COA PRESCRIPTION FOR HEALTH CARE REFORM: A POLICY BLUEPRINT FOR CONGRESS

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EXECUTIVE SUMMARY

A Health Care System in Crisis

The United States health care system has reached a critical tipping point. For more than two decades, systemic challenges have compounded while policymakers have failed to implement meaningful reform. As a result, Americans are paying more for health care that is harder to access, more bureaucratic, and with lower quality and outcomes. Consolidation, administrative burdens, and unsustainable escalating costs are frustrating patients and providers in an increasingly broken system. If Congress does not act now, these challenges will become even more entrenched, leading to worse outcomes for patients, higher costs, and fewer choices.

At the heart of this crisis lies the unchecked consolidation of hospitals, health systems, and corporate intermediaries, specifically insurers and their affiliated pharmacy benefit managers (PBMs). These mega-entities now dominate the health care market, prioritizing profits over patient care. Nonprofit hospitals have transformed into sprawling health systems that leverage tax benefits and federal programs—notably, the 340B Drug Pricing Program (340B)—to grow, increasingly at the expense of independent physician practices and local care options. Independent community oncology practices and other independent providers, such as independent pharmacies, long the foundation of American medicine, are being forced to close or consolidate simply to survive.

The result? Patients pay more and wait longer for care, while health care deserts emerge in rural and underserved communities. Meanwhile, the strain on independent medical practices, which provide essential, community-based medical care, threatens to push more patients into high-cost hospital systems. This system, designed to prioritize care at the local level, is at risk of collapsing under the weight of systemic inequities and inefficiencies.

To address these issues, the Community Oncology Alliance (COA) has developed the ***COA Prescription for Health Care Reform***. This five-part plan outlines targeted solutions to stabilize the system, prioritize patients, and protect access to high-quality, affordable care. Grounded in more than two decades of experience advocating for independent community oncology, this plan draws on insights from oncologists, pharmacists, practice administrators, and other health care experts.

A Five-Part Prescription for Reform

The ***COA Prescription for Health Care Reform*** is a comprehensive, actionable framework designed to address the systemic flaws in the U.S. health care system, including those impacting not only cancer care, but all medical care. Structured as a five-part plan, it diagnoses the root causes of inefficiencies, inequities, and rising costs while providing detailed, practical treatments to stabilize the system and prioritize patients.

1. **Addressing Hospital Consolidation:** For too long, hospitals have been permitted to consolidate into monopolistic mega "nonprofit" systems that raise costs, reduce provider choice, and limit competition. Reform must begin with site-neutral payment policies to ensure fairness in reimbursements, an overhaul of 340B to ensure patients are benefiting as Congress originally intended, an examination of what a "nonprofit" institution means, and restrictions on aggressive debt collection practices. Reimbursement must reflect the true costs of care and prioritize patient needs over system profits.
2. **Addressing Insurer/PBM Consolidation and Market Dominance:** Insurers and PBMs wield disproportionate power, inflating costs, and limiting access. Transparency in PBM operations, accountability for formulary practices, and protections against prior authorization delays are critical. Laws must prevent PBMs from steering patients toward affiliated pharmacies or imposing mandatory mail order requirements. Furthermore, insurers and their PBMs must divest themselves from owning any type of pharmacy. Strengthened Medicare Advantage guardrails will also protect patients and providers from restrictive and anticompetitive practices.
3. **Fixing Physician Reimbursement and Workforce Shortages:** Independent medical practices are buckling under outdated Medicare reimbursement models. Immediate reforms should halt Medicare Physician Fee Schedule (MPFS) cuts, align reimbursements with inflation, and eliminate harmful payment sequestration. To address workforce shortages, Congress must expand residency positions, offer incentives for rural practice, and ensure that reimbursement models adequately support practices in underserved areas. The Centers for Medicare & Medicaid Services (CMS) must be forced to enforce existing laws to stop hospitals from grossly overpaying their employed providers.
4. **Ensuring Access to Oncology Therapies:** Rising drug costs, chronic shortages of generic sterile injectable (GSI) drugs, and uncertainty in the biosimilar market jeopardize access to affordable cancer therapies. Reforms must address supply chain issues,

stabilize pricing for GSIs and biosimilars, and technically fix the Inflation Reduction Act (IRA) to protect independent medical practices from financial harm due to Medicare price negotiations. Insurer and PBM practices that restrict access to biosimilars through restrictive formularies and rebate-driven preferences must be reformed to ensure these cost-saving alternatives are accessible and sustainable.

