

Background Brief for NPAF Policy Principles 2020

National Patient Advocate Foundation (NPAF) represents patient and caregiver voices, both the powerful stories of individuals and the collective needs of the community. Since 1996, we have been dedicated to expanding equitable access to affordable quality care, particularly for our nation's most vulnerable populations. NPAF is the advocacy affiliate of Patient Advocate Foundation (PAF), which provides direct assistance and support services for primarily low-income families confronting complex, chronic and serious illness to help reduce distressing financial and other burdens they may experience because of their conditions.

NPAF develops and drives evidence-based solutions at federal, state and local levels that promote person-centered policies and practices in four key areas developed through its *Roadmap to Consumer Clarity* initiative: skilled communication, shared decision-making, quality care improvement and safety net services navigation. The goal is a system that matches treatments and services with patient and family values. Experiences reported from the thousands of people served annually through PAF's efforts and input from patients and caregivers about what they need and value throughout the care continuum fuels our person-centered and family-focused agenda.

Through targeted research, policy advancement, advocacy engagement, and stakeholder partnerships, NPAF uses its leadership and resources, supported by patient data, to influence system reforms that put people at the heart of healthcare.

NPAF's policy principles reflect a range of reform opportunities for promoting equitable access to affordable, high quality care, organized accordingly under the following topical areas:

1. Health Equity
 - a. Financial Toxicity and Social Needs Navigation
 - b. Federal Poverty Level and Safety Net Supports and Services
 - c. Medicaid and Children's Health Insurance Program (CHIP)
2. Access
 - a. Coverage Protections and Expansion
 - b. Insurance Benefit Design and Utilization Management
 - c. Personalized and Value-Based Care
3. Affordability
 - a. Total Costs of Care and Transparency
 - b. Surprise Medical Billing and Network Adequacy
 - c. Medical Debt and Credit Protections
4. Quality
 - a. Skilled Communication, Shared Decision Making and Patient Engagement
 - b. Palliative Care, Pain Management, Psychosocial Support and Rehabilitation Services Integration
 - c. Caregivers Engagement and Support

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Health Equity

The impact of social determinants of health (SDOH) on population health and health outcomes has garnered growing interest in health services research and public policy discourse in recent years. While the concept is not new, renewed commitment to SDOH from the World Health Organization (WHO) has spurred multiple health care stakeholders to integrate consideration of societal context, including the community-level conditions in which people live, work, play, worship, and age, and the wider set of forces and systems shaping the conditions of daily life¹ as underlying factors that potentially propagate health inequities, disparities and financial hardships that require thoughtful interventions.

Amidst this increased activity, public health experts have cautioned about conflating SDOH (a community's underlying social and economic conditions) with mitigating the social needs of individuals, reinforcing the distinction that a person may have many social risk factors but fewer immediate social needs. For example, an effort to provide fresh produce to people struggling to afford food mitigates an immediate individual need but does not address the underlying systemic issues that cause food insecurity. The result can be a disconnect in important conversations about how to improve health and reduce disparities. Moreover, mixed messaging may overstate the reach of purported SDOH interventions, "over-medicalize" peoples' social needs, and impede investment in upstream community interventions.²

Nationally, public and private-sector initiatives and partnerships have emerged to tackle the root causes and conditions that contribute to poor health and disparate outcomes in the US, alongside notable efforts to expand access to Medicaid and other safety net supports and services in multiple states. Yet concerning trends restricting eligibility in the current Administration's existing and emerging policies, including efforts to instill work requirements, shrink transportation benefits and nutrition programs, and introduce a new Medicaid block grant option, among other initiatives, threaten to thwart progress in addressing both SDOH challenges and unmet social needs by curbing access to vital entitlement programs for the seriously ill adults, children and families who rely on them.

In this current climate, Patient Advocate Foundation's (PAF) two plus decades of dedicated intervention experience assisting hundreds of thousands of individuals in overcoming access barriers often attributable to SDOH, backed by evidence from patient data collected, uniquely positions NPAF as a credible advocacy force for advancing a new platform of person-centered, system-level policy solutions to equitably and reliably scale sustainable, high quality financial and social needs navigation practices and services that can benefit vulnerable populations in their communities.

a. Financial Toxicity and Social Needs Navigation

People coping with serious illness and disability have always had to contend with the financial impact of their care on their lives. Costs of care influence decisions about treatment, but also have a significant

¹ World Health Organization. What are Social Determinants of Health? https://www.who.int/social_determinants/en/

² "When Talking About Social Determinants, Precision Matters," Health Affairs Blog, October 29, 2019. Available at: <https://www.healthaffairs.org/doi/10.1377/hblog20191025.776011/full/>

impact on the quality of life of patients and their families. Recognizing that they often lack the support and resources required to help address their needs, PAF has developed particularly specialized expertise in providing personalized financial navigation services and related community resource referrals for thousands of predominantly lower-income patients and families each year.

People incur high costs of care as a result of out-of-pocket (OOP) expenses for treatments and medical services as well as transportation to appointments, childcare, lost wages and other indirect expenses related to their condition. In some instances, families must make difficult tradeoffs between paying for medical care and basic living expenses such as groceries, utilities and rent. Caregivers also carry the brunt of costs related to medical care, long-term services and supports and assistance with activities of daily living. These distressing circumstances, often characterized as “financial toxicity”, have been associated with a greater likelihood of treatment nonadherence,³ poorer quality of life⁴ and higher mortality than those who do not experience financial hardship.⁵

Individuals who have no insurance or are underinsured typically endure the highest level of financial toxicity, but people of all socioeconomic backgrounds feel the effects of the costs of their care. Mounting medical bills, increasing copays and cost sharing and the emergence of more effective but high-priced treatments for many conditions all contribute to the financial burden. Accordingly, it is critical that patients and health professionals talk about cost of care issues and that these conversations are incorporated into the clinical workflow.⁶

Most research has studied the impact of financial toxicity on cancer patients, however, the extenuating circumstances are more severe in under-resourced individuals and likely span all diseases.^{7,8} Financial toxicity can affect anyone regardless of their insurance coverage and can be particularly confusing for the underinsured leading to uncertainty in navigating unexpected out-of-network costs, deductibles and copays among other complexities of the health care system.⁹ Additional studies indicate that patients facing financial toxicity may experience a higher risk of bankruptcy,¹⁰ unemployment and loss of employer-sponsored health coverage.¹¹

Few hospitals, health systems, advocacy organizations and communities provide comprehensive financial and social needs support, but those that do have shown to significantly increase treatment adherence,

³ Dusetzina SB, Winn AN, Abel GA, et al. Cost Sharing and Adherence to Tyrosine Kinase Inhibitors for Patients with Chronic Myeloid Leukemia. *Journal of Clinical Oncology* 2014 32:4, 306-311

⁴ Fenn KM, Evans SB, McCorkle R et al. Impact of Financial Burden of Cancer on Survivors' Quality of Life. *J Oncology Prac.* 2014 10:5, 332-338.

⁵ Ramsey SD, Bansal A, Fedorenko CR et al. Financial Insolvency as a Risk Factor for Early Mortality Among Patients with Cancer. *Journal of Clinical Oncology* 2016 34:9, 980-986

⁶ National Patient Advocate Foundation. Talking About the Costs of Health Care and the Impact of Financial Toxicity. 2019. Available at: <https://www.npaf.org/initiatives/cost-of-care-convo/>

⁷ Hincapie AL, Penm J, Burns CF. Factors Associated with Patient Preferences for Disease-Modifying Therapies in Multiple Sclerosis. *J Manag Care Spec Pharm.* 2017 Aug;23(8):822-830.

⁸ Valero-Elizondo J, Khera R, Saxena A et al. Financial Hardship from Medical Bills Among Nonelderly U.S. Adults with ASCVD. *JACC.* Feb 2019. 73(6):727-732

⁹ Chino F, Peppercorn JM, Rushing C, Kamal AH, Altomare I, Samsa G, Zafar SY. *Out-of-Pocket Costs, Financial Distress, and Underinsurance in Cancer Care.* *JAMA Oncol.* 2017;3(11):1582–1584. doi:10.1001/jamaoncol.2017.2148.

¹⁰ Ramsey S, Blough D, Kirchoff A et al. Washington State Cancer Patients Found To Be At Greater Risk For Bankruptcy Than People Without A Cancer Diagnosis. *Health Affairs.* 2013. 32(6):1143–1152

¹¹ Yabroff KR, Dowling EC, Guy Jr GP et al. Financial Hardship Associated With Cancer in the United States: Findings From a Population-Based Sample of Adult Cancer Survivors. *Journal of Clinical Oncology* 2016 34:3, 259-267

improve outcomes and reduce overall costs for both patients and health systems.^{12,13} Further, survey and focus group findings within NPAF's Roadmap report conclude that addressing financial toxicity can contribute to achieving more goal concordant care that matches treatment with a patient and family's stated preferences and values.¹⁴ Indeed, in a 2019 survey of over 2,800 patients served by PAF, 63 percent identified "avoiding financial distress" as the most important goal of care, and ranked "being able to take care of myself and my family" as a close second.

Adding to these PAF survey data, findings from recent NPAF costs of care project collaborations funded by Robert Wood Johnson Foundation demonstrate that patients want and need to have these conversations, but often do not. The project's featured studies and stakeholder convenings revealed that: (1) patients and caregivers may be reluctant for a variety of reasons to bring up their financial concerns, (2) physicians are often uncomfortable talking about the costs of care or do not believe it is their role, and (3) both patients and professionals on their care teams often lack the skills and tools to facilitate these conversations.¹⁵

At PAF, case managers talk to many thousands of patients and caregivers every year and have developed specialized expertise in handling the challenges of these cost conversations and other financial concerns. Virtually every one of these individuals contacts PAF because they are confronting serious issues related to the costs of their medical care, often agonizing about balancing those costs with the day to day demands of their lives. They may be experiencing problems with insurance coverage, inability to pay or even comprehend the bills that are piling up. Most know very little about the health care system, billing practices, insurance appeals or utilization management processes until they become seriously ill or disabled. They benefit from PAF's direct services, and in so doing, learn skills and locate resources that often help them become better advocates.

