinai Hospital. Dr. Peng taught oncology nurses and staff at the Robert Wood Johnson Oncology Fundamental Course, where she addressed the issues of pain control, antiemetics, and infection. She currently serves as a clinical preceptor for the PharmD program at Rutgers University-Ernest Mario School of Pharmacy. Dr. Peng received an MS in pharmaceuticals from the State University of New York, Buffalo, and a doctorate in pharmacy from the University of Colorado Denver School of Pharmacy.

LEIGH PURVIS »

Director, Health Services Research, AARP Public Policy Institute

As Director of Health Services Research in AARP's Public Policy Institute, Ms. Purvis leads a team of policy analysts and researchers who work on healthcare issues that are relevant to the 50+ population. In addition, Ms. Purvis heads the Institute's work on prescription drug and mental health issues. Her primary areas of expertise are prescription drug pricing, biologic drugs, and prescription drug coverage under Medicare. She is a coauthor of the Public Policy Institute's annual Rx Price Watch reports, which track price trends for prescription drugs widely used by older Americans. Ms. Purvis joined AARP in 2005 as a senior policy research analyst. Prior to her tenure at AARP, she worked for the American Psychological Association. Ms. Purvis is a recognized expert on prescription drug issues and frequently speaks with the press. She has an MPA with a concentration in health administration and policy from George Mason University, and a BS in psychology from the University of Mary Washington. She also holds a certificate in gerontology from the University of Washington.



« CESAR SANTA-MARIA, MD

Assistant Professor of Oncology, Department of Oncology, The Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins School of Medicine

In addition to his role at the Sidney Kimmel Comprehensive Cancer Center at the Johns Hopkins School of Medicine, Dr. Cesar Santa-Maria is an attending physician at Johns Hopkins Hospital Oncology Center. Involved in breast cancer research since medical school, Dr. Santa-Maria has contributed extensively to the areas of immunology in breast cancer; correlations among energy balance, metabolism, and breast cancer; and hypoxia and its role as an oncogenic driver in breast cancer. He has published more than 20 papers on these topics in publications that include *JAMA Oncology*, *Clinical Cancer Research*, and *Journal of the National Cancer Institute*. Dr. Santa-Maria is an active member of the American Society of Clinical Oncology and *the American Association of Cancer Research*, and is the Chair of the ASCO/Conquer Cancer Foundation Diversity in Oncology, Review and Selection Subcommittee. He received the ASCO Pain and Symptom Management Merit Award, the SABCS/AACR Scholar-in-Training Award, and the Northwestern Translational Bridge Program Award, among others. Before joining The Sidney Kimmel Comprehensive Cancer Center, Dr. Santa-Maria practiced at Northwestern University Feinberg School of Medicine.





« CLORINDA WALLEY

President, Good Days

Clorinda Walley leads the charity, Good Days, with more than 20 years of experience in the healthcare industry and more than 8 years in strategic philanthropy. She effectively oversees the strategic and operational responsibility for the staff and programs for Good Days, as well as the expansion and execution of its mission. With in-depth knowledge of the organization's core programs, operations, and business plans, Ms. Walley ensures the organization's programmatic excellence. With her proven expertise, Ms. Walley has continuously ensured consistent quality of finance and administration, procurement of donations, internal and external communications, and development of all patient care initiatives.

K. ROBIN YABROFF, PHD »

Strategic Director, Economic Burden of Cancer, American Cancer Society, Inc.

Dr. Robin Yabroff is an epidemiologist with more than 20 years of health services research experience. She recently joined the American Cancer Society to lead research about financial hardship and economic burden of cancer. Dr. Yabroff has also held positions within the U.S. Department of Health and Human Services, the National Cancer Institute and the faculty of the Lombardi Cancer Center, Georgetown University. She earned her PhD in epidemiology from the Johns Hopkins School of Public Health and received an MBA from the University of Rochester. Her areas of expertise relate to the economic burden of cancer, financial hardship, high cost of prescription drugs, and patient and provider factors associated with quality of care. Dr. Yabroff has co-authored over 150 peer-reviewed journal articles and other publications, and is an associate editor for the *Journal of the National Cancer Institute* and on the editorial board of the *Journal of Cancer Survivorship*. She recently led a multi-institutional collaborative effort to improve publicly available data for estimating the burden of cancer in the United States, entitled, *Medical Expenditure Panel Survey (MEPS): Experiences with Cancer Survivorship Supplement*.