5. **Modernizing Structural CMS Medicare Policies:** Medicare's fragmented and outdated payment system perpetuates inefficiencies and fuels consolidation. A payment approach that better balances equitable reimbursements across hospitals and independent practices is essential to a level, free market playing field. Oversight of the Center for Medicare and Medicaid Innovation (CMMI) must also be strengthened, ensuring its models align with patient-centered care and do not exacerbate administrative burdens or encourage consolidation.

This is just an executive summary of the five-point prescription for reform; there is much more detail in the full document. Each section of the prescription focuses on a critical aspect of reform—ranging from curbing consolidation and strengthening the health care workforce to ensuring access to life-saving therapies and modernizing outdated Medicare policies. The plan is tailored for immediate legislative action by the 119th Congress, with forward-looking recommendations for the 120th Congress and beyond. The intent is clear: to provide Congress with a blueprint for bold, meaningful reform that protects the independent community medical practices, which ensure patient access to high-quality, affordable medical care, and safeguards the financial sustainability of the health care system for patients and providers alike.

A Legislative Blueprint for All Areas of Medicine

The challenges and solutions outlined in the ***COA Prescription for Health Care Reform*** extend far beyond oncology. While the framework is rooted in the experience of community oncology practices, the systemic issues it addresses—consolidation, inequitable payment structures, workforce shortages, escalating costs, and access barriers—are universal across all of health care. Oncology serves as a lens for broader reform because it is one of the most multifaceted areas of health care, encompassing complex care delivery, diverse treatment modalities, and interactions with every aspect of the health care system.

From diagnostics and genetic testing to drug access and care coordination, the obstacles facing oncology providers mirror those encountered in other specialties. The recommendations within this document—such as rebalancing payments, improving workforce incentives, increasing transparency, and curbing consolidation—are applicable across the board. They aim to protect the independence of providers, enhance patient access, and restore competition, creating a framework for meaningful reform that benefits all specialties and the patients they serve. By addressing these shared systemic issues, the ***COA Prescription for Health Care Reform*** offers a scalable, specialty-agnostic blueprint for rebuilding a sustainable and equitable health care system.

The Time for Congress to Act is Now!

The status quo is unsustainable. The post-pandemic health care landscape has exposed and intensified systemic weaknesses. With rising costs, the implementation of the IRA, and bipartisan acknowledgment of the need for reform, this moment presents a rare and urgent opportunity for transformative action.

Every day Congress delays action, patients face higher costs, fewer choices, and worsening outcomes. Independent physician practices, which provide personalized, community-based, and affordable care, are disappearing under the weight of consolidation, administrative burdens, and outdated payment policies. Additionally, pharmacy deserts are popping up across the country. The systemic inequities and inefficiencies of the U.S. health care system are no longer just cracks—they are chasms, threatening to swallow the foundation of patient-centered care.

This is a once-in-a-generation opportunity to confront the rot at the core of our health care system. Congress must act decisively to break the cycle of consolidation and restore transparency, competition, and equity in health care. The ***COA Prescription for Health Care Reform*** provides an action plan to do this. This is not just a legislative imperative but a moral one. The time for action is now. The lives of millions of Americans—and the future of our health care system—hang in the balance.

INTRODUCTION

The United States health care system faces profound challenges stemming from unchecked consolidation within the greater health care sector. Consolidation has intensified at an alarming rate over the last two decades, particularly among health insurers, associated middlemen—notably, PBMs—and, as profoundly, the aggregation of hospitals into mega "nonprofit" health systems. Over time, these entities have fought to gain leverage over one another, steadily growing in power and fighting for market dominance. This has increased their ability to pressure independent physicians to merge or close their practices, thus reducing competition and continuing the cycle of consolidation.