NPAF's Roadmap findings and subsequent costs of care work made clear that patients and their health care providers should talk about these issues up front, regularly and as a normal part of care planning and shared decision-making processes. Literature also suggests that after a critical illness requiring a hospital stay, patients and families want information about insurance coverage and estimating expenses to avoid the worries of financial distress.¹⁶ Accordingly, NPAF's policy principles posit that health systems, payers and professionals should prioritize person-centered communication skills training and quality improvement initiatives that build competence and accountability for discussing financial concerns as part of delivering high quality, value-based care.

The Comprehensive Score for Financial Toxicity (COST) measure has demonstrated reliability and validity as a clinically relevant patient-reported outcome for measuring financial toxicity and its correlation with

¹² Yezefski T, Steelquist J, Watabayashi K et al. Impact of Trained Oncology Financial Navigators on Patient Out-of-Pocket Spending. *Am J Manag Care.* 2018;24(5 Suppl):S74-S79

¹³ Ell K, Vourlekis B, Xie B et al. Cancer Treatment Adherence among Low-Income Women with Breast or Gynecologic Cancer: A Randomized Controlled Trial of Patient Navigation. *Cancer.* 2009 October 1; 115(19): 4606–4615.

¹⁴ Patient Advocate Foundation. The Roadmap to Consumer Clarity in Health Care Decision Making. May 2017. Available at: https://www.npaf.org/wp-content/uploads/2017/07/RoadmapWhitePaper_ecopy.pdf

¹⁵ National Patient Advocate Foundation. Talking About the Costs of Health Care and the Impact of Financial Toxicity. 2019.

¹⁶ Khandelwal N, Engelberg RA, Hough CL et al. The Patient and Family Member Experience of Financial Stress Related to Critical Illness. *J of Palliative Medicine.* Jan 2, 2020.

worse health-related quality of life.¹⁷ Other tools, including PRAPARE¹⁸, and Health Leads' Social Needs Screening Toolkit¹⁹ also provide frameworks for assessing financial toxicity and patients' health-related social needs. Financial and social needs assessment and navigation services are not currently standardized in practice, and existing programs range from comprehensive, individualized support to services that simply determine eligibility for financial assistance. Notably, the Financial Advocacy Network, an initiative convened by the Association of Community Cancer Centers, has developed "Financial Advocacy Services Guidelines" providing recommendations on characteristics, roles and responsibilities of financial advocacy teams in the context of oncology practice.²⁰ Clinical practice standards for providing high quality financial navigation services, guidance and resource referrals that comprehensively address needs across diagnoses and care settings do not yet exist.

The Accountable Health Communities (AHC) model, an ongoing demonstration developed by the Center for Medicare and Medicaid Innovation, is a promising signal that policymakers are interested in pursuing delivery system reforms that include assessing financial and social needs. The AHC model is testing whether systematically identifying and addressing the health-related social needs of Medicare and Medicaid beneficiaries through screening, referral and navigation services will impact health care costs and reduce health care utilization.²¹ Concurrently, the Camden Core Model received national attention for its "hotspotting" approach that targets super-utilizers of the health care system for clinical and social services coordination. A recent study evaluating the model's impact found no statistically significant reduction of hospital readmissions, however, underscoring the persisting challenges in comprehensively meeting the needs of medically and socially complex patients in their communities.²²

Financial and social needs navigation is critical to increasing treatment adherence which produces better health outcomes, saves money for individuals and hospitals and reduces financial toxicity that patients, caregivers and families experience. Building understanding and awareness about the value of these services, as well as developing the evidence base and accountability standards that drive quality services delivery, are fundamental next steps in creating and advancing a robust policy platform that could ultimately integrate provision of financial and social needs navigation services throughout the care continuum as a standard of practice. NPAF's new policy principles reflect our commitment to the core belief that all populations should benefit from equitable and reliable access to affordable quality care that mitigates patient and family exposure to the distressing consequences of financial toxicity.

Principles: Financial Toxicity and Social Needs Navigation

1. Patients and families should have equitable, expeditious access to financial and social needs navigation in the setting of complex or chronic conditions as a standard of practice for quality care delivery.

¹⁷ de Souza JA, Yap BJ, Wroblewski K et al. Measuring Financial Toxicity as a Clinically Relevant Patient-Reported Outcome: The Validation of the COmprehensive Score for financial Toxicity (COST). *Cancer*. 2017 Feb 1;123(3):476-484.

¹⁸ NACHC. Protocol for Responding to and Assessing Patients' Assets, Risks and Experiences. Available at: <http://www.nachc.org/research-and-data/prapare/about-the-prapare-assessment-tool/>

¹⁹ The Health Leads Screening Toolkit. Available at: <https://healthleadsusa.org/resources/the-health-leads-screening-toolkit/>

²⁰ Association of Community Cancer Centers. Financial Advocacy Guidelines. Available at: <https://www.acc-cancer.org/home/learn/financial-advocacy/guidelines>

²¹ The Centers for Medicare and Medicaid Services. The Accountable Health Communities Model. Accessed January 24, 2019. Available at: <https://innovation.cms.gov/initiatives/ahcm>

²² Finkelstien A, Zhou A, Taubman S et al. Health Care Hotspotting — A Randomized, Controlled Trial. *N Engl J Med* 2020; 382:152-162

2. All patients and families should be assessed to identify the need for financial assistance, transportation, social and household material support (i.e., food, energy, and housing) early in the course of illness and throughout the care continuum, with referral processes in place so they can secure quality navigation services and safety net resources.
3. Research evaluating social determinants of health and the impact of financial toxicity, eligibility restrictions and the provision of navigation services in addressing these burdens should be prioritized to support accountability for quality care improvement and associated payment reforms.

b. Federal Poverty Level and Safety Net Supports and Services

Government entitlement programs are often referred to as the public “safety net”—protecting low-income individuals and families from the hardships and disparate outcomes of poverty. The patchwork of programs includes:

- Medicaid and CHIP
- Community health centers
- Supplemental Nutrition Assistance Program (SNAP - formerly “food stamps”)
- Low-Income Home Energy Assistance Program (LIHEAP)
- Family income support programs such as the Temporary Assistance for Needy Families (TANF), Supplemental Security Income (SSI), Social Security Disability, and others

The safety net also includes a variety of private charitable assistance programs offered through local churches, food banks and free clinics as well as national programs like Meals on Wheels, NeedyMeds and PAF services. Together, these public and private programs help address critical gaps in assistance with health care, financial or household material hardships such as food, energy and housing insecurity. Safety net programs serve as an essential layer of support and security for low income patients and families, insured and uninsured individuals, working families caring for a seriously ill family member, people with disabilities, the elderly, pregnant women, those in need of mental health or addiction services and veterans.

PAF case managers consistently report that safety net programs addressing non-medical costs are vital to help relieve the financial burdens of a serious illness diagnosis. Each year almost one-third (30 percent) of patients receiving PAF assistance confront debt crises that impair their ability to afford transportation expenses, housing, utilities, or nutritional needs.²³ In PAF’s 2019 survey of over 2,800 patients receiving its assistance, 43% reported that day-to-day living expenses including rent, mortgage and utilities were the most important financial burdens requiring relief, followed by health insurance premiums (39%) and hospital bills (33%).²⁴

²³ Patient Advocate Foundation. Internal Case Management Data. 2018.

²⁴ Patient Advocate Foundation. Retrospective Survey. February 2019.

Using data that correct for underreporting, safety net supports and services such as SNAP, TANF, SSI and tax credits lifted nearly 37 million people (including 7 million children) above the poverty line, according to a 2018 chart book from the Center of Budget and Policy Priorities.²⁵ Disregarding the demonstrated need, recent proposed regulations from the current Administration have targeted several key safety net programs including SNAP and SSI, and the President's budget has consistently proposed drastic cuts in funding for SNAP, the Department of Housing and Urban Development (HUD) and non-defense discretionary programs over the past three years. Policy experts warn that if enacted, these cuts would increase poverty, decrease the number of insured individuals and widen income and racial disparities.²⁶

Expanding the reach of these concerning trends, the Office of Management and Budget is considering technical changes to the federal poverty threshold by adopting a lower inflation adjustment measure that would further lower the poverty line. It is widely documented that the official poverty line is already too low and does not accurately represent income required to meet basic family needs.²⁷ This latest tactic may lead to harmful downstream effects that will impact peoples' eligibility for health, nutrition and other safety net programs at the same time that rising health care costs have increased pressure on scarce safety net resources. Many charities already struggle to keep pace with demand as public programs become increasingly vulnerable in the face of decreased funding.²⁸

Pursuing policies that bolster the network of safety net services and supports nationally and in communities will be an essential aspect of addressing SDOH challenges and social needs that contribute to inequities experienced among vulnerable populations.²⁹ Maintaining an appropriate federal poverty level and adequate access to safety net services and supports are vital strategies in addressing health inequities. Vigilant monitoring of the poverty level and safety net landscape and vigorous advocacy will be important to identify and neutralize threats to these essential supports. NPAF will also continue to examine new opportunities that may emerge for additional public policy action.

Principles: Federal Poverty Level and Safety Net Supports and Services

1. Federal poverty threshold adjustments and other program eligibility requirements should not interfere with the health and well-being of patients and families who rely on these safety net supports and services to access needed care.
2. Policymakers and investigators should prioritize research funding for the development and dissemination of effective interventions that link vulnerable populations with available safety net supports and services.

