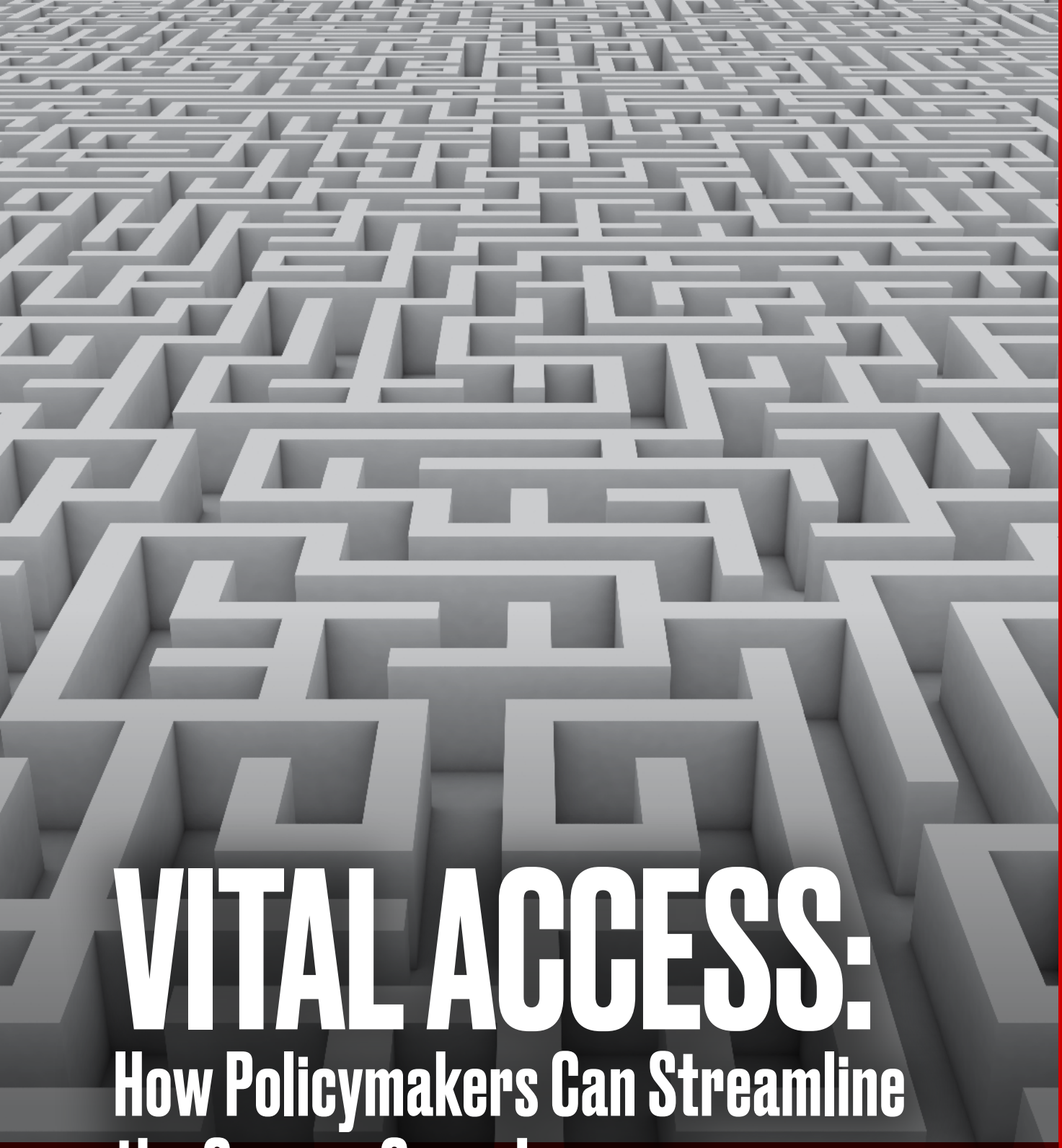


VITAL ACCESS:

How Policymakers Can Streamline the Cancer Care Journey

LEUKEMIA & LYMPHOMA SOCIETY®

LEUKEMIA & LYMPHOMA SOCIETY®

About The Leukemia & Lymphoma Society:

This report was commissioned by The Leukemia & Lymphoma Society and prepared by Steve Butterfield, Brian Connell, Lucy Culp, Ryan Holeywell, Marialanna Lee, and Phil Waters.

The Leukemia & Lymphoma Society® (LLS) is a global leader in the fight against cancer. The LLS mission: Cure leukemia, lymphoma, Hodgkin's disease, and myeloma, and improve the quality of life of patients and their families. LLS funds lifesaving blood cancer research around the world, provides free information and support services, and is the voice for all blood cancer patients seeking access to quality, affordable, coordinated care. To learn more, visit www.LLS.org.

For more information on this report, please contact steve.butterfield@lls.org or lucy.culp@lls.org.

manatt

About Manatt Health:

This analysis and report was prepared by Alex Morin, Donna O'Brien, Joel Ario, Tara Straw, and Julian Polaris of Manatt Health. Manatt Health is an interdisciplinary policy and business advisory division of Manatt, Phelps & Phillips, LLP, one of the nation's premier law and consulting firms. Manatt Health helps clients develop and implement strategies to address their greatest challenges, improve performance, and position themselves for long-term sustainability and growth. For more information, visit www.manatt.com/health.

Cover photo by Susan Q Yin on Unsplash

CONTENTS

01 EXECUTIVE SUMMARY

Over the past 50-plus years, there have been enormous advances in understanding the mechanisms that cause blood cancer. As a result, new and groundbreaking treatments have led to significantly improved overall blood cancer survival rates, which in some cases have more than doubled over the past 50 years.[1]

Problem

Patients' odds of surviving blood cancer often hinge on their ability to access specialists who can evaluate, diagnose, and treat them with optimal treatments as quickly as possible. But too often, patients encounter roadblocks that prevent them from accessing the best care and, in some cases, benefiting from incredible advancements. Recent data reveal continued disparities in outcomes for minority populations in particular.

Accessing medically necessary and high-quality blood cancer care in the United States is a process that remains overly complex and contingent on factors that are steeped in systemic, socioeconomic, and racial disparities. Numerous factors impact access, but a fragmented insurance system and similarly fragmented federal and state policies that set the rules for that insurance system are major contributors. Studies have noted the impact of narrow networks, which can restrict access to some specialty care providers such as hospitals designated as "cancer centers" or "comprehensive cancer centers" by the National Cancer Institute (NCI). Narrow networks are increasingly common in commercial insurance plans in the individual and group markets and in Medicaid-managed care organizations (MCOs).[2] Studies have also shown that cancer patients with certain types of insurance, such as Medicaid–which covers low-income people, a disproportionate share of whom are people of color–are more likely to experience worse mortality rates.[3] These disparities in coverage and access contribute to significant inequities by income, race, ethnicity, and other factors.

In the past three-plus decades, we have seen an explosion of new therapies, including immunotherapy (such as CAR T-cell) and other personalized medicine approaches that target therapies to an individual based on a range of phenotypic and genomic factors.

The policy frameworks[a] that govern insurance have not kept pace with advances in cancer treatment, and they continue to contribute to systemic inequities that prevent access to high-quality blood cancer care. Recent efforts by federal regulators to update access-related standards still fall short of ensuring equitable access to quality blood cancer care for all. And some elements of these frameworks have remained largely unchanged for decades. Meaning consumers still struggle to navigate their options when purchasing a plan and access medically appropriate treatment when a diagnosis is received.

New Research

This report offers nine recommendations in five reform pathways for state and federal policymakers to consider, as they work toward developing insurance regulations that advance a more equitable system of care–one that enables patients with blood cancer to access appropriate treatment and that maximizes the potential for long-term survival. Each of these reform pathways addresses specific deficiencies in the current insurance policy frameworks, and each is critical to pursue in order to ensure a more equitable coverage landscape for patients and families.

a We use the term "policy frameworks" to capture both legislative and regulatory authorities and issues.

Through real patient stories and anecdotes from stakeholders involved in blood cancer care, this report reveals the complicated–and often inequitable–journey confronting patients and families as a result of the complexities outlined above. The project team collected and analyzed more than 25 of these stories, which illustrate how policy frameworks within and across payer types are falling short of meeting patients' needs. Interviews with cancer care providers, including NCI-designated cancer centers, rounded out perspectives on the treatment access challenges.

Summary of Policy Reform Recommendations

Pathway 1: Addressing Burdens Posed by Inadequate Network Standards

- **Recommendation #1:** Strengthen the minimum standards for in-network access to cancer providers.
- **Recommendation #2:** Require plans to offer specialty cancer care providers and facilities in their networks.
- **Recommendation #3:** Strengthen coverage standards for second opinions and access to treatment based on second-opinion recommendations.
- **Recommendation #4:** Require plans to streamline their clinical trial enrollment processes and cover all patient costs associated with trial participation.

Pathway 2: Eliminating Administrative Red Tape Barring Access to Treatment

- **Recommendation #5:** Streamline prior authorization and appeals processes. Require plans to link coverage decisions to established clinical guidelines.

Pathway 3: Reducing Administrative Hurdles of Seeking Out-of-State Care

- **Recommendation #6:** Streamline access to out-of-state treatment.