While all health care system stakeholders share responsibility for the complexity and rising costs of medical care, the federal government has fueled consolidation through a vicious cycle of inaction and misaligned public policies. The Department of Health and Human Services (HHS) and its CMS, tasked with overseeing the U.S. health care system, have failed to align incentives that support a truly free-market ecosystem. Government regulators have disadvantaged independent physicians, who are documented as delivering high-quality, affordable medical care in communities across the country, while facilitating hospital consolidation. During the same time, Congress has largely stood on the sidelines, making at best minor adjustments and at worst passing legislation with unintended adverse consequences, while the country's health care system increasingly deteriorates.

Numerous data-backed studies clearly show that health system consolidation has resulted in worse systemic inefficiencies, limited patient choice, and increased costs, all without delivering improved outcomes or patient care. Consolidated mega nonprofit hospital systems and combined insurer and PBM conglomerates are profiting off the backs of American patients and taxpayers who face significantly increased costs of medical care. In short, health care consolidation remains unchecked to the detriment of Americans.

This document is the ***COA Prescription for Health Care Reform*** for the current 119th United States Congress and beyond. This five-part plan outlines targeted solutions to stabilize the system, prioritize patients, and protect access to high-quality, affordable care. It is specifically focused on what Congress needs to do to pass effective and relevant legislation to stop the decline of the country's health care system. It presents the fundamental **upstream challenges** our health care system faces, the **downstream consequences** for patients across America, and our recommended congressional **legislative solutions**. In short, it diagnoses the problems and then prescribes the treatment needed to heal what ails our health care system. There is much more to health care reform than what Congress can do, but congressional legislation is a significant and meaningful start given the breadth and influence of Medicare, Medicaid, and other federal health care programs.

Although the ***COA Prescription for Health Care Reform*** is presented through the lens of the specialty of oncology—which is among the most comprehensive and multifaceted areas in health care—the recommendations apply across virtually all medical specialties in health care. Reforming health care is a Herculean task that must involve every stakeholder in the system. This includes not only our federal and state governments but also the myriad of other stakeholders in the system, including patients, physicians, employers, and pharmaceutical manufacturers.

The overwhelming market power wielded by insurers and their owned or affiliated PBMs (referred to as "insurers/PBMs" for simplicity in this document), exacerbated by consolidated health systems, has forced independent physicians, including community oncology practices, in recent years to collaborate to explore new survival strategies. Some might call this consolidation, but it's fundamentally different; it is a true David versus Goliath battle. Unlike the mega hospital systems that continue to expand their dominance in an increasing number of markets, the alliances formed in community oncology and other independent physician specialties are designed to withstand immense consolidation pressures in order to preserve their independence and survive. By forming innovative networks and service agreements, these practices can share resources, negotiate more effectively, and continue to provide high-quality, patient-centered, and affordable care in local communities, surviving against formidable odds. It is either innovate, join forces, or be absorbed by insurers or large hospital systems.

The market dynamics in oncology and the experiences of independent community oncology physicians and allied medical professionals, combined with the collective expertise and knowledge of COA, our members, and consultants, have all contributed to the crafting of this ***COA Prescription for Health Care Reform***. These recommendations are informed by our experiences and strategies for delivering excellent, patient-centered care in communities across the country in the face of escalating consolidation pressures.

The ***COA Prescription for Health Care Reform*** is intended to serve as a call-to-action and policy blueprint for the 119th Congress, as well as beyond, to seriously address the nation's health care system crisis with urgency. We have sat at the edge of an escalating crisis for far too long, and it is time for our elected officials to act before it is too late and beyond repair. The lives of Americans with cancer and other serious diseases are counting on it.

Defining Community Oncology and the Community Oncology Alliance

Independent Community Oncology:

Community oncology refers to physician-owned and led independent oncology practices that are not owned or operated by a hospital, health system, academic medical center (collectively referred to as "hospitals" in this document), or a health insurer. Independent community oncology practices are where the majority of Americans with cancer receive their care. There are more than 15,000 community oncologists, pharmacists, nurses, and other clinical professionals spanning 3,750 practice locations treating patients in nearly every U.S. state and territory. Independent community oncology provides patients with high-quality, affordable, personal, cutting-edge, and equitable cancer care close to where they live and work.

Community Oncology Alliance:

The Community Oncology Alliance (COA) is a nonprofit organization dedicated to advocating for community oncology practices and, most importantly, the patients they serve. COA is the only organization dedicated solely to community oncology where the majority of Americans with cancer are treated. The mission of COA is to ensure that patients with cancer receive quality, affordable, and accessible cancer care in their own communities.