²⁵ Center of Budget and Policy Priorities. Chart Book: Economic Security and Health Insurance Programs Reduce Poverty and Provide Access to Needed Care. Updated Dec 11, 2019. Available at: <https://www.cbpp.org/sites/default/files/atoms/files/9-2-15pov.pdf>

²⁶ Center on Budget and Policy Priorities. Cuts to Low-Income Assistance Programs in President Trump's 2020 Budget Are Wide Ranging. May 15, 2019. Available at: <https://www.cbpp.org/research/federal-budget/cuts-to-low-income-assistance-programs-in-president-trumps-2020-budget-are>

²⁷ National Research Council 1995. Measuring Poverty: A New Approach. Washington, DC: The National Academies Press.

²⁸ Center for Medicare and Medicaid Services. Speech: Remarks by Administrator Seema Verma at the National Association of Medicaid Directors (NAMDD) 2017 Fall Conference. Nov, 11, 2017. Retrieved from: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-11-07.html#_ftn3

²⁹ Shekarchi A, Gantz L, Schickedanz. Social Determinant of Health Screening in a Safety Net Pediatric Primary Care Clinic. Pediatrics May 2018, 142 (1 Meeting Abstract) 748; DOI:10.1542/peds.142.1_MeetingAbstract.748

c. Medicaid and the Children's Health Insurance Program (CHIP)

Medicaid and CHIP are public safety net programs that provide health coverage to over 71 million low-income adults, disabled individuals, very low-income seniors as well as the infants and children who comprise approximately half (35 million) of the program beneficiaries.³⁰ Medicaid covers one in five people in the U.S. and accounts for more than half of all spending for long-term services and supports for the elderly population and others with complex chronic conditions.³¹ States are required to provide comprehensive benefits to Medicaid enrollees that span the entire continuum of care from birth and pediatric services to inpatient, outpatient, skilled nursing facilities and home health services.³²

The Patient Protection and Affordable Care Act (ACA) strengthened the nation's largest health care safety net by expanding Medicaid coverage to adults under age 65 and to working families that earn up to 138 percent of the federal poverty level. However, a June 2012 Supreme Court decision ruled that states could opt out, resulting in a patchwork of states that have decided to expand Medicaid eligibility. As of January 2020, thirty-six states and Washington, D.C. have adopted Medicaid expansion.³³ Recent analysis from the Commonwealth Fund links Medicaid expansion to racial equity improvements in health insurance coverage and access to care,³⁴ yet this policy strategy remains elusive as a viable step for improving access in these populations among the fourteen states that have yet to expand Medicaid coverage.

As Medicaid enrollment and health care costs trended upwards following ACA enactment, efforts to control spending and improve care delivery have prevailed through an influx of state proposals known as Section 1115 waivers. States may submit a 1115 waiver for approval to the Centers for Medicare and Medicaid Services (CMS) that would exempt them from certain federal Medicaid requirements. A recent tally from Kaiser Family Foundation reported that 54 waivers have been approved across 42 states, with 25 currently pending in 21 states.³⁵ Most waivers appear to serve vulnerable populations by expanding coverage eligibility to certain individuals and better managing benefits such as behavioral health or managed long-term services and supports. However, recent waivers focused solely on containing costs have concerning elements that effectively diminish access to coverage and benefits.

For instance, block grant proposals that restrict funding and impose stricter utilization management rules, such as closed formularies, represent a tradeoff between reducing costs and access to care. Work requirement waivers raise practical and administrative barriers to accessing coverage and have a substantial impact on seriously ill patients and families, many of whom report significant challenges

³⁰ Medicaid.gov. October 2019 Medicaid and CHIP Enrollment Data Highlights. Available at:

<https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html>

³¹ Kaiser Family Foundation. 10 Things to Know about Medicaid: Setting the Facts Straight. Updated March 6, 2019. Available at:

<https://www.kff.org/medicaid/fact-sheet/medicaid-pocket-primer/>

³² Medicaid.gov. Mandatory and Optional Medicaid Benefits. Accessed Jan 14, 2020. Available at:

<https://www.medicaid.gov/medicaid/benefits/mandatory-optional-medicaid-benefits/index.html>

³³ Kaiser Family Foundation. Status of State Action on the Medicaid Expansion Decision. As of Jan 10, 2019. Available at:

<https://www.kff.org/medicaid/issue-brief/status-of-state-medicaid-expansion-decisions-interactive-map/>

³⁴ Jesse C. Baumgartner et al., How the Affordable Care Act Has Narrowed Racial and Ethnic Disparities in Access to Health Care (Commonwealth Fund, Jan. 2020). Available at: <https://www.commonwealthfund.org/publications/2020/jan/how-aca-narrowed-racial-ethnic-disparities-access>

³⁵ Kaiser Family Foundation. Approved and Pending Section 1115 Medicaid Waivers as of Jan 23, 2020. Available at:

<https://www.kff.org/medicaid/issue-brief/medicaid-waiver-tracker-approved-and-pending-section-1115-waivers-by-state/>

maintaining employment as a direct result of their treatments or caregiving responsibilities. In fact, the work requirement proposal implemented in Arkansas led to 18,000 people losing their Medicaid coverage with a small decline in the employment rate. This restriction was fortunately set aside by the courts.³⁶

Similarly, many policy experts have warned that Tennessee's proposal to alter its Medicaid program's financing structure to a block grant would have concerning consequences in the form of many fewer eligible beneficiaries and much thinner coverage.³⁷ Additional guidance from CMS issued in January 2020 encourages states in pursuing block grant financing for their Medicaid programs.³⁸

Despite the gains in coverage following ACA enactment, a decline in Medicaid and CHIP enrollment has been observed since December 2017.³⁹ A variety of factors contribute to enrollment declines, but some states suggest that barriers to maintaining coverage may play a role which raises concern about recent and rising trends in waiver proposals. Fortunately for the children and families who rely on CHIP, Congress passed two continuing resolutions in 2018 that extended funding for ten years as well as an agreement that protects state CHIP programs even if they exhaust their funding.⁴⁰

Medicaid and CHIP have transformed over the decades since their inception to be critical safety net programs that ensure our nation's most vulnerable populations have access to comprehensive, quality health care. As policymakers continue to consider program reforms, NPAF will press for approaches that preserve and expand eligibility and benefits coverage for the millions of adults, children and families who need it.

Principles: Medicaid and the Children's Health Insurance Program (CHIP)

1. Congress and the states should expand and sustain Medicaid and CHIP coverage and services to meet the needs of low-income adults and children, particularly families confronting complex chronic conditions.
2. The Department of Health and Human Services (HHS) and the states must avoid limitations on Medicaid eligibility, coverage and benefits that impede equitable access to care, including block grant financing and burdensome cost-sharing or work requirements for beneficiaries.

³⁶ Sommers BD et al. Medicaid Work Requirements – Results from the First Year in Arkansas. *N Engl J Med* 2019; 381:1073-1082 <https://static.politico.com/8d/24/6ef0e361444bb034aabc884b2606/sommers-arworks.pdf>

³⁷ Health Affairs Blog. Looking Inside Tennessee's Block Grant Proposal. Oct 4, 2019. Available at: <https://www.healthaffairs.org/doi/10.1377/hblog20191002.734156/full/>

³⁸ Centers for Medicaid and Medicaid Services. Healthy Adult Opportunity. Jan 30, 2020. Available at: <https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/smd20001.pdf>

³⁹ Kaiser Family Foundation. Analysis of Recent Declines in Medicaid and CHIP Enrollment. Nov 25, 2019. Available at: <https://www.kff.org/medicaid/fact-sheet/analysis-of-recent-declines-in-medicaid-and-chip-enrollment/>

⁴⁰ Georgetown University Health Policy Institute. Center for Children and Families. 2018 Available at: <https://ccf.georgetown.edu/2018/09/19/clearing-up-confusion-about-the-impact-of-the-chip-funding-rescission-in-labor-hhs-education-appropriations-conference-agreement/>



Access

All patients and families, in both private and public insurance markets, deserve access to comprehensive health care that meets their needs and protects them from financial distress related to high out-of-pocket (OOP) costs or inadequate coverage.

NPAF promotes policies that ensure equitable access to insurance coverage and quality care under the Affordable Care Act, Medicare, Medicaid and other public and commercial plans, particularly to support needs of low-income and other disadvantaged populations confronting complex, chronic or serious illnesses.

a. Coverage Protections and Expansion

The Patient Protection and Affordable Care Act (ACA), passed in 2010, expanded health coverage to approximately 20 million people in its early years.⁴¹ The ACA spurred a decline in uninsured rates across all U.S. racial and ethnic groups and significantly closed gaps in health coverage between black, Hispanic and white populations in states that expanded Medicaid.⁴² Previously uninsured middle-income people could obtain private coverage through the newly created Marketplace, also known as the ACA exchanges, in which plan offerings and pricing are regulated, eliminating certain restrictions such as lifetime limits on coverage.

Perhaps the most well-known provision is the preexisting condition protection, which prohibits most plans from denying people coverage due to health conditions present prior to enrollment.⁴³ While people may have drastically different health care experiences depending on their type of plan, they are largely protected from discrimination, inadequate coverage and unfair pricing. Additionally, individual and small group private insurance plans must cover a basic set of health benefits known as the essential health benefits (EHBs). Defined across ten broad service categories they include⁴⁴:

1. Emergency services
2. hospitalizations
3. outpatient care
4. maternity and newborn care
5. mental health and substance use disorder treatment
6. prescription drugs
7. rehabilitation services
8. laboratory services
9. preventive services and chronic disease management
10. pediatric care.