Pathway 4: Increasing Transparency of Plan Network Composition and Performance

- **Recommendation #7:** Strengthen reporting requirements and monitor performance related to plan networks and access to care:
  - Reporting on and monitoring appeals, grievances, and fair hearings.
  - Reporting on and monitoring utilization.

Pathway 5: Elevating Patient-facing Support for Plan Selection and Navigation of Coverage and Treatment

- **Recommendation #8:** Enhance minimum standards for network composition disclosure and provider directories.
- **Recommendation #9:** Ensure patients and consumers have access to unbiased, independent patient-advocate and navigator supports.

PATIENT PERSPECTIVE

J.J.

> "This experience has forever changed the way I look at health insurance"

In 2019, J.J.'s 9-year-old son, Mason, was diagnosed with T cell Acute Lymphoblastic Leukemia and immediately admitted to Children's Hospital of Los Angeles (CHLA) to begin chemotherapy. At the time, J.J. was a television producer in between jobs, and her wife was starting up a company and lacked income or benefits. As a result, the family had health coverage through Medi-Cal, California's Medicaid program.

Mason went through a difficult eight months of chemotherapy, and J.J. devoted herself to taking care of him and their 6-year-old daughter, so she could not return to work. Mason entered remission, and he began what was to be a three-year maintenance chemotherapy plan. The family was attempting to get back to as normal as possible, when in June 2020, in the midst of the pandemic, Mason developed a fever and a concerning lump on his body. Mason had relapsed, and his doctors said he had only a 25% chance of survival. Mason began treatment immediately.

The regimen, as J.J. describes it, was "brutal". Mason's doctors went on to identify a promising clinical trial at nearby Children's Hospital of Orange County (CHOC), but he was so sick he needed to be transported by helicopter. When Mason arrived in Orange County, he was excluded from the trial because his liver enzymes were too high, so he was flown back to Los Angeles. Years later, the family is still getting bills for these trips that Medi-Cal wouldn't cover. Mason's family continued to search for more options and learned he qualified for CAR-T treatment at Texas Children's Hospital in Houston. However, Medi-Cal would not cover out-of-state treatment. Texas Children's did not promise to treat an uninsured patient, J.J. said, but the doctor there said to come anyway, and she would advocate for them.

Friends started a Go Fund Me account to raise money to cover expenses, including renting an apartment in Houston. "I don't know how someone without resources or friends and family to support them would manage," J.J. said. Everything about going to Texas was challenging and required constant attention. "We thought it would be easy to transfer Mason's routine prescriptions to manage pain and nausea from our California Walgreens to a Houston Walgreens, but that was not possible. We had to get a friend to pick up Mason's prescriptions in California and mail them to us." Ultimately, they were fortunate that Texas Children's wrote off the cost of Mason's care and they never even got a bill.

Sadly, the treatment was not successful, and Mason wanted to come home to Los Angeles for his final days. His family arranged for transportation through Angel Flight, a nonprofit that provides free air transportation for those impacted by severe illness. Mason passed away soon after, surrounded by his family at home.

"We have a sense of peace knowing we did everything possible for Mason," J.J. said. "This experience, however, has forever changed the way I look at health insurance. Now I read policies very carefully. Medi-Cal saved us and covered everything (except the helicopter ride), and we got excellent care in California. The challenge was out-of-state coverage for a treatment he could not get in-state. It would not have been an option if friends did not help and if Texas Children's did not accept us. It shouldn't be that hard for people to get the best treatments for their cancer."

02 IMPERATIVE FOR ACTION: WHY THIS STUDY, AND WHY NOW?

In 2021, The Leukemia & Lymphoma Society (LLS) published the report "Accessing Out-of-Network Subspecialty Cancer Care in Marketplace Plans: Key Findings from a Scan of Four States." The report described at a high level several challenging aspects of the coverage and treatment journey that blood cancer patients with Marketplace plans face in accessing medically necessary care from out-of-network providers. It also outlined seven broad recommendations for federal and state policymakers to consider in the design of policy and regulatory frameworks that govern access, including those related to network adequacy standards and consumer protections such as appeals and grievance rights.[4]

In this new report, we build on those findings and recommendations in two ways. First, this report expands the scope of the inquiry to include multiple insurance categories that are regulated by intersecting federal and state regulatory frameworks. We again consider in this report beneficiaries enrolled in the individual market through qualified health plans (QHPs)[b] and, to the extent applicable, other state-regulated commercial plans.[c] We also consider beneficiaries enrolled in Medicaid,[d] specifically in Medicaid-managed care via managed care organizations (MCOs), which is now the dominant delivery model for Medicaid coverage across the country.[5] Both these beneficiary categories represent populations served by insurers governed by intersecting federal and state regulatory frameworks in different ways.

Second, this report offers concrete policy reform recommendations that federal and/or state regulators should adopt to positively impact beneficiaries and in turn blood cancer patients, as they navigate their coverage and treatment journey to achieve the best outcome.

b Unless otherwise noted, QHPs refer to both State-Based Marketplace (SBM) and Federally Facilitated Marketplace (FFM) plans.

c Self-insured large group plans are excluded from this analysis given their different regulatory landscape that involves the departments of Health & Human Services, Treasury, and Labor.

d While the primary focus is on managed care and the provision of care via private plans, we also note where opportunity exists in Medicaid fee-for-service (FFS).

Federal and State Regulatory Authority—High-Level Summary

Medicaid. Each state administers its Medicaid program–whether fee-for-service (FFS) or managed care–in accordance with federal standards set forth and enforced by the Centers for Medicare & Medicaid Services (CMS). These federal standards afford states broad discretion in many elements of program design, including network adequacy for MCOs.

Commercial Plans. As a general matter, states have the primary role in regulating commercial health plans offered in the individual market and certain group markets (particularly small groups), although certain federal baseline requirements apply, particularly with respect to the 27 states that rely on the Federally-Facilitated Marketplace (FFM) as opposed to administering a State-Based Marketplace (SBM). The health plans offered by large, self-insured employers are exempt from most state insurance laws and subject to a more limited set of federal requirements than plans sold on the marketplaces.

Consideration of multiple payer/plan types allows us to consider where there is potential for harmonization of policy and regulatory frameworks.

Necessity for Action to Advance Equity

People of color experience worse cancer outcomes, including a higher incidence of cancer, later disease stage at diagnosis, and lower rates of survival.[6]

While treatments continue to advance significantly, not all patients and survivors have equal access to treatment, including newer and more effective treatments. Some groups–including, but not limited to racial and ethnic minority groups, individuals with low income, and rural residents–face substantial social, economic, and environmental disadvantages that hinder or prevent access to the treatment and care they need.[7,8,9] Further, differences in access to care can become more pronounced as new, more effective treatments, such as immunotherapy, become available.[10]

These disparities exist across payers and income levels and highlight the imperative for all payers to focus on mechanisms to improve equitable access. That said, the Medicaid population includes those most significantly impacted by disparities in access. People of color are disproportionately served by the Medicaid program. Notably, 60% of the U.S. population as a whole, but only 15% of Medicaid beneficiaries, identifies as non-Hispanic white. Meanwhile, Black people represent 13% of the population but 33% of Medicaid beneficiaries; similarly, Hispanic and Latino people make up 19% of the population but represent 30% of Medicaid beneficiaries.[11]

A 2017 study examined "multiple quality measures across several cancer types" and concluded that the quality of care received by Medicaid beneficiaries was significantly lower than the overall quality of care received by privately insured persons, even after accounting for demographics and stage at diagnosis. Specifically, Medicaid beneficiaries "had significantly lower odds of receiving recommended radiation and/or chemotherapy after diagnosis or surgery" for several cancers that were analyzed.[12]

In its 2022 CMS Strategic Framework, the agency has stated an imperative for action on health equity and access as linked issues that significantly affect beneficiaries in programs that it regulates. The first two pillars of this new strategic plan link directly to these issues of advancing health equity and expanding access.[13] We can expect CMS to act on these issues as a regulator and to push for more partnerships from health plans and providers to address these issues from multiple angles.

CMS Strategic Pillars






ADVANCE EQUITY

Advance health equity by addressing the health disparities that underlie our health systems

EXPAND ACCESS

Build on the Affordable Care Act and expand access to quality, affordable health coverage and care

ENGAGE PARTNERS

Engage our partners and the communities we serve throughout the policymaking and implementation process

DRIVE INNOVATION

Drive Innovation to tackle our health system challenges and promote value-based, person-centered care

PROTECT PROGRAMS

Protect our programs' sustainability for future generations by serving as a responsible steward of public funds

FOSTER EXCELLENCE

Foster a positive and inclusive workplace and workforce, and promote excellence in all aspects of CMS's operations

Text via CMS.
Source: https://www.cms.gov/cms-strategic-plan

Changing Nature of Our Understanding of Blood Cancer and Blood Cancer Care

Our understanding of the biology of cancer changed dramatically with the sequencing of the human genome in 2003, and this has led to a new age in which more personalized therapies can be offered to patients. Historically, doctors depended on chemotherapy, surgery, and radiation, but today, it is possible to analyze the DNA of a person's cancer cells and offer therapies designed to target the specific mutations found. These developments are making cures or the management of cancer as a chronic disease more possible.

As research and available treatments rapidly evolve, it can be difficult for physicians to stay abreast of every advancement and evolve their practice accordingly, which necessitates access to specialists who may be more aware of the latest advanced treatments in a particular disease area.