WHAT IS THE COA PRESCRIPTION FOR HEALTH CARE REFORM?

The ***COA Prescription for Health Care Reform*** is a comprehensive policy blueprint for Congress to enact meaningful health care reform through legislation. This "prescription" is divided into three targeted sections:

1 Diagnosis of What Ails the Current Health Care System

A clear, evidence-driven analysis of the current health care system's failures—why it has become overly complex, prohibitively expensive, and increasingly ineffective for patients and providers alike.

2 Prescription and Treatment Blueprint for the 119th Congress

Actionable steps the 119th Congress must take to address these critical issues now. This includes specific legislative and regulatory changes designed to tackle the system's most pressing problems immediatley.

3 Ongoing Treatment Plan for the 120th Congress and Beyond

Ongoing steps for future Congresses (120th and beyond) to implement comprehensive, sustainable reforms that solidify progress and address evolving challenges within the health care system.

The ***COA Prescription for Health Care Reform*** is framed from the perspective of oncology, a specialty that offers an expansive view of the health care landscape and diverse patient journeys, including diagnostics, genetic testing, surgery, radiation, and a wide range of therapies and medications (infused and oral), all delivered across multiple sites of care and payers (Medicare, Veterans Administration, commercial insurers, employers, etc.). This breadth of experience provides oncologists with a unique perspective of what is wrong with the health care system in general and specifically relating to cancer care.

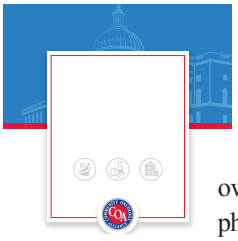
Through this "prescription," COA aims to identify key legislative priorities and recommend "treatments" that ensure patients have access to the highest quality, most affordable medical care in their own communities. Our approach not only addresses cancer care but also provides scalable solutions applicable across other medical specialties and the broader health care system.

WHAT AILS HEALTH CARE? CONSOLIDATION.

In one word, *consolidation* is the root problem plaguing the U.S. health care system. It is driven by financial motivations, rather than clinical outcomes and patient wellbeing. It drives up costs while limiting patient choice. The hyper-consolidation that exists today is driven by several key factors including:

1. Hospital consolidation

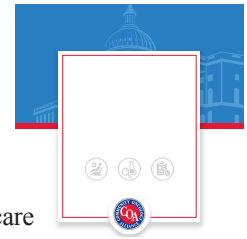
With access to the significant and increasing revenue that 340B generates, hospitals have enormous financial advantages and incentives to dominate the landscape via consolidation. Targets include other hospitals and physician-owned practices, especially in oncology. The immense capital enjoyed by 340B hospitals has allowed them to consolidate their markets in specialty care through acquisition or expansion, such as in oncology where expensive drugs generate enormous 340B drug discounts and drug margins.[1 2]



The current physician payment and reimbursement system is unsustainable in the face of escalating hospital consolidation. This makes it difficult, if not impossible, for independent practices to remain viable. Many physician-owned practices are ultimately forced to close, merge with a hospital, or for their physicians to simply retire as the physician workforce is aging.[3 4 5 6] The disappearance of physician-owned practices is not only a result of hospital consolidation but also is fueling it.

2. Vertical integration of insurers, PBMs, mail order specialty pharmacies, and employed physicians

Vertical integration of these key groups has created an environment where the financial interests of corporations dominate over clinical decision-making and patient wellbeing. Decisions about patient care are increasingly made by corporations focused on profits rather than health outcomes, taking away clinical decision-making from physicians and introducing significant economic and operational burden.[7]



Not only have insurers merged with pharmacies of all types—retail, specialty, and mail order—and PBMs, but they have also acquired physicians. For example, it is noteworthy that as of 2023, 90,000 doctors, or 10 percent of the physician workforce in this country, were employees of, or affiliated with, the largest health care insurer, UnitedHealthcare.[8]

The forces of consolidation in our health care system are like a growing cancer that Congress is not even patching with band-aids, let alone fundamentally attempting to cure. If the tumor of consolidation remains unchecked, it will continue to spread and threaten the viability of independent physicians while pricing health care beyond the means of most Americans. Congress must address health care system consolidation immediately before it metastasizes and becomes incurable.