⁴¹ Urban Institute. Who Gained Health Insurance Coverage Under the ACA, and Where Do They Live? December 2016. Available at: <https://www.urban.org/sites/default/files/publication/86761/2001041-who-gained-health-insurance-coverage-under-the-aca-and-where-do-they-live.pdf>

⁴² Ajay Chaudry, Adlan Jackson, and Sherry A. Glied, Did the Affordable Care Act Reduce Racial and Ethnic Disparities in Health Insurance Coverage? Commonwealth Fund, Aug. 2019.

⁴³ Congressional Research Service. Private Health Insurance Market Reforms in the Patient Protection and Affordable Care Act (ACA). February 2016. Available at: <https://fas.org/sgp/crs/misc/R42069.pdf>

⁴⁴ The Center for Consumer Information & Insurance Oversight. Information on Essential Health Benefits Benchmark Plans. Available at: <https://www.cms.gov/ccio/resources/data-resources/ehb.html>

Since the implementation of the ACA, the exchange market has been volatile and difficult to predict leading to high premium increases for patients and families. The current Administration has prioritized market-based solutions that give states greater latitude to modify covered benefits on an annual basis and loosened the interpretation of statutory guardrails that ensure coverage is adequate and affordable.^{45,46} A recent analysis concludes that the ACA market has entered its second straight year of marginal premium fluctuation and appears to be stable⁴⁷, yet there are still people who do not qualify for subsidies or cannot afford Marketplace coverage even with a subsidy.

As Republicans led efforts in Congress to repeal and replace the ACA throughout 2017, patient and consumer advocates fought to maintain its far-reaching benefits. The ACA remains in effect and largely unchanged; however, its future is uncertain due to the ongoing Texas v. U.S. litigation, which challenges the individual mandate and questions the entire law's constitutionality.⁴⁸ At the same time, the range of universal coverage and single-payer proposals such as "Medicare for All" have quickly become core elements of the health reform debate. Several Democratic candidates for president in 2020 have endorsed the concept and single-payer legislation in the House of Representatives gained 118 cosponsors by mid-December 2019. Expanding coverage through a single-payer system raises important questions about the private sector's role, payment approach and financing that policymakers are beginning to assess.⁴⁹ Moreover, care under a single payer system has the potential to prioritize care standardization over care personalization. The details of these various proposals will matter a great deal.

The ACA's historic coverage gains and improvements in access to care have begun to erode due in part to Congressional inaction to enforce or enhance the law and legislative and executive actions including repeal of the individual mandate penalty; reductions in funding for outreach and enrollment assistance; and loosening restrictions on non-ACA compliant plans. Ultimately, solutions involve expanding Medicaid coverage and making Marketplace subsidies available to more people. While the future of the ACA remains unclear, advocacy efforts can put pressure on lawmakers to ensure that affordable, quality coverage is equitably accessible for all people.

Principles: Coverage Protections and Expansion

1. All people regardless of race, ethnicity, gender, age or geographic location deserve access to adequate, affordable health insurance coverage options that meet their unique health care needs and socioeconomic circumstances.

⁴⁵ HHS Notice of Benefit and Payment Parameters for 2019. Proposed Rule. November 2017. Available at: <https://www.federalregister.gov/documents/2017/11/02/2017-23599/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2019>

⁴⁶ Department of Health and Human Services. State Relief and Empowerment Waivers. Federal Register/Vol. 83, No. 206. October 24, 2018. Available at: <https://www.govinfo.gov/content/pkg/FR-2018-10-24/pdf/2018-23182.pdf>

⁴⁷ American Action Forum. 2020 ACA Marketplace Premiums. November 21, 2019. Available at: <https://www.americanactionforum.org/research/2020-aca-marketplace-premiums/>

⁴⁸ Kaiser Family Foundation. Explaining Texas v. U.S.: A Guide to the Case Challenging the ACA. Jan 28, 2020. Available at: <https://www.kff.org/health-reform/issue-brief/explaining-texas-v-u-s-a-guide-to-the-case-challenging-the-aca/>

⁴⁹ Johnson M et al. Medicare For All: An Analysis of Key Policy Issues. Jan 2020. HEALTH AFFAIRS 39, NO. 1 (2020): 133–141. Available at: <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2019.01040>

2. Understandable educational resources and information about health insurance coverage, accessibility and beneficiary responsibility should be readily available to the public.
3. Key provisions that safeguard patients from discriminatory practices and disparate outcomes should be expanded or at least preserved among all health insurance plans and utilization review activities. This may include opposing any policies that will:
 - a. Remove pre-existing conditions restrictions
 - b. Impose continuous coverage requirements and penalties
 - c. Impede individual choices among plans and prescribed treatments
 - d. Significantly increase premium and out of pocket costs (deductibles, coinsurance and copayments)
 - e. Restrict coverage and impose lifetime limits
 - f. Destabilize the insurance market
 - g. Undermine federal cost-sharing reduction payments that lower out-of-pocket costs for qualifying, lower-income enrollees
4. Policymakers should hold all health plans accountable for providing:
 - a. Adequate coverage of essential health benefits
 - b. Clear and understandable appeals processes
 - c. Transparent provider networks and formularies
 - d. Consistent coverage that does not make plan changes after open enrollment ends
 - e. Quality evaluation and understandable reporting about insurance plans available in the market

b. Insurance Benefit Design and Utilization Management

Health insurance plans employ various techniques to minimize costs and make coverage decisions on prescribed treatments. The practice of utilization management refers to the evaluation of medical necessity, and the appropriateness and efficient use of health care services, procedures, and facilities under the provisions of the patient's health insurance plan. To control financial risk and minimize burden of prescription drug costs, insurance plans often design their benefit structure so that patients share more of the cost-burdens for newer, innovative or more expensive treatments.

Two common utilization management tools are prior authorization and step therapy. Prior authorization refers to pre-approval by the health plan for certain – usually costly – medications, imaging or services before they are covered.⁵⁰ Step therapy, sometimes called “fail first”, require patients to try medicines on an insurer's preferred drug list before the insurer will cover the cost of another medicine. Step therapy is the most common type of coverage restriction used by commercial health insurers for high-cost specialty drugs and is more likely to be used where three or more treatment alternatives exist.⁵¹ One study found significant variation in the frequency that commercial health plans apply step therapy (ranging from 2 to 49 percent) which may contribute to patient access issues that arise due to underlying geographic

⁵⁰ Optum Rx®. Utilization Management Strategies. 2015. Available at: <https://cdn-aem.optum.com/content/dam/optum3/optum/en/resources/fact-sheets/utilization-management-strategies-optumrx.pdf>

⁵¹ Chambers JD et al. Specialty Drug Coverage Varies Across Commercial Health Plans in the US. *Health Affairs*. July 2018. 37(7):1041–1047. Available at: <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2017.1553>

variation.⁵² In the context of Medicare, step therapy has historically been used only in the Part D benefit; however, guidance from CMS in 2018 allowed Medicare Advantage plans to apply step therapy to physician-administered drugs covered under Part B.⁵³

In certain cases, prior authorization and step therapy can serve an important purpose in standardizing quality care, but requirements that lack flexibility create administrative burdens and tremendous access problems for patients and can lead to poor medication adherence and higher total costs.⁵⁴ As a result, patients are unable to access the medications, diagnostic tests or other therapies discussed and agreed upon with their physician to treat their condition in a timely and effective manner. Switching to another treatment due to cost, a situation known as non-medical switching, puts patients' health and well-being at risk. Although patients can appeal a coverage denial, the final decision usually rests with the health plan or insurance commissioner.

In recent years, some plans have leveraged technical innovations to improve transmission of claims through electronic prior authorization (ePA) systems, allowing physicians to submit authorization requests quicker and easier.⁵⁵ These efforts, if and when more broadly applied, should simplify the prior authorization process enabling patients to seamlessly begin a prescribed treatment or schedule a recommended service after the decision takes place.

Prescribed treatments, medications, diagnostic tests, or other therapies should be the result of shared decision making between patients and their physicians based on what best meets the patient's needs and circumstances. Maintaining availability of personalized treatments will be increasingly critical to realize the full return on our national investment in human genome research and precision medicine, which has delivered an array of highly targeted therapies that offer improved outcomes. While step therapy and other protocols may be a useful strategy to reduce health care costs, it's imperative to apply these policies in a way that improves quality care rather than impedes it.

Principles: Insurance Benefit Design and Utilization Management

1. Health plans and regulatory agencies should be accountable for:
 - a. Ensuring benefit design and utilization management practices are clear, understandable, flexible and evidence-based.
 - b. Transparent processes that inform patients and practitioners about plan updates that may result in changes to prescribed treatments.
 - c. Completing utilization management determinations within 24 hours for urgent medical needs, and within 48 to 72 hours for all other medical needs.
2. Step therapy protocols and other utilization management practices should not impede on professional clinical judgement or diminish the patient-provider relationship and their shared decision-making.

⁵² Variation In The Use Of Step Therapy Protocols Across US Health Plans, " Health Affairs Blog, September 14, 2018. Accessed January 18, 2019. Available at: <https://www.healthaffairs.org/doi/10.1377/hblog20180912.391231/full/>

⁵³ Centers for Medicare and Medicaid Services. Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage. Available at: https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf

⁵⁴ Seabury SA et al. Formulary Restrictions on Atypical Antipsychotics: Impact on Costs for Patients with Schizophrenia and Bipolar Disorder in Medicaid. *American Journal of Managed Care*. 2014;20(2), p. e52-e60.

⁵⁵ EMD Serono Specialty Digest TM Managed Care Strategies for Specialty Pharmaceuticals. 14th Edition. 2018.

c. Personalized and Value-Based Care

Major life-saving advances in treatments continue to evolve through clinical trials investigation as researchers employ innovative methods in drug discovery, development and delivery. Researchers must recruit enough patients for participation in clinical trials to validate results. Clinical trial researchers have documented multiple challenges including delays in recruiting, conducting and completing trials, which can diminish research efforts and increase overall study costs.