It is also challenging for payers to stay abreast of which new treatments should be covered in their health plans. Payers must better understand the unique nature of cancer as a series of different diseases benefiting frequently from discoveries that lead to breakthrough treatments. This requires recognizing that cancer subspecialists are needed for a large percentage of cancer patients and that mechanisms need to be in place to update their coverage policies based on the latest science.

Approach to Analysis and Recommendation Development

This report began by documenting the lived experiences of blood cancer patients and their families. More than 25 individual patients and families volunteered to share their stories with the authors of this report about navigating the coverage and treatment journey. These stories were collected by LLS staff who work closely with patients with a blood cancer diagnosis and their families. Interviews with several of these patients and families were conducted to fully document their experiences–both positive and negative–as they navigated the coverage and treatment journey. In addition, interviews were conducted by the authors with eight cancer centers from across the country, including NCI-designated cancer centers and community cancer centers, focused on the experience of providers in engaging with blood cancer patients and families seeking care at their facilities for a range of reasons (standard-of-care treatment, second opinions, clinical trials, etc.). Primary research on the current regulatory landscape for individual and group commercial insurance plans, Medicaid, and Medicaid-managed care supplemented the interviews.

03 DOCUMENTING THE COMPLEX PATIENT JOURNEY: BARRIERS TO TREATMENT AND POLICY REFORM RECOMMENDATIONS

When an individual receives a blood cancer diagnosis, they begin a complex journey. The complexity is rooted in the nature of blood cancer as a disease and the landscape of treatments available across the country and around the world. The complexity also relates to "coverage complexity"—that is, navigating coverage, reimbursement, and the associated administrative processes inextricably linked to a patient's treatment journey. This means patients and families must bear the burden of navigating parallel and linked processes to ensure not just a positive treatment outcome but also to prevent significant economic hardship.

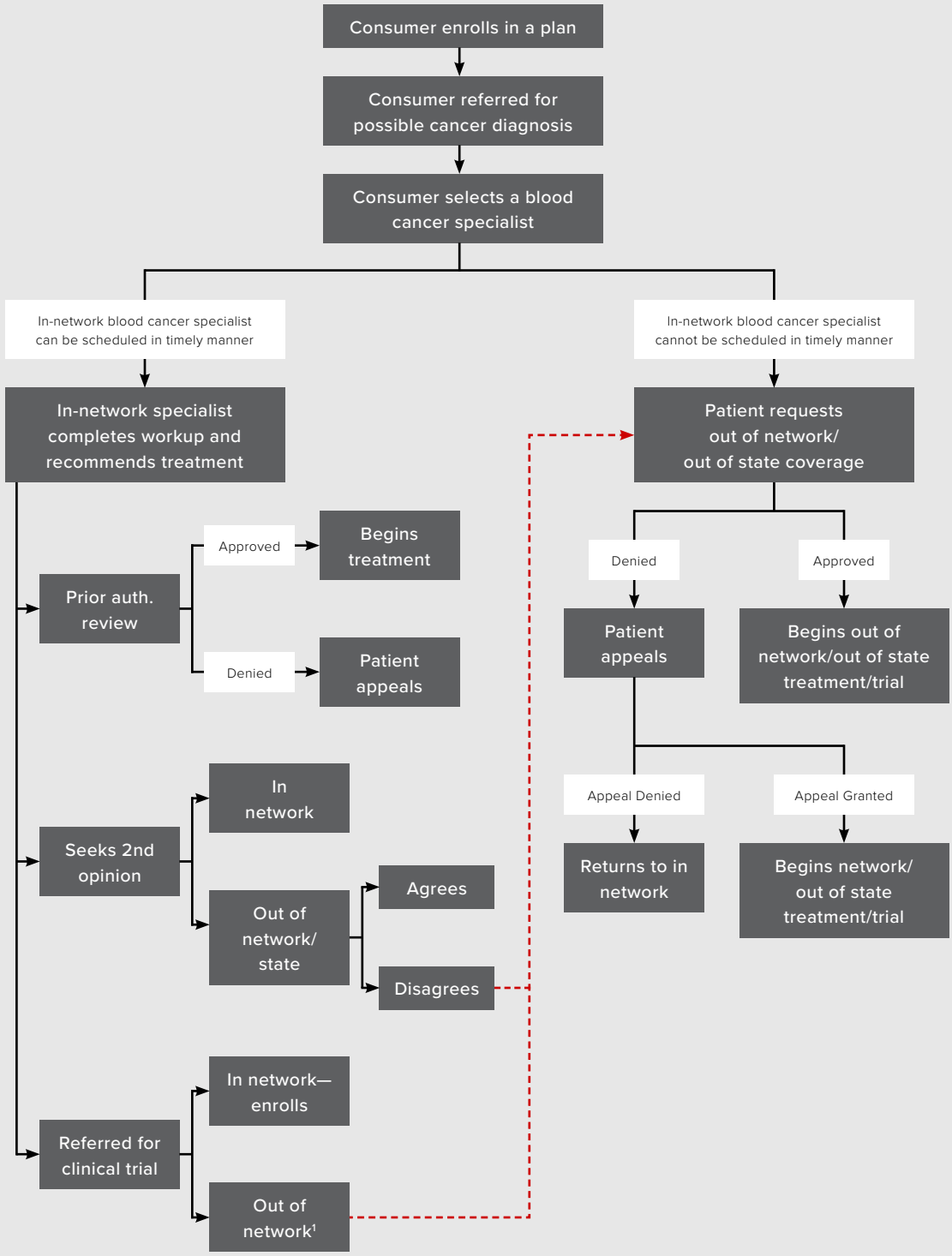
The cancer coverage and treatment journey involves many different steps, each of which represents an intertwining of science and clinical care and insurance coverage policies and costs.

This report is grounded in that patient and family experience navigating the coverage and treatment landscape. We consider five pathways through which improvements to the patient and family experience and more equitable access to high-quality blood cancer care may be achieved:

- **Pathway 1:** Addressing Burdens Posed by Inadequate Network Standards
- **Pathway 2:** Eliminating Administrative Red Tape Barring Access to Treatment
- **Pathway 3:** Reducing Administrative Hurdles to Seeking Out-of-State Care
- **Pathway 4:** Increasing Transparency of Plan Network Composition and Performance
- **Pathway 5:** Elevating Patient-facing Support for Plan Selection and Navigation of Coverage and Treatment

We note that each pathway is necessary but insufficient on its own to address the totality of the issue; rather, each pathway should be pursued by policymakers to address specific issues that combined, would materially improve equitable access to medically necessary cancer care in the United States.

FIGURE 1: HIGH-LEVEL COVERAGE AND TREATMENT JOURNEY[e]



e Appendix to this report contains a listing of technical and policy terms and definitions.

Pathway 1:
Addressing Burdens Posed by Inadequate Network Standards

Blood cancer patients need access to high-quality care. But their ability to get that care is influenced heavily by (1) the availability of those providers within their insurance network and (2) patients' knowledge (either firsthand or via their primary care physician) of those specialists and treatment options. Having access in network ensures coverage and mitigates the significant financial burden of out-of-network care. In-network coverage also can reduce treatment delays and the administrative burden of requesting out-of-network care and negotiating single-case agreements. Finally, the availability of high-quality, in-network providers can streamline care coordination across multiple providers. Patients need access to not only in-network primary treating physicians (in this case, blood cancer specialists) but also facility-based care and ancillary services required as part of standard-of-care treatment.

Unfortunately, today, an insurance network may be able to describe itself as having sufficient in-network blood cancer specialists if it includes hematology/oncology providers–regardless of whether those providers have expertise specific to particular diseases. For patients whose lives depend on access to expertise regarding their specific condition, this is insufficient. The federal standards for network adequacy–the primary tool regulators use to ensure adequate providers are available to beneficiaries–fall short. The standards vary across different insurance categories and are insufficient to meet the needs of blood cancer patients who require rapid access to *specialized treatment*, including second opinions and clinical trials.[14,15,16,17]

Network adequacy standards and related regulatory requirements are in transition for both QHPs in the individual market and Medicaid managed care plans. In April 2022, CMS finalized the Notice of Benefit and Payment Parameters for 2023 for issuers offering QHPs, which created federal network adequacy requirements for plans offered through the FFM.[18] In addition, rulemaking is expected in 2023 that will impact network adequacy standards, among other aspects of access in the Medicaid FFS program and in Medicaid managed care, following up on a CMS request for information on access issues in the spring of 2022.

Policy Reform Recommendations

01 RECOMMENDATION #1: STRENGTHEN THE MINIMUM STANDARDS FOR IN-NETWORK ACCESS TO CANCER PROVIDERS.

Network adequacy standards for oncology care continue to be defined broadly, without the level of specificity needed to ensure the availability of subspecialty blood cancer care. There are no standards for disease-specific specialty care, including blood cancer specialty care.

1a. Create and leverage state data sources to establish disease site-specific access standards in blood cancer care.

Over time, state governments should evaluate available data and tools, such as all-payer claims databases (APCDs) and consumer complaint records, to establish network adequacy standards at the subspecialty level across all payer categories.

Most states provide mechanisms for their residents to file consumer protection-related complaints for a range of issues across multiple industries, including with respect to their insurance. While it is unclear how often people may utilize this mechanism to seek assistance when navigating issues relating to insurance coverage, it represents a tool that states can use for the purpose of monitoring insurance plans over which a state has regulatory authority.