CHAPTER 1:
Addressing Hospital Consolidation: Diagnosis, Prescription, and Treatment

ADDRESSING HOSPITAL CONSOLIDATION: DIAGNOSIS

Trend: Hospital consolidation has surged over the last 30 years, leading to a rise in mergers, acquisitions, and physicians employed by hospitals.[9] [10] This trend has driven the formation of large mega hospital systems that prioritize "profitability" over clinical objectives and patient wellbeing, resulting in highly concentrated markets where there is little meaningful competition.[11] [12] Also contributing to hospital consolidation is the payment differential between different sites of care—the more expensive hospital setting versus far less expensive independent physician practices. Research has found that payment differentials by site of care create incentives to consolidate health care markets.[13]

Patient Impact: Hospital consolidation has significantly increased health care costs and inefficiencies for patients and primary payers (i.e., employers, Medicare, state governments, and other payers) and reduced access.[14] [15] [16] Patients face higher insurance and out-of-pocket costs, restricted choice and access of providers and clinic locations, and greater administrative barriers from administrative red tape.[17] Consolidated hospital systems often result in "medical care deserts" for rural or underserved areas by closing less profitable satellite clinics, forcing patients to travel further for treatment or forego it altogether.[18] The consolidation model also shifts the focus from personalized, community-based care with local providers to a one-size-fits-all depersonalized health care model.[19] Despite promises of improved care coordination and efficiency, hospital consolidation has consistently failed to enhance the quality of care.[20] [21]

The Facts: Hospital-Physician Vertical Integration Results in Higher Costs

Vertical Integration Has Accelerated in the Last Decade

Hospital-physician vertical integration occurs when hospitals acquire independent physician practices or employ physicians to compete with independent physician practices. Hospitals typically force their employed physicians to cut off referrals to independent physicians, which in turn pressures additional independent physicians to become employed by the hospital.[i] Hospital-physician vertical integration has increased rapidly in recent years: from 2007 to 2017, the share of oncology physician practices that were vertically integrated within a hospital increased from 20 percent to 54 percent.[ii]

Consolidation Through Vertical Integration Raises Costs

A recent Health Economics study found that hospital-physician vertical integration is associated with increased Medicare Part B spending on physician-administered drugs. With oncology and hematology drugs, the average spend on these drugs increased 30 percent on a per physician basis after a physician went from being independent to integrated into a hospital. This increase is driven in part by using more expensive drugs, as well as shifts in site of care away from physician offices and toward higher cost hospital outpatient departments, a finding of multiple other studies on hospital-physician vertical integration. [i iii iv]

Sources:

i. *Capps C., et al. "The effect of hospital acquisitions of physician practices on prices and spending." J Health Econ. May 2018.* https://pubmed.ncbi.nlm.nih.gov/29727744/

ii. *Nikpay, Sayeh S., et al. "Hospital-Physician Consolidation Accelerated in the Past Decade in Cardiology, Oncology." Health Affairs. July 2018.* https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.1520

iii. *Levin, Jonathan S., et al. "Impact of hospital-physician vertical integration on physician-administered drug spending and utilization." Health Economics. 2024.* https://pubmed.ncbi.nlm.nih.gov/39533535/

iv. *Jung, Jeah, et al. "The Impact of Integration on Outpatient Chemotherapy Use and Spending in Medicare." Health Economics. 2019.* https://pmc.ncbi.nlm.nih.gov/articles/PMC6405302/

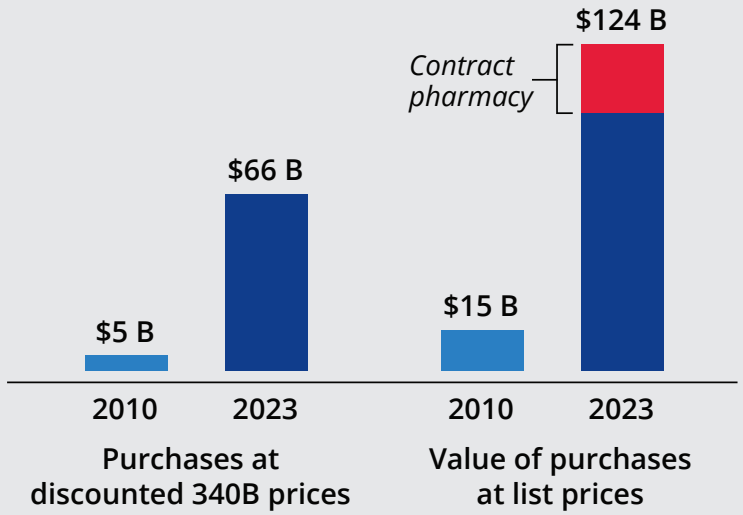
The Facts: 340B Drives Consolidation and Costs