In oncology research, structural and clinical barriers such as trial availability and eligibility are the reasons that three in four patients do not participate in clinical trials, resulting in adult participation rates at about 8 percent.⁵⁶ In addition, many patients otherwise eligible for trial participation may face transportation or mobility barriers and are unable to travel to clinical trial sites. Regulatory agencies and researchers have begun taking steps to improve access to innovative medicines whether through clinical trials or by other means.

The Food and Drug Administration (FDA) has long facilitated expanded access, use of an investigational drug to treat a patient's disease prior to drug approval, with formal guidance to increase awareness about the opportunity for patients with life threatening or serious conditions lacking therapeutic alternatives.⁵⁷ Other non-regulatory efforts to expand accessibility and improve convenience for patient participation in trials are emerging to decentralize clinical research away from the current study site model through use of in-home technology and community-based data collection at satellite locations. Such changes could revolutionize enrollment diversity in clinical trials across racial, ethnic and socioeconomic populations and help narrow a well-documented gap in health disparities.⁵⁸ Importantly, efforts should aim to promote equitable access to clinical trials for disadvantaged populations who would otherwise not be aware of the opportunities.

Concurrently, researchers are prioritizing development of precision medicines which help drive more personalized and value-based care tailored to a patient's genetic profile or immune system, including delivery of molecularly targeted therapies. Advancing precision medicine is a national priority under the 21st Century Cures Act passed in 2016, which authorized National Institutes of Health (NIH) funding directed to research in genetic, lifestyle and environmental variations of disease.⁵⁹ Precision medicine emphasizes person-centered practices that consider individual patient characteristics such as age, comorbid conditions, preferences and beliefs in crafting individualized treatment plans.

Targeted therapies use diagnostic and other tests to identify a patient's genomic variations that may reveal predispositions to a disease or likely therapeutic response, providing information about which therapies may

⁵⁶ Unger JM, Vaidya R, Hershman DL et al. Systematic Review and Meta-Analysis of the Magnitude of Structural, Clinical, and Physician and Patient Barriers to Cancer Clinical Trial Participation. *Journal of the National Cancer Institute*, 2019

⁵⁷ Food and Drug Administration. Expanded Access to Investigational Drugs for Treatment Use – Q&A. Guidance for Industry. June 2016, Updated October 2017. Available at: <https://www.fda.gov/downloads/drugs/guidances/ucm351261.pdf>

⁵⁸ Oh SS et al. Diversity in Clinical and Biomedical Research: A Promise Yet to Be Fulfilled. *PLoS Med*. Dec 2015. 12(12): e1001918

⁵⁹ U.S. House of Representatives Committee on Energy and Commerce. The 21st Century Cures Act. Fact Sheet. November 2016. Retrieved on Jan 8, 2018. Available at: <https://archives-energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/documents/114/analysis/20161128%20Cures%20FactSheet.pdf>

improve outcomes with fewer clinical adverse effects.⁶⁰ These clinical advances have the potential to not only improve health outcomes, but also reduce costly acute services utilization such as emergency department visits and inpatient hospitalizations, enhance clinical communication and treatment discussions and promote shared decision-making focused on treating the person as well as the disease.

Despite the national investment in developing precision medicines, insurance plans often place innovative or specialty drugs on higher benefit tiers, leading to greater out-of-pocket costs. Plans also have limited coverage of genomic testing, such as Next Generation Sequencing (NGS), which may preclude patients' ability to access the treatments. Fortunately, CMS has taken steps to address this issue by finalizing a National Coverage Determination (NCD) covering NGS tests for patients with advanced cancer.⁶¹

The implementation of the Medicare and CHIP Reauthorization Act of 2015 (MACRA) and its quality payment program emphasizes quality measurement and value-based payment over fee-for-service payment models. Because of this priority shift to value, the opportunity to reshape health care delivery and payment systems in ways that reflect person-centered care and precision medicine is pivotal. As precision medicine evolves, and more life-saving therapies are assessed in clinical trials, all health care stakeholders should ensure these innovations are equitably available to all populations who can benefit.

Principles: Personalized and Value-Based Care

1. Access to personalized care, diagnostics and precision medicine should be equitably available to foster shared decision-making and value-based care that prioritizes patient and family preferences while also improving health and quality of life outcomes.
2. Promoting equitable and affordable access to clinical trials for all populations is an essential aspect of quality care delivery, and trials participation expansion efforts should include:
 - a. Streamlined implementation and enrollment processes
 - b. Collaborative development and dissemination of culturally appropriate information about clinical trials and enrollment opportunities to reach diverse patient populations
 - c. Coverage of routine health costs and support for non-medical costs associated with trial participation (e.g., transportation costs)
 - d. Increasing access to and participation from currently underrepresented groups
 - e. Implementation of and improvement in expanded access provisions that follow established ethical guidelines enabling therapeutic availability for individuals unable to participate in a clinical trial and who have exhausted other treatment options
3. Adequate funding for medical and health services research and innovation should be available, with emphasis on advancing innovations in development and delivery of person-centered care.

⁶⁰ Personalized Medicine Coalition. The Age of Personalized Medicine. Fact Sheet. Retrieved Jan 8, 2018. Available at:

http://www.personalizedmedicincoalition.org/Userfiles/PMC-Corporate/file/pmc_age_of_pmc_factsheet.pdf

⁶¹ Centers for Medicare and Medicaid Services. National Coverage Determination for Next Generation Sequencing (NGS) (90.2) Effective Date March, 16, 2018. Available at: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=372&ncdver=1&bc=AAAAGAAAAAA&>

3

Affordable Care

High total costs of care often force families to choose between the burdens of paying for treatments and meeting living expenses. Out-of-pocket (OOP) costs refer to the amount people must pay for medical care outside of what their insurance covers, including monthly premiums for insurance, annual deductibles and cost-sharing through coinsurance and/or copayment at the point of service.

Many patients have a poor understanding of their OOP cost obligations, and lack understandable, curated information that helps them consider and compare costs when choosing among insurance plans or selecting a treatment with their care team. Patients also incur costs far beyond what their plan's benefit design outlines, such as transportation and lost wages associated with frequent medical appointments that can pose an equal or greater financial burden than traditional OOP expenses.

NPAF prioritizes policies that contain total costs of care from all sources and minimize financial distress and household material hardships that disproportionately affect vulnerable populations.

a. Total Costs of Care and Transparency

National health spending on hospital, physician and clinical services represents half of all health care spending and continues to grow, fortunately at a lower rate than prior years; while OOP spending is projected to increase in the coming years.⁶² Cost-containment measures have prevailed across the health care ecosystem while Congress and the President have specifically expressed desire to reign in prescription drug costs, end surprise medical bills and increase price transparency across the health care industry.^{63,64} Patients struggle to afford prescription drugs due to high drug prices, high OOP costs and restrictive benefit designs which place certain drugs on more expensive tiers. In addition, some plans have implemented accumulator adjustment programs that no longer apply manufacturer copay coupons to patient deductibles or OOP maximums, thereby increasing the overall amount patients must spend to reach their deductible.⁶⁵

Some of these dynamics are attributable to a greater number of prescriptions per person, economy-wide inflation, a change in prescribing habits towards higher priced drugs and drug price increases.⁶⁶ However, cost-sharing is directly influenced by drug price negotiations among manufacturers, pharmacies and providers, health plans and pharmacy benefit managers (PBMs) who leverage buying power to secure low prices under a plan's pharmacy benefit.⁶⁷ Since contracting discussions are confidential and PBMs maintain multiple financial arrangements, only PBMs know the actual net prices paid by health plans to

⁶² Peterson-KFF. Health System Tracker. How has U.S. spending on healthcare changed over time? Posted Dec 20, 2019. Available at: <https://www.healthsystemtracker.org/chart-collection/u-s-spending-healthcare-changed-time/#item-start>

⁶³ American Patient First. Trump Administration Blueprint to Lower Drug Prices and Reduce OOP Costs. May 2018.

⁶⁴ Congress.gov S.1895 – Lower Health Care Costs Act. Available at: <https://www.congress.gov/bill/116th-congress/senate-bill/1895/text>

⁶⁵ New Accumulator Adjustment Programs Threaten Chronically Ill Patients. Health Affairs Blog. August 31, 2018. Available at: <https://www.healthaffairs.org/doi/10.1377/hblog20180824.55133/full/>

⁶⁶ HHS Office of the Assistant Secretary for Planning and Evaluation. Issue Brief. Observations on Trends in Prescription Drug Spending. March 8, 2016. Available at: <https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf>

⁶⁷ Milliman White Paper. Medicare Part D PBM Contracting Strategy. February 2017.

pharmacies and providers. As a result, the question arises whether PBM negotiations translate to lower patient cost-sharing at their provider or pharmacy counter. Similarly, there are discount programs (e.g., 340B) and other negotiations commonly used to lower prices between stakeholders in the system, the benefits of which do not always reach patients even though some of the policies that create such savings were intended to help vulnerable and low-income patients. To address this discrepancy, legislation and regulations now require more granular reporting of certain PBM fees and contracting arrangements.

The total costs of health care are beyond what many families can afford. Estimated average health care costs of over \$28,000 for a family of four⁶⁸ far exceeds the annual income of families living at the federal poverty line. Even with health insurance, patients and families are exposed to significant cost-sharing, including annual deductibles, monthly premiums, coinsurance or copayments for covered services. A recent Kaiser Family Foundation report found that the percentage of covered workers with a general annual deductible of \$2,000 or more for single coverage has grown from 18 percent to 28 percent, and that the average annual premiums for employer-sponsored health insurance in 2019 are \$20,576 for family coverage.⁶⁹

Data from primarily low-income patients served through PAF programs reinforce some of the challenges of rising OOP costs. In 2018, two top issues raised by patients in the case management program included debt crisis and copayment assistance for drugs and medical visits.⁷⁰ High OOP health care costs can influence a patient's ability to afford cost-of-living expenses and prevent or delay patients from seeing their doctor and receiving prescribed treatment. While Congressional activity on health care costs appear to have slowed, Administrative efforts to improve transparency about patients' OOP costs continue.