Further, under CMS' market conduct auditing authority, CMS collects complaint information and has the authority to investigate or require an individual state to investigate, should CMS deem it necessary. Again, the degree to which this function is used by the pub-

lic and in turn by CMS for monitoring issues relating to access is unknown but represents yet another tool to identify where potential standards for access are falling short and to motivate corrective action.

APCDs are centralized, statewide databases that collect and organize claims data across payer types, including, often, individual market, small group, large group, Medicare Advantage, Medicaid managed care, and Medicaid FFS. APCDs offer policymakers, regulators, and researchers a unique tool to better understand how health systems of health are performing within a state. Eighteen states have an operating APCD, representing a population of 103 million, and a further six to eight states have an APCD in development, representing an additional population of 94 million. These tools have been–or have the potential to be–used to:

- Create a baseline understanding of state residents' coverage, service utilization, costs, and health, and how those measures have changed over time.
- Support regulatory oversight of payers and providers, from compliance with network adequacy requirements to projections for how mergers or expansions may impact consumer costs, to supporting system transparency.
- Identify health system failures–including coverage disruptions, excessive cost growth or provider price variation, irregular billing practices, and health disparities–and inform the design of strategies to address them.
- Facilitate an understanding of "whole person" needs through their ability to internally link member data (e.g., Medicare/Medicaid dual-eligible analyses) or bridge health and social/public health data sources (e.g., COVID-19 long-hauler analyses, opioid impact analyses).

As an example in the blood cancer network adequacy context, states could use their APCDs to identify a class of "blood cancer specialists," defined as oncologists with a threshold percentage (e.g., 25%-50%) of their practice volume in blood cancer, as measured by actual claims. This information could be used to enable states to set new standards to ensure access, including standards for time and distance and/or wait times for multiple subspecialties within oncology, across all state-regulated insurance categories.

New Hampshire is the first state in the country to use all-payer claims data to support a network adequacy approach that allows for greater transparency and accountability in its review of health insurers' provider networks.[19] The state uses actual claims experience to review carrier networks and mandate providers for services rather than particular specialists.

At the federal level, CMS should work with states to set a framework for utilizing APCD claims data to set new, more specific network standards and monitor and engage with states using these data sources to document and then push to scale best practices and create capacity in all states to follow suit.

1b. Align minimum time, distance, and access requirements across insurance categories through federal and state actions.

CMS should consider extending the new time and distance standards that go into effect in 2023 to *all QHPs*, including those on SBMs, which it declined to do in this most recent round of rulemaking. This change would create unified standards for access to two classes of oncologists (medical/surgical and radiation) and achieve closer alignment to standards in the Medicare Advantage program.

Beginning in 2024, individual marketplace plans on the FFM will also need to comply with wait time standards, but these standards will differentiate only between primary care (general), specialty care (nonurgent), and behavioral health care.[20] Similar to the time and distance standards, CMS should extend these to all QHPs.

Last, CMS should ensure that the new federal standards that will be promulgated this year for Medicaid beneficiaries in FFS or MCOs *are at least as protective* of beneficiary access as those currently developed for QHPs in FFM states.

At the state level, all states should be encouraged to set stricter standards across their commercial markets.

02 RECOMMENDATION #2: REQUIRE PLANS TO OFFER SPECIALTY CANCER CARE PROVIDERS AND FACILITIES IN THEIR NETWORKS.

Access to cancer care at a small general hospital or community oncology clinic is not the same as access to federally recognized centers that specialize in treatments for serious diseases. Some of the most specialized treatments available to blood cancer patients, and clinical trials, are typically available at a smaller number of specialized cancer care providers, including academic medical centers, NCI-designated cancer centers, and some community-based providers with large and advanced cancer programs. In many states, these providers are excluded from plan networks.[21] In many cases, medically necessary blood cancer care may require that patients travel to one of these centers that offer specialized treatment, including clinical trials, not available in their plan's network or possibly not even available in their state.

New York recently passed a law that seeks to expand access for beneficiaries with Medicaid managed care and individual market plans to cancer providers, including hospitals designated by the NCI as "cancer centers" or "comprehensive cancer centers" for their leadership in "developing new and better approaches to preventing, diagnosing, and treating cancer."[22] The law establishes an "any willing provider" requirement for NCI-designated cancer centers in both Medicaid managed care plans and individual markets. The law requires that any NCI-designated cancer center willing to contract at Medicaid FFS rates set by the state *must be included in network in both plan types* and reimbursed at least at the Medicaid FFS rate set in that state.[23]

The California Cancer Care Equity Act, which was signed into law in 2022, would provide a similar but less stringent requirement for plans to contract with specialty cancer centers. The new law requires that plans make a good faith effort to contract with at least one statute-defined specialty cancer center located within the beneficiary's county of residence or the nearest county. It also requires expedited prior authorization (PA) and that beneficiaries with a "complex cancer diagnosis" may request a referral to a cancer center.

At the federal level, CMS could require Medicaid managed care and QHPs to mirror the New York policy and also adopt more stringent requirements for expedited PA and referrals such as those contemplated under the California law. States could also pursue this as a requirement for Medicaid managed care and QHPs. To date, states have focused on expanding access to NCI-designated cancer centers because this government designation represents the gold standard in oncology treatment and research. One challenge, however, is that NCI-designated comprehensive cancer centers do not exist in every state or close to where patients live. While we recommend that all states allow access to these national resources, additional coverage for specialty cancer providers and hospitals is likely needed to ensure access for all patients to subspecialty blood cancer care.

States without NCI-designated comprehensive cancer centers or where NCI-designated cancer centers are geographically far from some of the state's residents should explore requiring access to providers who achieve certain volumes in treating specific conditions (as measured by data such as new cancer cases by disease sites as reported to state cancer registries or APCDs), associated survival rates and other patient-centered outcomes (to the extent such data exist), and participation in condition-specific research and clinical trials (active National Institutes of Health or industry clinical trials and others). Organizations such as the American College of Surgeon's Commission on Cancer may be able to assist with criteria on quality and expertise.

03 RECOMMENDATION #3: STRENGTHEN COVERAGE STANDARDS FOR SECOND OPINIONS AND ACCESS TO TREATMENT BASED ON SECOND-OPINION RECOMMENDATIONS.

When faced with a cancer diagnosis, many patients seek a second opinion for their diagnosis or treatment plan. Most initial cancer care is provided by community oncologists, but particularly for more rare and complex cancer diagnoses, securing a second opinion from an oncologist with specialized expertise in their cancer subtype is an important step patients can take to ensure the most appropriate treatment. Studies have shown the prevalence of changes in diagnosis and treatment recommendations upon receiving second opinions at specialized cancer centers such as NCI-designated cancer centers, can be substantial.[24]

With respect to coverage for second opinions, unaligned and insufficient standards are in place for the individual market and in Medicaid. Under federal law, Medicaid MCO contracts "must ensure" that the MCO "provides for a second opinion from a network provider, or arranges for the enrollee to obtain one outside the network, at no cost to the enrollee."

Individual (and group) market plans are not required to provide coverage for second opinions as a matter of federal law, though some states may require such coverage for plans they have the authority to regulate, and other plans may voluntarily provide this form of coverage.

Even if coverage is available for an out-of-network second opinion, a referral must come from an in-network provider, and some plans will refuse to cover continued care at the specialized center and will instead limit treatment coverage to an in-network provider, regardless of whether that provider has experience with a given treatment. This practice can be particularly troubling in scenarios where an out-of-network clinician at a specialized cancer center corrects a mistaken diagnosis, recommends a different treatment plan, or offers an innovative treatment. And even if the plan agrees to provide coverage for continued treatment with the out-of-network provider–perhaps after the patient challenged an initial denial through the complex appeals process–there may be significant delays due to burdensome and lengthy PA processes, as well as the need for the plan and provider to negotiate a single-case agreement (and potentially to renegotiate the agreement whenever there's a modification to the treatment plan).

Coverage decisions for treatment should be based on the best medical guidance within a particular medical specialty. In instances where a second opinion from a specialist offers a significantly different diagnosis and treatment regimen that can only be provided to a patient at an out-of-network provider, plans should be required to cover the treatment at no incremental cost to the patient. "Best medical guidance" can be grounded in expert-developed treatment pathways and guidance from medical societies that continuously update recommended treatments for particular diseases, based on the newest treatment breakthroughs. Decisions should not be based on cost factors or the treatment pathways suggested by plans alone.[f]

f See Recommendation 5b for additional information about expert-developed clinical pathways.

04 RECOMMENDATION #4: REQUIRE PLANS TO STREAMLINE THEIR CLINICAL TRIAL ENROLLMENT PROCESSES AND COVER ALL PATIENT COSTS ASSOCIATED WITH TRIAL PARTICIPATION.

A critical factor of equitable access in blood cancer care is access to the most cutting-edge clinical trials, which, for many blood cancer patients, offer the best hope for a positive treatment outcome.[25] Clinical trials are associated with quality cancer care, yet there are many barriers to access.

The Affordable Care Act (ACA) requires individual, group, and self-insured plans to cover the "routine costs"[g] associated with participation in clinical trials, including when the trial is out of network. However, out-of-network coverage applies only when the plan otherwise covers out-of-network services. Some do not, creating a critical gap for blood cancer patients that should be addressed.