The 340B Program Has Grown Enormously

340B has seen explosive growth in recent years, with no indication of slowing down. A Congressional Budget Office (CBO) analysis revealed that 340B drug spending grew from $6.6 billion in 2010 to $43.9 billion in 2021. Seventy-three percent of this growth is attributed to spending on cancer drugs, anti-infectives, and immunosuppressants.[i] These expensive drugs provide hospitals with substantial drug margins that further fuel consolidation. Unfortunately, a lack of legislative oversight has inadvertently created opportunities for hospitals, as well as vertically integrated PBM pharmacies, to exploit the program's well-intentioned framework, contributing to its massive growth.

In a recent report, the Health Resources and Services Administration (HRSA), which oversees 340B, highlighted that under 340B, drug purchases at discounted 340B spending reached a record of $66.3 billion in 2023, representing a 24 percent year-over-year increase (Figure 1).[ii, iii, iv] According to this report, sales for the top 10 340B drugs accounted for nearly one-third of all 340B purchases. An Avalere analysis compared 340B spending to Medicare spending and found that sales for the top 10 340B drugs exceeded sales for those drugs in Medicare.[v]

Figure 1: 340B Drug Pricing Program, Purchases by Covered Entities iv



Growing evidence shows that many hospitals abuse 340B, acquiring drugs at substantial discounts and generating huge profits. Originally created to serve a small number of safety-net hospitals, the program now covers thousands of covered entities and generates billions of dollars for hospitals.[vi] 340B has created unintended consequences that are harmful to patients and the health care system writ large through increasing prices and consolidation.

Hospitals are able to generate revenue through 340B based on the difference between the drug acquisition cost (discounted to the 340B ceiling price or even lower) and the reimbursement rate. 340B hospitals are not required to pass savings on to patients.

340B Hospitals Provide Inadequate Charity Care

There is little evidence that 340B hospitals are increasing care for underserved populations or using the revenue for charitable purposes. A 2021 study found no evidence that hospitals entering the 340B program increased their care for underserved populations any more than institutions not participating in the program—the core justification for receiving 340B discounts.[vi] A 2019 analysis of charity care data reported by hospitals in fiscal year (FY) 2017 Medicare cost reports reveal that many 340B hospitals are continuing to fall short of Congress' expectations when it comes to providing care to vulnerable patients. While some 340B hospitals provide considerable charity care, nearly one-third (29 percent) of 340B Disproportionate Share Hospitals (DSH) have charity care that represents less than one percent of total patient care costs.[vii] A 2024 study of charity care in U.S. nonprofit hospitals found wide variation in requirements for hospital financial assistance (including extensive paperwork requirements, inconsistent income limits, residency requirements), which pose significant barriers to equitable access to care.[viii]

It should be noted that many smaller rural hospitals use 340B as intended to benefit patients in need and rely on the program to stay viable. It is largely the mega hospital systems that are abusing the program to the detriment of certain smaller 340B providers, including rural hospitals, community health centers, and other 340B grantees.

The 340B Program's Negative Impact to Patients, Health Care Costs, and the Health Care System

The shift of cancer care out of independent community oncology practices and into hospital outpatient sites is costly for both patients and the health care system. Medicare Part B spending is higher in 340B DSH hospitals compared to non-340B hospitals, suggesting that there is a strong financial incentive at 340B hospitals to prescribe more drugs or more expensive drugs to Medicare beneficiaries.[viii] Unnecessary spending has negative implications, not just for the Medicare program, but for Medicare beneficiaries as well, who would be financially liable for larger copayments as a result of receiving more drugs or more expensive drugs.