Currently, patients may not be receiving meaningful or actionable cost information consistently, but a few initiatives have emerged to address this issue. Innovative care delivery models such as the Center for Medicare and Medicaid Innovation's (CMMI) Oncology Care Model require that patients are provided estimates of OOP costs for treatment as one of the thirteen required elements that should comprise a person-centered care plan for cancer patients. Medicare's Plan Finder tool has been updated to better estimate OOP drug copayments, coinsurance, and premiums for specific beneficiary plans. Recent executive actions direct hospitals and health plans to publicly disclose cost-sharing estimates.⁷¹

More can and should be done to expand how the concept of cost is considered among clinical and other factors to reflect the economic realities and toxicities that influence patients and in their health care decisions. Patients, families and their care team must become more involved in care planning that includes cost as a factor. Finding meaningful ways to reduce overall health care and OOP costs will require concerted collaboration and innovative policy development by health systems, clinicians, policymakers, manufacturers, patient advocates and other stakeholders.

⁶⁸ Milliman. *2019 Milliman Medical Index*. 25 July 2019. Retrieved from: <https://www.milliman.com/insight/2019-Milliman-Medical-Index>

⁶⁹ Kaiser Family Foundation, NORC at the University of Chicago. *Employer Health Benefits: 2019 Annual Survey*. 25 Sept 2019. Retrieved from: <http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2019>

⁷⁰ Patient Advocate Foundation. Case Management Program. Internal 2018 Data.

⁷¹ Health Affairs. Trump Administration Proposes Transparency Rule For Health Insurers. November 17, 2019. Available at: <https://www.healthaffairs.org/doi/10.1377/hblog20191117.364191/full/>

Principles: Total Costs of Care and Transparency

1. Policy makers should prioritize solutions that directly lower patients' out of pocket costs. Policies that affect other stakeholders should not inadvertently raise the amount that patients are expected to pay, including through deductibles, cost-sharing and premiums.
2. Understandable and transparent cost information and resources should be publicly available so that patients may consider treatment benefits and tradeoffs in the context of person-centered care planning and shared decision-making throughout the care continuum and across all care settings.
3. Patients should have opportunities to learn about and meaningfully discuss the cost of their care, both before and after making a treatment decision, in ways that are culturally appropriate and sensitive to their needs and circumstances.
4. Pricing transparency regulations should be applicable to all sources of patient cost so that patients can make more informed choices and prepare for the financial obligations associated with their care.
5. Savings generated through discount programs or price negotiations need to benefit low- income patients.

b. Surprise Medical Billing and Network Adequacy

When patients unknowingly or involuntarily seek medical care from a health care provider or facility that is out-of-network, they may later receive an unexpected or “surprise” medical bill. The practice is known as balance billing because patients are left responsible for the balance of bills—the difference between what the health plan covers and what the provider or facility charges. Surprise medical bills are prevalent in almost all areas of the country, for enrollees in both employer and individual market health plans, and across plan types.⁷² The bills can range from hundreds to thousands of dollars due, contributing to financial distress and medical debt. In a 2018 survey conducted by Kaiser Family Foundation, Americans cited unexpected medical bills as their top health cost concern.⁷³

Surprise medical bills often lead to confusion about coverage, benefits and network parameters. While federal and state network adequacy standards exist, limited or narrow network plans are becoming increasingly popular to reign in health care costs. In one study, 54 percent of participants received a medical bill for an amount they thought was covered by their health insurance, and 53 percent received a higher than expected bill.⁷⁴ In a similar survey, more than 60 percent of the respondents mistakenly assumed that if they went to an in-network hospital, then all the doctors at the hospital would also be in-network.⁷⁵ When patients are not equipped with adequate information about network status, they are unlikely to know their OOP expenses which can affect key health care decisions.

⁷² Adler, L., Fiedler M, Ginsburg, P, et. al. State Approaches to Mitigating Surprise Out-of-Network Billing. Feb 2019.

⁷³ Kaiser Family Foundation. Health Tracking Poll. September 2018. Available at: <https://www.kff.org/health-reform/poll-finding/kaiser-health-tracking-poll-late-summer-2018-the-election-pre-existing-conditions-and-surprises-on-medical-bills/>

⁷⁴ West Health Institute, NORC University of Chicago. Americans' Views of Healthcare Costs, Coverage, and Policy. March 2018. Available at: <http://www.norc.org/PDFs/WHI%20Healthcare%20Costs%20Coverage%20and%20Policy/WHI%20Healthcare%20Costs%20Coverage%20and%20Policy%20Issue%20Brief.pdf>

⁷⁵ Consumers Union. *Getting Started on Surprise Medical Bills: An Advocate's Guide*. Nov 3, 2015. Retrieved Dec 1, 2015 from <http://consumersunion.org/research/getting-started-on-surprise-medical-bills-an-advocates-guide/>

Legislation to protect patients from surprise out-of-network bills is being considered throughout state legislatures and in Congress. While there is agreement among health care stakeholders and lawmakers that patients should not be financially responsible for surprise out-of-network bills, disagreement exists among physician groups, hospitals and insurers on how best to achieve that outcome. Physicians and hospitals largely support using an independent dispute resolution approach to determine payment for out-of-network services whereas health plans prefer to use a payment standard.

At a minimum, all patients should be protected from surprise out-of-network medical bills regardless of setting or service (e.g., emergency, inpatient, ground or air ambulance). A comprehensive and person-centered approach should include: enhanced patient education about their health plan options and benefits at the time they enroll in health care coverage; tools for patients so that they can easily determine if a provider or facility is in-network or out-of-network; directly notifying patients, when possible, about a provider's or facility's network status; costs conversations with patients that include a discussion of their expected OOP costs, assessment for financial need with referrals for services and support when necessary, and allowing patients the opportunity to ask questions, explore other options and consent to treatments.

Principles: Surprise Medical Bills and Network Adequacy

1. Patients should not be held financially responsible for balance bills due to unexpected out-of-network care.
2. Patients should be notified when they use out-of-network providers, facilities or services and information regarding network status should be publicly available, up-to-date and easily accessible.
3. Patients should be directly informed of estimated out-of-pocket costs for health services prior to delivery when feasible so they have the opportunity to explore other options, if available, and consent to the services.

c. Medical Debt and Credit Protections

Millions of people in the U.S. each year are at risk for losing their health, homes, credit standing and financial security because of the harms of medical debt. Unlike regular consumer debt, which is often incurred in a voluntary and predictable manner, a serious illness diagnosis or other medical emergency is unplanned and leaves families little time to anticipate and prepare for the unexpected costs of treatments or ability to maintain steady income.

A University of Chicago 2018 survey found that over half of respondents (53 percent) have had at least one of the following situations occur because of health care costs in the last year: could not save any money, depleted their savings, racked up credit card debt, and decided between paying medical bills and basic necessities like food, heat and housing. Additionally, more than a quarter said they had a medical bill turned over to a collection agency.⁷⁶ The most recent Report on the Economic Well-Being of U.S.

⁷⁶ West Health Institute, NORC at the University of Chicago. *American Views of Healthcare Costs, Coverage, and Policy*. March 2018. Retrieved from: <https://s8637.pcdn.co/wp-content/uploads/2018/03/WHI-Healthcare-Costs-Coverage-and-Policy-Issue-Brief.pdf>

Households found that 40 percent of U.S. adults claim they did not have \$400 for an emergency without turning to credit cards, family and friends, or selling off possessions.⁷⁷

Balance billing practices or billing errors can further exacerbate medical debt problems. The complexity of medical billing and the third-party reimbursement is a potential source of confusion or misunderstanding between patient, medical provider and insurer.⁷⁸ The complexity could lead patients and families to try and fix a billing problem that occurred through no fault of their own. Even in cases where a medical bill has been paid in full or otherwise resolved, the recorded debt may remain on credit reports and negatively affect a patient's credit score for up to seven years.

Fortunately, in 2017, the three major credit reporting agencies—Experian, Equifax and TransUnion— instituted a 180-day waiting period before medical debt can be included on a consumer's credit report. This reform is an important first step in giving patients and families more time to resolve coverage or billing disputes with insurers, so they are not unfairly penalized in circumstances where they may delay making payments pending a resolution. Additional protections for patients and families are still necessary, however, to minimize the impact of medical debt and its distressing consequences.

Health system changes are also needed to protect patients and families from financial hardship associated with treatments. To support improved health outcomes, cost of care discussions and assessment of risk for financial support and other needs should be incorporated as a standard of care beginning at the time of diagnosis for all serious illnesses with referrals to safety net services and supports based on the results of the assessment.⁷⁹ By examining methods for increased coordination of care and specialized protections for those at risk for economic distress related to medical bills, policies can be crafted that help minimize financial toxicity harms associated with medical care.

Principles: Medical Debt and Credit Protections

1. Patients should have sufficient protections and time to either contest or reconcile medical bills and debts with providers or payers.
2. Consumer reporting agencies should prioritize equitable credit rating and fair reporting practices in order to minimize distressing medical debt burdens that can follow patients and families for years, even after the debt has been settled.