With respect to Medicaid, the recently enacted Clinical Treatment Act (CTA) requires states and MCOs, as of January 1, 2022, to cover all routine services when furnished in connection with certain federally funded clinical trials that study serious or life-threatening diseases, regardless of whether the clinical trial is offered by an in-network or out-of-network provider or whether the trial is offered out of state.[26,27] The act further establishes expedited PA procedures for qualifying clinical trials, requiring that states and MCOs accept a template attestation form from the provider regarding the clinical trial's features and make coverage determinations within 72 hours.

Several enhancements could be made to the policy frameworks set by the ACA and CTA for privately insured and Medicaid managed care beneficiaries:

- Policymakers should ensure that trial-related standard-of-care costs for private insurance and Medicaid managed care plans are fairly reimbursed at rates no less than Medicaid, MCOs, or private plans would normally pay for similar services furnished by an in-network provider, consistent with the long-standing Medicare National Coverage Determination (NCD) that similarly extends coverage for costs associated with clinical trials.[28] This approach is consistent with Congress's intent in enacting broad requirements for the coverage of clinical trials and eliminates the possibility that plans will offer lower rates or increased cost sharing for trial-related standard-of-care costs when patients go out of network for a trial.
- Congress should require private plans to cover out-of-network clinical trial costs, even for plans without out-of-network coverage. These plans should also be required to offer rapid PA procedures for out-of-network or out-of-state clinical trials, consistent with Medicaid managed care plans in the CTA.
- For the Medicaid population, CMS and/or state policymakers should work to address long-standing procedural barriers for out-of-state providers regarding screening and enrollment requirements in each state's Medicaid program, as well as the need to negotiate a single-case agreement with the MCO (if applicable). These processes can extend the time frame to access clinical trials, even when coverage is mandated. Similar process improvements to shorten time frames from clinical trial identification to enrollment are needed in private coverage as well. We comment on these further in Recommendation #6.

g These are defined as all items and services consistent with the coverage provided in the plan that are typically covered for a qualified individual who is not enrolled in a clinical trial.

Pathway 2:
Eliminating Administrative Red Tape Barring Access to Treatment

Patients who are being assessed or awaiting treatment for cancer often face administrative burdens through mechanisms such as PA requirements, which prevent patients from having insurance coverage for particular treatments or procedures until they have received approval from their insurer. PA is often required for services such as diagnostic scans or particular treatments that are the standard of care but high cost. Time is critical, yet the patient or their family, or their medical team, have to spend weeks or longer navigating authorization for treatment and appeals, should services be denied. [29]

While insurers utilize PA to reduce costs and eliminate medically unnecessary care, the impact on patients can be significant. PA can create an administrative burden and financial uncertainty for patients, providers, and plans. At its worst, PA can prevent patients from necessary medical care in a timely fashion–and with cancer, time is often of the essence.

Federal and state regulators can begin to ease the burden of these processes on patients and families in several ways.

05 RECOMMENDATION #5: STREAMLINE PRIOR AUTHORIZATION AND APPEALS PROCESSES AND REQUIRE PLANS TO LINK COVERAGE DECISIONS TO ESTABLISHED CLINICAL GUIDELINES.

Recent evidence suggests that at least some plans improperly deny coverage for standard-of-care services, resulting in frequent reversals on appeal. A recent Office of the Inspector General report noted that in the Medicare Advantage market, 13% of PA denials were for services that met Medicare coverage rules, delaying or denying care that likely should have been approved. Further, 18% of payment denials fully met Medicare coverage rules and payment policies. While these data are specific to Medicare Advantage, one could expect similar data in the individual market plans and in Medicaid managed care, particularly since many national insurance companies offer products across all three markets.[30] This effectively puts the burden on patients and providers to enforce their rights by filing an appeal, which can be a complex and time-consuming process, especially for a very ill person.

Patients who do not file an appeal (whether due to lack of awareness, lack of capacity, or being very ill) or who do not perfectly follow complete procedures to pursue appeals may be denied services to which they are entitled.

Interviews with several cancer centers completed by the project team revealed regular difficulty in providing standard-of-care treatment according to expertly developed and maintained clinical protocols, due to PA delays and often denials that required appeals.

PATIENT PERSPECTIVE

Hannah

> "How many families are bankrupt or homeless for healthcare bills that their insurance company should be paying?"

In 2016, Hannah—a pseudonym used at this patient's request—was a small business owner with her husband and led an active life which included earning a third degree black belt in karate. She began experiencing ever-increasing pain in her shoulder and went to her doctor multiple times over several months. Then, one day, she coughed and suddenly felt "lightning bolts" down her legs, and her legs stopped working right. She went to the doctor, and after a series of tests, received the dreaded call. "'It's cancer,'" she recalled her doctor saying. "'Be in this office in one hour, and pack a bag because you're not going home, you're being admitted directly to the hospital from the office. We have to begin chemotherapy today. We have to try to save your spinal cord and your life.'"

Hannah had stage 4A non-Hodgkin lymphoma. She immediately started a regimen of 96 continuous hours of chemotherapy administered every three weeks for almost six months. At the time of diagnosis, the oncologists' consensus was that she was just days from paralysis and three weeks from death. The initial treatment regimen would be followed by a high dose methotrexate at a nearby academic medical center, followed by proton therapy.

Hannah had a top tier health plan that she had bought as a small employer. Facing the potential of daunting healthcare expenses before she proceeded with further treatment, she said to her husband "I am terrified this is going to bankrupt us." He said they had to go ahead, no matter what. Fortunately, all her treatments could be received in network, which they thought was a blessing. They planned to be very careful to get approval for every treatment before it was started. For the first year in treatment, there were days, she was "a dishrag" and unable to do anything about large, confusing billing statements, but as those days passed, she had to focus on the paperwork. Despite approvals for all treatments, she began receiving very large bills.

She began to fight, and it was a battle. She had authorizations in hand when she called her insurer, but got the "run around" over and over. Her proton therapy was pre-approved, and the provider also confirmed this ahead of time, but then she was shocked to get a 50% balance bill for $100,000. It was eventually resolved, but she said it was "heart-stopping to say the least."

In a moment of complete frustration, Hannah decided to circle the wagons and arrange a conference call with her oncologist's billing office and an insurance representative. They painstakingly went through each claim that was not fully paid. With a thorough approach and persistence, she started to have success getting bills resolved. But today, there are still significant out-of-pocket expenses associated with her serious cancer diagnosis. She has lingering nerve damage and chronic pain from the cancer and must continue physical therapy, with much of it paid out-of-pocket due to an annual limit imposed by her plan on physical therapy visits. Hannah went from training from being a martial arts expert to needing a walker, but she is grateful to be alive and walking once again. She worries constantly about healthcare costs as she needs ongoing monitoring of her health. "It should not be this hard to get coverage for the care you need to live, from the health plan that you pay for," she said. She has turned her experience into advocacy, as she wonders "how many families are bankrupt or homeless for healthcare bills that the insurance company should be paying."

5a. Streamline PA processes and communication of decisions.

In December 2020, CMS proposed regulatory reforms to digitize, standardize, and streamline PA in Medicaid, Children's Health Insurance Program (CHIP), and FFM QHPs; the Biden administration has not taken any action to finalize that rule or otherwise address Medicaid MCO PA. CMS is planning rulemaking later this fall; however, that will place new requirements on plans, including Medicaid managed care plans, CHIP managed care entities, state Medicaid and CHIP FFS programs, and QHP issuers on the FFMs to improve the electronic exchange of health care data and streamline processes related to PA, while continuing CMS' drive toward interoperability.[31]

The impact of PA requirements on patients links very closely to the time frame within which patients can access medically necessary care, which in cancer is of critical importance, as well as to clinical outcomes. One study published in 2018, which was based on a survey of physicians, found that more than one-third (34%) of physicians reported that PA led to a serious adverse event, which could include hospitalization (24%), disability, or even death (8%) for a patient in their care.[32]

Studies have well documented the administrative cost and time burden increases on providers due to the current PA processes. According to a study by the Healthcare Financial Management Association, processed PAs amounted to a $528 million administrative cost for providers in 2019.[33] The study also quantified the time consumed by providers per transaction for different types of transactions: 21 minutes for a manual PA, 8 minutes for PA through a web portal, and 4 minutes per PA for electronic ones. Streamlining these processes is essential, and CMS and/or states should ensure that requirements are in place to expedite and streamline them.

Last, several interviews with cancer centers and patients conducted by the project team revealed regular instances where patients received bills for services that were authorized under PA processes yet still denied or only partly covered. In some cases, clerical errors by plans were to blame. But patients and families were given the burden of navigating insurance companies, sometimes months or years later, to resolve billing issues, despite the evidence of PA. States in particular should hold plans accountable for incorrect bills, particularly when services were authorized by lengthy and complex PA and appeals processes, to ensure better processes are established internal to plans to prevent these errors that unduly burden patients.

5b. Alleviate PA requirements for providers with strong approval records and/or when treatments are suggested by accepted clinical practice guidelines.

Some states are implementing PA "gold card" laws, which exempt providers from preauthorization of some services if they reach a certain PA approval rating for more than six months. Special attention is needed for high-cost treatments such as bone marrow transplants, CAR T-cell treatments, and treatments that use very high-cost drugs, to ensure against disproportionate denials for these treatments.

West Virginia was the first state to implement such a law, requiring a 100% approval rating for a particular service over six months. Since then, several other states have implemented, or are considering, similar laws with varying degrees of approval ratings and degrees of services included. These states include **Texas, Vermont, Connecticut, Kentucky,** and **New York**.