Sources:

i. *Congressional Budget Office. "Spending in the 340B Drug Pricing Program, 2010 to 2021." 17 June 2024. https://www.cbo. gov/publication/60339*

ii. *Health Resources and Services Administration. "2023 340B Covered Entity Purchases." October 2024. https://www.hrsa.gov/opa/updates/2023-340B-covered-entity-purchases*

iii. *DiGiorgio, Anthony M, and Wayne Winegarden. "Reforming 340B to Serve the Interests of Patients, Not Institutions." JAMA Health Forum. 26 July 2024. https://jamanetwork.com/journals/jama-health-forum/fullarticle/2821579*

iv. *Fein, Adam J. "The 340B Program Reached $66 Billion in 2023—up 23% vs. 2022: Analyzing the Numbers and HRSA's Curious Actions." Drug Channels. 22 October 2024. http://www.drugchannels.net/2024/10/the-340B-program-reached-66-billion-in.html*

v. *Knox, Ryan P., et al. "Outcomes of the 340B Drug Pricing Program: A Scoping Review." JAMA Health Forum, 22 November 2023. https://jamanetwork.com/journals/jama-health-forum/fullarticle/2812107*

vi. *Alliance for 340B Integrity and Reform. "Left Behind: An Analysis of Charity Care Provided by Hospitals Enrolled in the 340B Program." Nov. 2019. https://340Breform.org/wp-content/uploads/2024/03/AIR340_LeftBehind-v6.pdf*

vii. *Messac, Luke, et al. "US Nonprofit Hospitals Have Widely Varying Criteria to Decide Who Qualifies for Free and Discounted Charity Care." Health Affairs. November 2024. https://www.healthaffairs.org/doi/10.1377/hlthaff.2023.01615*

viii. *United States Government Accountability Office. "Medicare Part B Drugs Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals Report to Congressional Requesters." June 2015. https://www.gao.gov/assets/gao-15-442.pdf*

ADDRESSING HOSPITAL CONSOLIDATION: PRESCRIPTION AND TREATMENT

The 119th Congress must build on the momentum of site-neutral payment policy, 340B reform, and transparency requirements to stem the tide of hospital consolidation and negative impacts on patients and the health care system more broadly.

Implement Site-Neutral Payment Policies

- Legislate total site payment parity. Remove the "grandfathering" exception in Section 603 of the Bipartisan Budget Act of 2015, ensuring that the site-neutral payment policy is extended to all hospital-owned sites of care off-campus from the main hospital campus. Reimbursement will be based on independent physician office reimbursement, per the Medicare Physician Fee Schedule (MPFS).
- Ban all facility fees for hospital off-campus outpatient departments. Prevent hospital-owned off-campus outpatient departments from charging additional facility fees, reducing costs for patients and payers.
- Bundle and align radiation therapy technical payments at the hospital outpatient rate.

Tighten Hospital "Nonprofit" Status Requirements

- Modernize requirements for charity care in all nonprofit hospitals, which should provide a level of charity care commensurate with the tax breaks that accompany their nonprofit status.
- Require nonprofit hospitals to meet specific charity care standards or lose their nonprofit status. Nonprofit hospitals provide less charity care, on average, compared to other types of hospitals (government and for-profit hospitals).[1]

Strengthen 340B Participation Requirements

- Require that 340B hospitals deliver charity care that meets or exceeds their tax exemptions.
- Establish clear 340B patient eligibility requirements by defining who qualifies as a "340B patient" to ensure the program serves patients in need.
- Define standards for 340B hospital child sites such that 340B hospitals cannot funnel 340B savings through hospitals in disadvantaged areas to child sites in wealthy areas.
- Exclude for-profit PBMs from serving as 340B mail order contract pharmacies to prevent corporate profit-seeking from undermining the intent of the program by diverting 340B funds from helping patients to feeding corporate coffers.

CBO Estimate: Site-Neutral Payments Would Save $156.9 Billion Over 10 Years

Background

Medicare typically pays more for the same service when provided in a hospital outpatient department (HOPD) versus other settings, such as a physician office (e.g., independent community-based oncology practices) or ambulatory surgical center.

Policy Proposal and Estimated Savings

Congress has passed partial Medicare "site-neutral payment" legislation, under which certain HOPDs are paid the same as independent physician practices, but some in Congress want to expand that legislation to all HOPDs.