⁷⁷ The Federal Reserve System. *Report on the Economic Well-Being of US Households in 2017*. May 2018. Retrieved from: <https://www.federalreserve.gov/publications/files/2017-report-economic-well-being-us-households-201805.pdf>

⁷⁸ Consumer Financial Protection Bureau. Consumer credit reports: A study medical and non-medical collections. Dec 2014. Retrieved from: https://files.consumerfinance.gov/f/201412_cfpb_reports_consumer-credit-medical-and-non-medical-collections.pdf

⁷⁹ Pelletier, W. and Bona, K. (2015), Assessment of Financial Burden as a Standard of Care in Pediatric Oncology. *Pediatric Blood Cancer*, 62: S619–S631. doi:10.1002/pbc.25714

4

Quality Care

Patients and families confronting serious illness require reliable and affordable access to high quality therapies and supportive services throughout the care continuum in the settings that are best for them. Today's disease-centric care environment is fragmented across multiple specialists and settings, creating pressures to navigate pathways-driven treatments that often overlook quality of life, functional outcomes, financial impairments and other patient-reported priorities or individual characteristics that matter a great deal to patients and their families.

Increasingly, government officials, policymakers, researchers and other health care stakeholders have begun prioritizing both survival and improved quality of life. For example, value-based care continues to be a top reform initiative with the goal of better aligning financial incentives to reward those who deliver improved outcomes at lower cost. The shift driven by MACRA creates opportunities for reshaping health care delivery, accountability and payment systems to integrate patient and caregiver input about how the concept of "value" applies to them through reliance on patient-reported outcomes and other measures built around their priorities, preferences and stated goals for care.

CMMI was established under CMS to design, launch and test new payment models that lower spending while improving quality care. CMMI intends to continue developing models and soliciting feedback from all stakeholders on a new direction to promote patient-centered care and price transparency while reducing costs and improving outcomes. In this capacity, NPAF will continue to support improvement efforts among payment and delivery systems reform that provide higher quality care to patients based on the factors that matter most to them.

a. Skilled Communication, Shared Decision-Making and Patient Engagement

To accomplish person-centered health care transformation, knowing precisely what is important to patients and families is of paramount importance. PAF research found that patients define "value" as having a relationship with their care team rooted in respect and compassion with truthful and empathetic communication. This relationship affects adherence and decisions about treatment options, and patients want a discussion of both direct and indirect costs. Additionally, 80 percent of survey respondents felt it was important to be able to express their goals, preferences related to costs and other concerns with their medical providers.⁸⁰ These patient priorities are particularly important considerations as health care system delivery reform continues shifting its emphasis toward quality and value.

The patient-physician or provider relationship can be strengthened by enhancing clinical communication that is both person-centered and goal-directed. Research shows that professional skills development

⁸⁰ Patient Advocate Foundation. The Roadmap to Consumer Clarity in Health Care Decision Making. May 2017. Available at: https://www.npaf.org/wp-content/uploads/2017/07/RoadmapWhitePaper_ecopy.pdf

training in person-centered communication yields positive results: physicians use more empathy and ask more questions to understand and explore patient values.⁸¹ A focused effort to teach these communication skills to various health care providers is essential to delivering quality care, and the basic elements of person-centered quality care must be incorporated across health care education professional training programs as well as integrated within the tools and systems developed to support decision-making, create care plans and measure the quality of care.

Shared decision-making, a key pillar of person-centered care, refers to the process in which clinicians and patients work together to co-create care plans involving tests, treatments and supportive services based on clinical evidence that balances risks and expected outcomes with patient preferences and values. Yet patients are often reluctant to be assertive, ask questions, request clarification, express emotions directly, or state opinions and preferences.⁸² While both patients and clinicians alike express a willingness to practice shared decision-making, they often do not know how to begin such a process, and there is no current clinical standard of practice or consensus guideline for doing so.

Many of the existing decision-support tools used by clinicians to identify the most appropriate treatment within practice guidelines, such as clinical pathways and value frameworks, do not always incorporate patient-reported outcomes. While professional guidelines have long provided information about what constitutes the most appropriate care for a given medical condition,⁸³ some clinical pathways are overly standardized and don't reflect the true range of factors known to be appropriate for personalizing care. This can undermine the shared decision-making process as well as commonly cited barriers such as feeling overworked, time constraints, insufficient provider training and clinical information systems that do not track patients throughout the decision-making process.⁸⁴

Decision-support tools must be paired with strong communication skills to truly be effective. Evidence-based communication skills training programs and resources already exist and are available in multiple formats and platforms.⁸⁵ In addition to workforce training and skill building, modifications that prioritize communication and hold health systems and practitioners to accountability standards for securing such training can provide a foundation for creating a standardized approach to shared decision-making.

Prominent patient and caregiver engagement in health services research is critically important to improve the quality of care, how it is delivered, and evaluate progress. Patient-reported outcomes development and patient/caregiver engagement in policy boards, government committees, research and educational opportunities will not only lead to better outcomes but will also help advance high quality care that is person- and family-centered. Patients should receive supportive training so they feel comfortable to provide feedback throughout the care experience, play an active role in shaping health care decisions affecting treatment and become more aware about the opportunities to do so when

⁸¹ Back AL, and Arnold RM. *Journal of Palliative Medicine*. February 2014, 17(2): 141-144. <https://doi.org/10.1089/jpm.2013.0197>

⁸² Frosch DL, May SG, Rendle KA, Tietbohl C, Elwyn G. Authoritarian physicians and patients' fear of being labeled "difficult" among key obstacles to shared decision making. *Health Aff (Millwood)*. 2012;31(5):1030-103

⁸³ Peer-reviewed, published, and promulgated by the communities and societies trusted to establish the appropriate courses of treatment.

⁸⁴ Legare, France, and Holly O. Witterman, "Shared Decision Making: Examining Key Elements and Barriers to Adoption into Routine Clinical Practice," *Health Affairs* 32, no. 2(2013): 276-84.)

⁸⁵ National Academies of Sciences Engineering and Medicine. *Integrating the Patient and Caregiver Voice into Serious Illness Care: Proceedings of a Workshop*. Washington, DC, 2017. <https://doi.org/10.17226/24802>

they arise. These steps will ensure greater patient and caregiver engagement in the myriad of health care transformation efforts generated in the wake of MACRA and other transformative policies.

Principles: Skilled Communication, Shared-Decision Making and Patient Engagement

1. Patients and families should be positioned as essential stakeholders for contributing person-centered quality care perspectives and expertise in all value-based health reform initiatives including value assessments and clinical pathways.
2. Health systems and insurers should outline and employ transparent processes that consistently include patient and family perspectives throughout development, implementation and evaluation of new payment and care delivery models.
3. Value-based health reform initiatives should prioritize standards, quality measures and patient- and caregiver-reported outcomes to evaluate availability of skilled communication, shared decision-making, care coordination and essential support services that match treatments with values.
4. In order to support shared decision-making and goal concordant care, care teams should provide patients and families with care planning resources and decision support tools to encourage communication about their personal values and preferences.

b. Palliative Care, Pain Management, Psychosocial Support and Rehabilitation Services Integration

Evidence has established the importance of pairing palliative care, psychosocial support, and impairment-driven rehabilitation services with treatment early in the course of disease to improve physical and psychological function and alleviate pain, symptoms, and other preventable suffering.^{86,87,88} Patients, caregivers and frontline clinicians caring for them may lack understanding about how such services can be helpful in improving patient and family quality of life, especially in the context of serious illness. As a result, patients may experience significant symptom burden and functional impairments that are often undetected or untreated.

Palliative care serves as a practical and well-established person-centered care model for bringing what matters to patients and families to the forefront of value-based care delivery. Palliative care strives to meet patient and family needs and helps them avoid unwanted and expensive crisis care by determining goals through skilled communication, treating distressing symptoms and coordinating care.⁸⁹ These gains in quality also have been shown to reduce costs⁹⁰ – all essential elements for meeting the Institute for Healthcare Improvement’s (IHI) Triple Aim.

⁸⁶ Early Specialty Palliative Care — Translating Data in Oncology into Practice. Parikh RB, Kirch RA, Smith TJ, Temel JS. *New England Journal of Medicine*. 2013

⁸⁷ Advancing a comprehensive cancer care agenda for children and their families: Institute of Medicine Workshop highlights and next steps. Kirch R, Reaman G, Feudtner C, et al. *CA: A Cancer Journal for Clinicians* 2016

⁸⁸ Cancer rehabilitation and palliative care: critical components in the delivery of high-quality oncology services. Silver J, Raj V, Fu J, Wisotzky E, Robinson Smith S, Kirch R. *Supportive Care in Cancer* 2015

⁸⁹ Lukas L, Foltz C, Paxton H. Hospital outcomes for a home-based palliative medicine consulting service. *J Palliat Med*. 2013;16(2):179-184.

⁹⁰ Penrod JD, Deb P, Dellenbaugh C, et al. Hospital-based palliative care consultation: effects on hospital cost. *J Palliat Med*. 2010;13(8):973-979.

Pain management is an integral part of palliative care for many patients with serious illness. Palliative care helps prevent and relieve pain by systematically screening and assessing for pain and other symptoms, tailoring pharmacological and other interventions to patients' individual circumstances, and carefully monitoring and adjusting treatment regimens as needed over the course of the illness.⁹¹ Psychosocial support is another important, yet widely underutilized person-centered approach to address mental and emotional health. It has been found to reduce distress for patients, families and caregivers by providing coping resources after diagnosis, screening for and addressing behavioral changes and maintaining well-being in a culturally relevant context.⁹²

Despite the supportive evidence, gaps persist in professional, public and policymaker understanding about the need to provide these person-centered interventions. Most large hospitals now have palliative care programs, yet availability in community settings where most patients receive their care is highly variable and remains difficult for many to access.^{93,94} Psychosocial care availability also varies across care settings, is underfunded and is emphasized and studied almost exclusively in the context of cancer, even though this type of comprehensive support is applicable to all illnesses.^{95,96}

Some barriers to accessing pain treatments have been due to a lack of information provided to both patients and health care professionals on pain management, particularly opioid use and other non-pharmacological therapies,⁹⁷ as well as limits to prescribing opioids in an effort to address the nation's opioid epidemic. Balanced policy approaches that prioritize evidence-based screening and risk assessments, and do not interfere with patient access to pain medications, should be incorporated into practice.^{98,99} In order to preserve the functional status and quality of life for many individuals suffering as a result of their serious illness, increased funding; education and research for palliative care; pain management; psychosocial support and rehabilitation services are needed to move towards integrating these approaches to all care settings.