CMS should be engaging these states on the success of these laws and consider how best to facilitate best practice adoption across the country and expand to even more service categories.

Beyond the providers themselves, PA should be streamlined when treatments being recommended adhere to clinical practice guidelines established by the medical community (in this case, blood cancer specialists). In interviews with several cancer centers, even care that adhered to National Cancer Consortium Network clinical guidelines was subject to PA delays and in some cases, denials. Several cancer clinical pathway products have been developed by NCI-designated cancer centers to inform oncologist decision-making and utilization of personalized medicine based on the latest evidence, including varying degrees of cancer complexity. Products include ClinicalPath (formerly Via Oncology) at the UPMC Hillman Cancer Center,[34] Philips pathways developed with the Dana-Farber Cancer Institute,[35] and those developed by the Moffitt Cancer Center.[36] Many community cancer programs across the country are implementing these pathways to ensure the latest treatments for their patients and to standardize care across providers. The use of these tools could be a criterion for gold-carding providers. Some Blue Cross plans (e.g., Massachusetts, Michigan, and North Carolina) are requiring the use of a clinical pathways program that they endorse to be reimbursed, but experts note that they generally address cases that are more common.[37] In some cases, the payers allow an expert-informed plan such as those noted above.

While not specific to cancer, **California** has implemented a law that prohibits plans from using proprietary, in-house medical standards for mental health and substance use disorders and requires that plans use standards developed by relevant expert associations when considering service authorization.[h],[38] A similar model is appropriate for conditions such as cancer, given the complexity and ever-changing treatment landscape.

5c. Improve required appeal timelines for beneficiaries who appeal negative coverage determinations.

When appeals are necessary, either for a negative coverage determination or when patients appeal for out-of-network coverage, the time frames for a final resolution should be tightened. For individual market plans in **Washington**, patients can move through the entire appeals process (including initial determination of authorization, initial appeal, and secondary appeal) in a total of nine days. PA determinations must be made in 72 hours, initial appeals determined in another 72 hours, and secondary appeals in 72 more hours.

States and CMS should work to set more stringent standards for these determinations, particularly when a patient has a life-threatening condition. Further, policymakers should consider laws to expand the circumstances under which managed care plans and QHPs must provide benefits during the pendency of an appeal and refrain from recouping the costs of those services if the appeal is ultimately unsuccessful. States could explore these interim coverage mechanisms for patients with life-threatening diseases in Medicaid managed care and in the individual market.

h The law states, "In conducting utilization review of all covered health care services and benefits for the diagnosis, prevention, and treatment of mental health and substance use disorders in children, adolescents, and adults, a health care service plan shall apply the criteria and guidelines set forth in the most recent versions of treatment criteria developed by the nonprofit professional association for the relevant clinical specialty."

PATIENT PERSPECTIVE

Chris

> "I never imagined that my insurance company would be managing my cancer care"

Chris was working in Zurich, Switzerland in July 2021 when he found a lump in his neck. Immediately, his primary care doctor there sent him to Zurich University Hospital, which diagnosed him with lymphoma. Following additional tests, he began chemotherapy within a week. "Their only priority," Chris said, "was providing the best care for me." Chris returned to New Jersey to complete treatment, and now he is being monitored for a recurrence.

While his care here has been very good, his experience in the U.S. has been a stark contrast from that in Switzerland—especially for imaging tests. His insurance company consistently denied his U.S. doctor's recommendations for imaging and other tests. Chris and his doctors worked through appeals but were still denied. As the six-month mark following his treatment had passed, he was getting nervous about the scan and decided to pay for it out-of-pocket. But even then, he ran into a roadblock: the imaging provider would not let him pay the out-of-pocket rates without a denial in writing, and it took Chris to get a month to get a formal denial letter from his insurance company.

As Chris faces ongoing surveillance, he wonders if he will have to go through this process every time his doctors order a test. He compares this to his experience in Zurich, where his needs came first and the care was timely. He had no idea that his insurance company would be making the decisions on his cancer care and that there would be no sense of urgency.

Pathway 3:
Reducing Administrative Hurdles of Seeking Out-of-State Care

Needing to receive care in another state may present additional navigation hurdles for patients and families. In some cases–particularly for patients facing rare cancers–there may only be a few providers with the appropriate expertise needed to provide effective treatment. Those providers may be in a different state than the patient who needs their care and they may be out of network as well. This is a problem facing patients in the Medicaid program in particular, though many issues also apply in the context of care for the individual insurance market.

There are multiple barriers to accessing out-of-state services:

- **Provider enrollment**: Providers must generally enroll separately in each state's Medicaid program to receive reimbursement. Although federal rules permit states to provide expedited enrollment to out-of-state providers already enrolled in Medicare or another state's Medicaid program, states generally do not do so, instead requiring providers to undergo duplicative screening and credentialing processes. According to the Medicaid and CHIP Payment and Access Commission, some states, such as **California**, do not require separate screening for out-of-state providers and have established an express enrollment process for them.[39]
- **Travel and lodging coverage**: Many state Medicaid programs have limited coverage for out-of-state travel, with limited direct reimbursements to enrollees for lodging, meals, and attendants; QHPs also are not required to provide this coverage and support.
- **Reimbursement**: In some states, out-of-state Medicaid providers are paid lower rates than in-state providers, even though the in-state providers often are already paid below cost.

06 RECOMMENDATION #6. STREAMLINE ACCESS TO OUT-OF-STATE-TREATMENT.

In addition to streamlining PA, appeals, and single-case agreements in general, as discussed above, several other reforms could be pursued that would improve access to out-of-state, medically necessary coverage.

6a. Enhance monitoring of out-of-state denials. Federal law already requires states and Medicaid MCOs to cover out-of-state services when, among other scenarios, "the state determines, on the basis of medical advice, that the needed medical services, or necessary supplementary resources, are more readily available in the other state; or it is general practice for beneficiaries in a particular locality to use medical resources in another state."[40] If MCOs are routinely reversing denials of out-of-state coverage on appeal, that suggests that MCOs are denying too many claims in the first place. We note this further under Pathway #4.

6b. Streamline Medicaid provider screening and enrollment requirements. These time-intensive procedures duplicate screenings the provider has already undergone for Medicare and other state Medicaid programs. Recent CMS guidance recommended that states voluntarily establish expedited screening procedures, and Congress could further act to require it.[41]

6c. Prohibit discriminatory reimbursement rates for out-of-state providers. In addition to receiving lower rates than in-state providers in some cases, out-of-state providers typically do not receive supplemental payments, further widening the disparities in reimbursement for what are often lifesaving treatments.

6d. Reduce barriers to out-of-state access due to social determinants of health drivers. Federal law could be amended to mandate all states cover travel, lodging, meals, and attendants, rather than leaving it up to ambiguous regulations and a patchwork of approaches across the states in the Medicaid program, and to further mandate that QHPs develop similar benefits for individuals who meet certain means tests.

Pathway 4:
Increasing Transparency of Plan Network Composition and Performance

One of the primary tools that federal and state regulators can wield to ensure equitable access to blood cancer care is the authority to require insurance plans to report on various metrics. Regulators can use that data to monitor and enforce adherence to existing standards, and to inform future policy design. States vary in their reporting requirements for individual market plans and Medicaid MCOs and how states use that information to enforce access requirements. Further, there is variability in whether and how that information is reported to the public, which who could then use that information to make decisions about plan selection in the individual market or in Medicaid managed care.[i]

07 RECOMMENDATION #7: STRENGTHEN REPORTING REQUIREMENTS AND MONITOR PERFORMANCE RELATED TO PLAN NETWORKS AND ACCESS TO CARE.

7a. Strengthen monitoring and reporting on appeals, grievances, and fair hearings.

For MCOs, CMS issued a new mandatory reporting template in June 2021 that requires reported data on the number of appeals in general categories such as inpatient, outpatient, drugs, skilled nursing facility, dental, and others.[42] This level of detail is insufficient to adequately assess access to subspecialty cancer care.

At a minimum, states should require data be reported to monitor the diagnoses and specialties most commonly associated with appeals, grievances, and fair hearings related to timely access to care, including:

- Denied, limited, or delayed authorization of a service
- Denied, limited, or delayed authorization of a patient's request to receive services from an out-of-network provider including second opinions
- Denied, limited, or delayed authorization of a patient's request to receive services from an out-of-state provider

Better, more detailed characterizations of the reasons for denials are also needed. While in some cases, these data are reported at the *aggregate plan level,* the reasons reported for denials can be nonspecific. In a recent analysis of claim denials and appeals in QHPs, 70% of denials reported were characterized as "other" as the underlying reason.[43]

In addition, data on the number of single-case agreements and the associated specialties, diagnoses, and treatments associated with them should be reported.

States should be required to report these data to CMS for QHPs and Medicaid MCOs, and to assess how those diagnoses/specialties resulting in the most single-case agreements compare to the overall average on metrics such as frequency of appeals and grievances, the proportion of appeals that result in service approvals, and the average time frame for appeal resolution. If substantial discrepancies are identified, plans should be required to offer an explanation for the discrepancies and a proposed strategy to mitigate them.

i These requirements would apply over and above state/federal oversight of network adequacy and timely access, which may include data-driven standards such as maximum wait times. These monitoring and reporting requirements are retrospective and intended to identify access problems that may exist. The network adequacy and timely access standards themselves and associated enforcement by regulators are critical prospective functions to avoid access problems, to begin with.

Several states have requirements in place for plans to report these data to the state in a more limited fashion than is recommended here. **California**, for example, passed a law in 2021 requiring annual public reporting of health care complaints for state-regulated plans that include written or oral complaints, grievances, appeals, independent medical reviews, hearings, and similar processes. The data are not reported at the specialty or service level but rather within particular geographies and broad, high-level service categories.[44]

7b. Strengthen monitoring and reporting on utilization.

Federal and state regulators should also utilize existing data sources, such as APCDs and Transformed Medicaid Statistical Information System data, to identify outlier plans with low utilization of high-impact innovation therapies, which can be used to identify access barriers due to narrow networks, inadequate reimbursement, or unreasonable and burdensome PA processes. At the minimum, CMS should track the utilization of treatments that have been designated by the Food & Drug Administration as "breakthrough therapies," a designation for "drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy."

In one anecdote collected by the authors from an NCI-designated cancer center, any patient requiring a new and high-cost CAR T-cell treatment requires a single-case agreement, and it is not uncommon for approval from a Medicaid plan to take more than one year. Patients eligible for CAR T-cell therapy often have a very short window for curative treatment. CMS could work with patient advocacy organizations, providers, and other stakeholders to identify additional specialized treatments that should be monitored for signs of potential access barriers that may include:

- Inadequate access to specialty providers due to a combination of narrow provider networks, gatekeeping requirements, and burdensome procedures for out-of-network or out-of-state access
- Unduly restricted coverage
- Inadequate reimbursement
- Unreasonably burdensome processes for PA

Pathway 5:
Elevating Patient-Facing Support for Plan Selection and Navigation of Coverage and Treatment

Federal and state policymakers and regulators can improve consumers' ability to make informed plan selections. Today, the details of coverage are not always offered in a clear, accessible manner. Moreover, when consumers are choosing an insurance plan, they typically *don't* expect to ever receive a blood cancer diagnosis. Instead, they simply assume insurance will provide protection in the event of this (or any other) unlikely diagnosis. As a result, the detailed nuances of a plan's provider network and benefit design are often not be part of their calculation.

These issues are important since many consumers enrolled in Medicare, Medicaid, and the commercial market have the ability to shop between plans.[45]

Further, the complexity of the coverage and treatment journey for many, particularly those without caregivers, can be so daunting that patients are unable to pursue all avenues available to them to secure medically appropriate treatment.

08 RECOMMENDATION #8: ENHANCE MINIMUM STANDARDS FOR NETWORK COMPOSITION DISCLOSURE AND PROVIDER DIRECTORIES.

Empowering consumers with more robust information about the plans from which they are selecting will help those with blood cancer or concerned about cancer fully assess their options. Aside from provider directories, which must be furnished to consumers as they navigate the selection of a plan, consumers receive very little information about the breadth and quality of the networks they can choose from–and what information consumers do receive often is not provided in an accessible manner. Consumers for whom the information is accessible may spend more time evaluating issues such as the range of specialists available to them in network or research providers in their region for indicators of "quality." But most do not, and even when they do, the provider directories they find may be inaccurate or out of date. New requirements for provider directories under the No Surprises Act will positively impact consumer access to timely and updated information, but it is unclear what impact these will have on plan selection.

Under new Marketplace rules that will go into effect in 2023 in the FFM, QHPs will be ranked as having networks that are Basic (<30% of available providers), Standard (30%-69%), or Broad (70% or more).[46] This represents a positive first step and can be replicated across all QHPs (including those in SBMs) and in Medicaid managed care and further refined over time, as information available to regulators about provider networks in the states via data and tools such as APCDs allows for more granular measures of network breadth at the specialty and subspecialty levels. For cancer specifically, it is not sufficient to list hematology/oncology physicians. Plans should develop a list of disease-site cancer specialists–those physicians who devote greater than 50% of their clinical practice to a specific cancer disease site such as the breast, lung, colon, or blood. This type of information should also be required to be provided to enrollees *upon receiving* a diagnosis, to better assist them in finding an appropriate subspecialist.

Other information that could be collected and provided to consumers about their plans that would positively impact their ability to make informed decisions includes clearer details on plan-level appeals, grievances, and single-case agreements, as discussed in Recommendation #6. This information should be summarized and reported for consumers as an additional measure of network breadth and quality. In 2020, a proposed rule would have required disclosure of some/all of the following: average length of time to respond to PA requests, percentage of service denials, the average duration of appeal pendency, and percentage of service denials overturned on appeal. It is unclear whether those elements will be included in the forthcoming Biden administration rule on PA, but these represent positive, consumer-friendly data points that could inform plan selection.

09 RECOMMENDATION #9: ENSURE PATIENTS AND CONSUMERS HAVE ACCESS TO UNBIASED, INDEPENDENT PATIENT ADVOCATE AND NAVIGATOR SUPPORT.

Today, navigating access to the right provider and course of treatment, including a clinical trial, remains largely a challenge the patient bears in partnership with a primary care physician or the initial treating oncologist. Patients who are ill and may not have the support of a family or personal caregiving team must largely carry this burden, with respect to both navigating coverage complications and treatment, which only worsens the overall stress of the situation when the sole focus of patients should be on getting better.

Many of the cancer centers the authors interviewed noted that they often provide cancer clinical navigation services to patients and in some cases, provide dedicated resources for navigation of insurance, including PA, and appeals as needed, *once they are referred to a center for treatment*. These services are largely non-reimbursable, and the costs are borne by these centers.

Innovation is needed to address this personal and financial burden borne by both patients and providers.

9a. Clinical navigation support. Many Medicaid programs and MCOs offer navigation/coordination/case management services to certain groups of patients. States could require MCOs and QHPs to provide these types of support through a third-party, independent function to individuals who receive a serious cancer diagnosis. This support service would intersect with several recommendations above regarding securing second opinions and navigating certain aspects of the treatment journey. While treating clinical teams will likely be the best source of navigation support for finding optimal treatments and trials, navigators can alleviate some of the administrative burdens that result from those activities.

9b. Support for appeals. In the Medicaid program, MCOs are already required to "give enrollees any reasonable assistance in completing forms and taking other procedural steps related to a grievance or appeal." While such assistance is helpful in theory, anecdotes collected by the project team revealed that the assistance isn't very good in practice, especially when it comes to actually building the case for reversing a service denial.

It is not uncommon for well-resourced (or particularly kindhearted) providers to assist patients with their appeals over and above the often burdensome process of requesting PA in the first place. In an effort to support providers who dedicate resources and work with beneficiaries to navigate appeals (and other coverage processes) and to disincentivize plans from erring on the side of service denials in hopes that the patient will not appeal, states could require that, in a scenario where a provider assists a patient with a successful appeal concerning care for a serious or life-threatening condition, the plan pay the provider a fee for "patient navigation support." This could also be adopted more broadly as a required benefit in QHPs. Given the unique complexity of cancer care, this type of benefit is important.

9c. Consumer assistance programs. The ACA provided grants to states to establish "consumer assistance programs (CAPs)" that support consumers in navigating both health care coverage options and problems with their health insurance, including complaints and appeals. CAPs also play a key role in collecting, tracking, and quantifying problems that could be elevated for action by state policymakers and regulators. Today, 20 states no longer offer these CAPs, and all others operate them without federal support.[47] In some cases, this has meant drastic reductions in the capacity and capability of these programs and supports, limiting their success in helping patients. Federal action could re-fund these programs and provide long-term sustainability to ensure capacity and consistency across the states in providing this service to consumers navigating the complex insurance landscape.

04 CONCLUSION

The struggle to ensure access to a fair and equitable system of care for blood cancer patients is likely to continue for decades. However, as this report makes clear, there are very reasonable steps that federal and state policymakers and regulators can take to begin to address long-standing and systemic barriers. We increasingly have the data and tools at our disposal to inform new approaches to setting and maintaining standards for access and for setting new policies for the way insurance plan networks and benefits are designed to meet the complex needs of blood cancer patients.

The journeys in the patient stories below could have been significantly different, had these recommended policy changes been in place.

- JJ's (p. 6) son Mason could have had a vastly improved experience getting care in Texas, with his care more easily transferred to the treating team in Texas from California under his Medicaid coverage, with the treating facility reimbursed and support for the families' travel costs covered. His prescriptions could have been available from pharmacies in Texas, not requiring family members to purchase in and mail from California. It is uncertain that Mason would have survived long-term, but the overall experience and the burden on the family and the community that lifted them up might have been significantly lighter.
- Hannah's (p. 18) insurance company could have paid for the treatments for which it was responsible without intervention from her navigating appeals and unnecessary battles. She would have saved hundreds of hours, and not had the added stress of financial issues on top of her physical battle with the disease. Her story mirrors that of so many families across the country. But it is a cautionary one, as so many are not as tenacious in their battle to get what they are entitled to from their insurance company. Many just pay or go bankrupt.
- Chris (p. 21) could have returned to the United States and had a similar experience as he had overseas in navigating his ongoing monitoring for cancer recurrence. He would not have spent hours navigating denials for routine follow-up monitoring that his treating physician agreed was medically necessary to confirm the success of his treatment and remission, and would not have even had to consider paying out of pocket for scans that should have been covered.