The recently released 4th edition of National Consensus Project Clinical Practice Guidelines for Quality Palliative Care (NCP) provide evidence-driven guidance for health systems, payers, policymakers and clinicians to prioritize delivery of person-centered and family-focused quality care. Evidence-based standards for psychosocial support in pediatric cancer also exist and are integrated within the NCP

⁹¹ Morrison LJ, and Morrison RS. Palliative care and pain management. *Med Clin N Am*. 2006; 90(5):983-1004. doi: 10.1016/j.mcna.2006.05.016. Retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/16962853>

⁹² National Consensus Project for Quality Palliative Care. *Clinical Practice Guidelines for Quality Palliative Care*, 4th edition. Richmond, VA: National Coalition for Hospice and Palliative Care; 2018. <https://www.nationalcoalitionhpc.org/ncp>

⁹³ America's Care of Serious Illness, 2019 State-By-State Report Card on Access to Palliative Care in Our Nation's Hospitals. Retrieved from: <https://reportcard.ccapc.org>

⁹⁴ National Academy for State Health Policy (NASHP) "Advancing Palliative Care for Adults with Serious Illness: A National Review of State Palliative Care Policies and Programs (December 2018) available at <https://www.iohnahtford.org/events/view/report-advancing-palliative-care-for-adults-with-serious-illness-a-national/>

⁹⁵ Scialla MA et al. Delivery of care consistent with the psychosocial standards in pediatric cancer: Current practices in the United States. *Ped Blood & Cancer*. 2017;65(3) Available at: <https://onlinelibrary.wiley.com/doi/abs/10.1002/pbc.26869>

⁹⁶ Chan KY, Chan ML. Enhanced psychosocial support as important component of neuro-palliative service. *Ann Palliat Med* 2018;7(3):355-358. Available at: <http://apm.amegroups.com/article/view/16394/20137>

⁹⁷ National Academies Press. *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use* (2017). Retrieved Jan 16, 2018 from <https://www.nap.edu/read/24781/chapter/1>

⁹⁸ National Academy of Medicine. *Marshaling Clinician Leadership to Counter the Opioid Epidemic: A Special Publication of the National Academy of Medicine* (2017). Retrieved from <https://nam.edu/wp-content/uploads/2017/09/Key-Messages-Opioid-SP.pdf>

⁹⁹ Twillman B, Kirch R, Gilson A. Efforts to control prescription drug abuse: Why clinicians should be concerned and take action as essential advocates for rational policy (July 14, 2014). Available at: <https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21243>

guidelines.^{100 101} Value-based payment reforms, associated quality measures development, health system investment in core competency skills training applicable to all clinicians and ensuring accountability for adhering to these practice guidelines will help support national strategies for integrating these services in all settings.¹⁰²

Moving forward, all patients and caregivers should be routinely assessed for their physical, psychosocial and functional impairments or symptoms and offered supportive services throughout the care continuum to improve their quality of life and well-being. These essential steps will help enhance shared decision-making and improve the patient and family lived experience – key markers for delivering high-quality care.

Principles: Palliative Care, Pain management, Psychosocial Support and Rehabilitation Services Integration

1. Clinicians should routinely assess patients and families for palliative care, pain management, psychosocial support and/or rehabilitation needs throughout the care continuum. By appropriately integrating services and referral processes across care settings, clinicians can maximize their patients' quality of life and minimize functional impairments.
2. Improving public and professional awareness about these supportive services as standard of practice in the setting of complex chronic conditions for quality care delivery alongside disease-directed treatment is imperative.
3. Clinicians in all care settings should receive frontline clinician training in person-centered communication skills, care coordination and transitions, symptom management and shared decision-making.
4. Policymakers and investigators should prioritize research on practices for improving palliative care, psychosocial support, impairment-driven rehabilitation and integrative pain management.

c. Caregivers Engagement and Support

Caregivers are unpaid individuals, often family members or friends, involved with assisting seriously or chronically ill patients with activities of daily living (i.e., feeding, bathing, or walking) or even complex medical tasks (i.e., medication management, administering injections). While they serve a vital role in providing the quality care that patients need, our health care, long-term care and social systems are growing increasingly dependent on individuals who are not compensated or trained to carry out the complex caregiving tasks often expected of them. Nearly 44 million caregivers provide approximately \$470 billion annually in unpaid care to seriously and chronically ill adults and children across the country.¹⁰³

¹⁰⁰ Kazak AE, Abrams AN, Banks J, et al. Psychosocial Assessment as a Standard of Care in Pediatric Cancer. *Pediatric blood & cancer*. 2015;62(S5):S426-S459.

¹⁰¹ Wiener L et al. Standards for the Psychosocial Care of Children with Cancer and Their Families: An Introduction to the Special Issue. *Pediatr Blood Cancer*. 2015;62:S419–S424. Available at: https://docs.wixstatic.com/ugd/27074d_4456612ec4674f9f865b8c784509ff90.pdf

¹⁰² Meier DE, Back AL, Berman A, et al. A National Strategy for Palliative Care. *Health Affairs (Project Hope)*. 2017;36(7):1265-1273.

¹⁰³ AARP. Valuing the Invaluable: 2015 Update Undeniable Progress, but Big Gaps Remain. July 2015. Retrieved from:

<https://www.aarp.org/content/dam/aarp/ppi/2015/valuing-the-invaluable-2015-update-new.pdf>

In fulfilling their role, many caregivers experience distressing physical, emotional and economic effects that strain their own health, well-being and financial security. Individuals experiencing the highest financial strain tend to be lower income, non-White/non-Asian caregivers providing support for a relative or close friend who needs assistance with at least one activity of daily living¹⁰⁴. Like patients suffering from a chronic or serious illness, caregivers may also take time off work, cut back on paid work hours or leave the workforce altogether to care for a loved one. As a result, they lose income and may receive reduced Social Security and other retirement benefits.¹⁰⁵

Caregivers are often referred to as the backbone of our nation's long-term supports and services system; yet perhaps the biggest complaint that caregivers share is the inability to effectively carry out their caregiving roles and responsibilities because they are excluded from important conversations and decisions with the health care team and do not receive the necessary training to perform complex medical tasks at home. Almost half of the 40 million caregivers have performed medical or nursing tasks for their loved ones, often without first having any training or support from the health care team to help them perform those tasks.¹⁰⁶ Further compounding the problems caregivers face, health care professionals often expect caregivers to coordinate care or manage treatments—leaving many caregivers to learn by trial and error.

The Recognize, Assist, Include, Support, and Engage (RAISE) Family Caregivers Act, enacted in 2018, directed the Department of Health and Human Services to build and advance a coordinated national strategy to address many of the challenges confronting caregivers today, as called for by consensus recommendations from the National Academies of Sciences, Engineering and Medicine (NASEM) 2016 report, *Families Caring for an Aging America*. The passage marks a critical step in recognizing caregivers as part of the unit of care and addressing their specific needs to better equip them with the information, training and resources they require to undertake their roles and responsibilities.

While studies have started to emerge demonstrating the positive impact of providing supports and services to caregivers,^{107,108} consensus NASEM recommendations also call for further research investment to support the development and testing of national and community interventions that will help address the unmet needs of caregivers.¹⁰⁹ Caregivers should be routinely assessed for their knowledge, understanding or proficiency in the tasks they are expected to perform as well as their individual strengths, challenges and preferences; and tailored training and support should be provided to address identified needs. As with developing quality measures for patients, these national and community interventions should include caregiver input and engagement to ensure that solutions are person-centered and family-focused.

¹⁰⁴ AARP. *Family Caregiving and Out-of-Pocket Costs: 2016 Report*. November 2016. Retrieved from: <https://doi.org/10.26419/res.00138.001>

¹⁰⁵ National Academies of Sciences Engineering and Medicine. *Families caring for an aging America*. Washington, DC, doi: 10.17226/23606;2016.

¹⁰⁶ Jennifer L. Wolff, Ph.D., Judy Feder, Ph.D., and Richard Schulz, Ph.D. *N Engl J Med* 2016; 375:2513-2515. [December 29, 2016](https://doi.org/10.1056/NEJMp1612351), DOI: 10.1056/NEJMp1612351

¹⁰⁷ Courtney Harold Van Houtven, et al. Development and Initial Validation of the Caregiver Perceptions About Communication with Clinical Team Members (CAPACITY) Measure. *Medical Care Research and Review*. Dec 21, 2017. Available at: <https://doi.org/10.1177/1077558717747985>

¹⁰⁸ Elizabeth B Fauth, et al. *External Validity of the New York University Caregiver Intervention: Key Caregiver Outcomes Across Multiple Demonstration Projects*. *Journal of Applied Gerontology*. June 23, 2017 Available at: <https://doi.org/10.1177/0733464817714564>

¹⁰⁹ National Academies of Sciences Engineering and Medicine. *Families caring for an aging America*. Washington, DC, doi: 10.17226/23606;2016.

Principles: Caregivers Engagement and Support

1. Clinicians and health systems should routinely assess caregivers, an essential part of the unit of care, for their information and support needs.
2. Caregivers should systematically receive the information, training and resources they need to perform their caregiving roles and responsibilities.
3. Policymakers and investigators should prioritize new research focusing on the development and implementation of effective interventions for caregivers.