In the coming years, policymakers at the state and federal levels must continue to refine standards for access in the insurance markets they regulate, to better account for the nature of treating cancer. States offer the opportunity to test innovative new standards for access and policies that make better tools and resources available to blood cancer patients to navigate their coverage and treatment journey. In certain areas, direct federal action can be taken, particularly as we see positive evidence in the states of different approaches meaningfully improving access, reducing disparities, and improving positive treatment outcomes.

A patient's access to necessary care–whether new standard-of-care treatments or a clinical trial–should not depend on the type of insurance they have or unduly burdensome operational practices in insurance plans.

ENDNOTES

1 Leukemia and Lymphoma Society Updated Data on Blood Cancers. 2021. Internet. Available from: https://www.lls.org/sites/default/files/2021-08/PS80%20FactsBook_2020_2021_FINAL.pdf.

2 Yasaitis L, Bekelman JE, Polsky D. Relation Between Narrow Networks and Providers of Cancer Care. *Journal of Clinical Oncology*. 2017 Sep 20;35(27):3131–5.

3 Suh W, Master S, Liu L, et al. (February 13, 2021). The Effect of Payer Status on Survival of Patients With Prostate Cancer. *Cureus*. 13(2): e13329. doi:10.7759/cureus.13329.

4 Accessing Out-of-Network Subspecialty Cancer Care in Marketplace Plans: Key Findings from a Scan of Four States [Internet]. Leukemia & Lymphoma Society and Manatt Health Strategies. Available from: https://www.lls.org/sites/default/files/2021-06/Network-Adequacy-June-2021-Final.pdf.

5 Kaiser Family Foundation, "Medicaid Managed Care Penetration Rates by Eligibility Group" (last updated July 1, 2019), https://www.kff.org/medicaid/state-indicator/managed-care-penetration-rates-by-eligibility-group/.

6 National Cancer Institute, *Cancer Disparities*. [Internet]. Available from: https://www.cancer.gov/about-cancer/understanding/disparities; Zavala VA, et al., Cancer Health Disparities in Racial/Ethnic Minorities in the United States, *British Journal of Cancer* (2020), doi:10.1038/s41416-020-01038-6; Falcone M, et al., Evidence for Racial/Ethnic Disparities in Emergency Department Visits Following Breast Cancer Surgery Among Women in California: A Population-Based Study, *Breast Cancer Research & Treatment* (2021), https://doi.org/10.1007/s10549-021-06119-5.

7 Cancer Action Network. Cancer disparities: a chartbook. American Cancer Society Cancer Action Network. Accessed June 15, 2021. https://www.fightcancer.org/sites/default/files/National%20Documents/Disparities-in-Cancer-Chartbook.pdf.

8 American Association for Cancer Research. AACR cancer disparities progress report 2020. Accessed June 15, 2021. https://cancerprogressreport.aacr.org/wp-content/uploads/sites/2/2020/09/AACR_CDPR_2020.pdf.

9 Tong M, Hill L, Artiga S. Racial disparities in cancer outcomes, screening, and treatment. Kaiser Family Foundation. Accessed June 1, 2022. https://www.kff.org/racial-equity-and-healthpolicy/issue-brief/racial-disparities-in-cancer-outcomes-screening-and-treatment/.

10 Osarogiagbon RU, Sineshaw HM, Unger JM, Acuna-Villaorduna A, Goel S. Immune-based cancer treatment: addressing disparities in access and outcomes. *Am Soc Clin Oncol Educ Book*. 2021;41:1-13. doi:10.1200/EDBK_323523.

11 Kaiser Family Foundation, Medicaid Coverage Rates for the Nonelderly by Race/Ethnicity (2019), https://www.kff.org/medicaid/state-indicator/nonelderly-medicaid-rate-by-raceethnicity/?; U.S. Census, QuickFacts (2019). https://www.census.gov/quickfacts/fact/table/US/PST045219.

12 Parikh-Patel A, et al. Disparities in Quality of Cancer Care: The Role of Health Insurance and Population Demographics. *Medicine* (2018), doi:10.1097/MD.0000000000009125; *see also* Ellis RJ, et al. Failure to administer recommended chemotherapy: acceptable variation or cancer care quality blind spot? *BMJ Quality & Safety* (2021). doi:10.1136/bmjqs-2019-009742.

13 2022 CMS Strategic Framework. Centers for Medicare & Medicaid Services. [Internet]. Available from: https://www.cms.gov/files/document/2022-cms-strategic-framework.pdf.

14 Social Security Act § 1902(a)(30)(A).

15 42 C.F.R. Part 447, Subpart B.

16 Social Security Act § 1932(b)(5).

17 45 CFR Parts 144, 147, 153, 155, 156, 158.

18 45 CFR Parts 144, 147, 153, 155, 156, 158.

19 Health and Dental Benefit Plan Network Adequacy. NH Ins 2701.

20 45 CFR Parts 144, 147, 153, 155, 156, 158.

21 For published data documenting similar exclusion of NCI-designated comprehensive cancer centers from the networks of commercial plans offered on the Marketplace, see Schatz A, Winckworth-Prejsnar K. Survey of NCI-Designated Cancer Centers Finds Most Are Out-of-Network on Exchanges, *American Journal of Managed Care* (2018), https://www.ajmc.com/view/survey-of-ncidesignated-cancer-centers-finds-most-are-outofnetwork-on-exchanges; Leukemia & Lymphoma Society, Accessing Out-of-Network Subspecialty Cancer Care in Marketplace Plans (June 2021). https://www.lls.org/sites/default/files/2021-06/Network-Adequacy-June-2021-Final.pdf.

22 NCI-Designated Cancer Centers Overview. https://www.cancer.gov/research/infrastructure/cancer-centers.

23 New York State Assembly Bill A9007C. https://www.nysenate.gov/legislation/bills/2021/a9007/amendment/c

24 Van Such M, Lohr R, Beckman T, Naessens JM. Extent of diagnostic agreement among medical referrals. *J Eval Clin Pract*. 2017;23:870-874. https://doi.org/10.1111/jep.12747.

25 DOI: 10.1200/JOP.091099 Journal of Oncology Practice 6, no. 3 (May 01, 2010) 170-171.

26 42 USC § 1396d(a)(30), (gg).

27 Mandatory Medicaid Coverage of Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials. Letter to State Medicaid Directors, April 13, 2022. https://www.medicaid.gov/federal-policy-guidance/downloads/smd21005.pdf.

28 *See* CMS, NCD for Routine Costs in Clinical Trials (310.1) (effective July 9, 2007). https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1.

29 2021 AMA Prior Authorization Physician Survey. American Medical Association. https://www.ama-assn.org/system/files/prior-authorization-survey.pdf

30 Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care. Office of the Inspector General. Report. Accessed Online. [Internet]. https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf.

31 42 CFR 422, 431, 438

32 2021 AMA Prior Authorization Physician Survey. American Medical Association. https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

33 2019 CAQH Index. Conducting Electronic Business Transactions. https://www.hfma.org/topics/news/2020/01/prior-authorization-cost-and-time-burdens-increase-for-providers.html.

34 ClinicalPath Evidence-based oncology decision support and analytics for cancer care. https://www.elsevier.com/solutions/clinicalpath.

35 Evidence-based Oncology Pathways. Phillips. https://www.usa.philips.com/healthcare/solutions/diagnostic-informatics/oncology-informatics/pathways#triggername=close_pathways_tabs.

36 Moffitt Cancer Center Clinical Pathways. https://moffitt.org/treatments/clinical-pathways/.

37 Massachusetts Quality Cancer Care Program FAQs. https://provider.bluecrossma.com/ProviderHome/wcm/connect/16a2758f-aa92-4172-86d3-e3c0001f0527/Blue+Cross+Quality+Care+Cancer+Program+FAQ_FINAL+MPC_011819-1U-9-QA.pdf?MOD=AJPERES.

38 California Senate Bill 855. CA SB-855.

39 Medicaid Payment Policy for Out-of-State Hospital Services. MACPAC Issue Brief. https://www.macpac.gov/wp-content/uploads/2020/01/Medicaid-Payment-Policy-for-Out-of-State-Hospital-Services.pdf.

40 42 CFR § 431.52(b).

41 Guidance on Coordinating Care Provided by Out-of-State Providers for Children with Medically Complex Conditions. CMS Informational Bulletin. https://www.medicaid.gov/federal-policy-guidance/downloads/cib102021.pdf.

42 Medicaid and CHIP Managed Care Monitoring and Oversight Tools. CMS Informational Bulletin. https://www.medicaid.gov/medicaid/managed-care/guidance/medicaid-and-chip-managed-care-reporting/index.html#AMCPR

43 Pollitz, K, Rae, M., and Mengistu, Ss. Claims Denials and Appeals in ACA Marketplace Plans in 2020. Kaiser Family Foundation. https://www.kff.org/private-insurance/issue-brief/claims-denials-and-appeals-in-aca-marketplace-plans/.

44 AB 172 (Chapter 696, Statutes of 2021).

45 Health Insurance Coverage of the Total Population. Kaiser State Health Facts. https://www.kff.org/other/state-indicator/total-population/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

46 Notice of Benefit and Payment Parameters for 2023 Final Rule Fact Sheet. CMS. https://www.cms.gov/newsroom/fact-sheets/hhs-notice-benefit-and-payment-parameters-2023-final-rule-fact-sheet

47 Consumer Assistance Program. Overview from CMS. https://www.cms.gov/CCIIO/Resources/Consumer-Assistance-Grants.