CBO notes that paying all HOPDs the same Medicare reimbursement paid to independent physician practices would save $156.9 billion over 10 years if this policy was implemented starting in 2026.[i]

Source:

i. *Congressional Budget Office. "Options for Reducing the Deficit: 2025 to 2034." December 2024.* https://www.cbo.gov/system/files/2024-12/60557-budget-options.pdf

Require Transparency and Reporting in 340B

- Require transparency and accountability as to how 340B discounts are used to help patients in need in conjunction with strengthened 340B participation requirements, with sufficient penalties for program misuse.
- Strengthen oversight of the 340B program by granting additional authority and resources to federal agencies to enforce 340B rules and oversee program compliance.
- Require 340B hospitals to have standardized charity care requirements and reporting processes.

Reimburse 340B Hospitals Based on Surveyed Acquisition Cost Prices

- Adjust 340B hospitals' reimbursement rate to be based on the CMS survey data of acquisition costs, as proposed in the 2021 Medicare Hospital Outpatient Prospective Payment System (HOPPS) proposed rule. In changing the reimbursement rate, exempt smaller rural 340B hospitals.[22]
- Mandate CMS to conduct an updated survey of hospitals' 340B acquisition costs and discounts to ensure that Medicare reimbursement accurately reflects net drug acquisition costs.

Restrict Aggressive Debt Collection Practices by 340B Hospitals

- Prohibit 340B hospitals from using aggressive debt collection tactics (e.g., wage garnishment, property liens, credit reporting) against patients, especially low-income, uninsured, or underinsured patients.
- Require 340B hospitals to document and exhaust all financial assistance options (e.g., sliding scale of charity care) before pursuing collections and ensure transparent disclosure of these options to patients at admission and discharge.

CBO Estimates: Reining in 340B Spending Would Save Over $73 Billion Over 10 Years

Background

In 2018, CMS implemented a policy that significantly reduced Medicare reimbursement rates for 340B outpatient drugs, from average sales price (ASP) plus six percent to ASP minus 22.5 percent. The change was intended to better align Medicare's payments with the prices hospitals actually paid for 340B drugs, reducing what CMS viewed as excessive drug margins. Legal challenges and subsequent reversal of the policy set the payment rate back to ASP plus six percent, where it remains today.

Policy Proposal and Estimated Savings

In a 2024 CBO report, CBO estimates that if the ASP minus 22.5 percent payment rate for 340B drugs was instituted in January 2026, the policy would save approximately $24.2 billion from 2025-2029 and $73.5 billion from 2025 through 2034.[i]

In reality, the potential for 340B savings is much greater. CMS conducted a survey with 340B hospitals in 2020 and published the results in the 2021 HOPPS proposed rule. The survey found that the average acquisition cost discount for 340B drugs was 34.7 percent (a conservative estimate according to CMS). In order to set reimbursement closer to the average estimated acquisition cost from the survey, CMS would have to pay for Part B 340B drugs at ASP minus 28.7 percent (ASP minus 34.7 percent based on the survey results plus the six percent add-on).

The savings to Medicare from this lower 340B payment rate would be $93.8 billion from 2025 through 2034. This lower rate would also result in savings to Medicare beneficiaries.

Source:

i. Congressional Budget Office. "Options for Reducing the Deficit: 2025 to 2034." December 2024. https://www.cbo.gov/system/files/2024-12/60557-budget-options.pdf

ADDRESSING HOSPITAL CONSOLIDATION: ONGOING TREATMENT

The 120th Congress and beyond must ensure that there are effective guardrails for the 340B program, address anticompetitive hospital behavior, and ensure that rural hospitals and practices have a sustainable path forward.

Curb Unrestrained 340B Growth

- Transform 340B into a ***patient-centered*** program instead of a ***facility-centered*** program. 340B discounts should follow eligible patients in need, regardless of the care setting, providing direct out-of-pocket cost relief for qualifying individuals. Patient eligibility may be determined annually by issuing cards based on patients' tax returns, which may be used either for Medicaid enrollment or rebates paid to the entity purchasing the drugs.

Restrict Anticompetitive or Punitive Hospital Actions Against Independent Providers

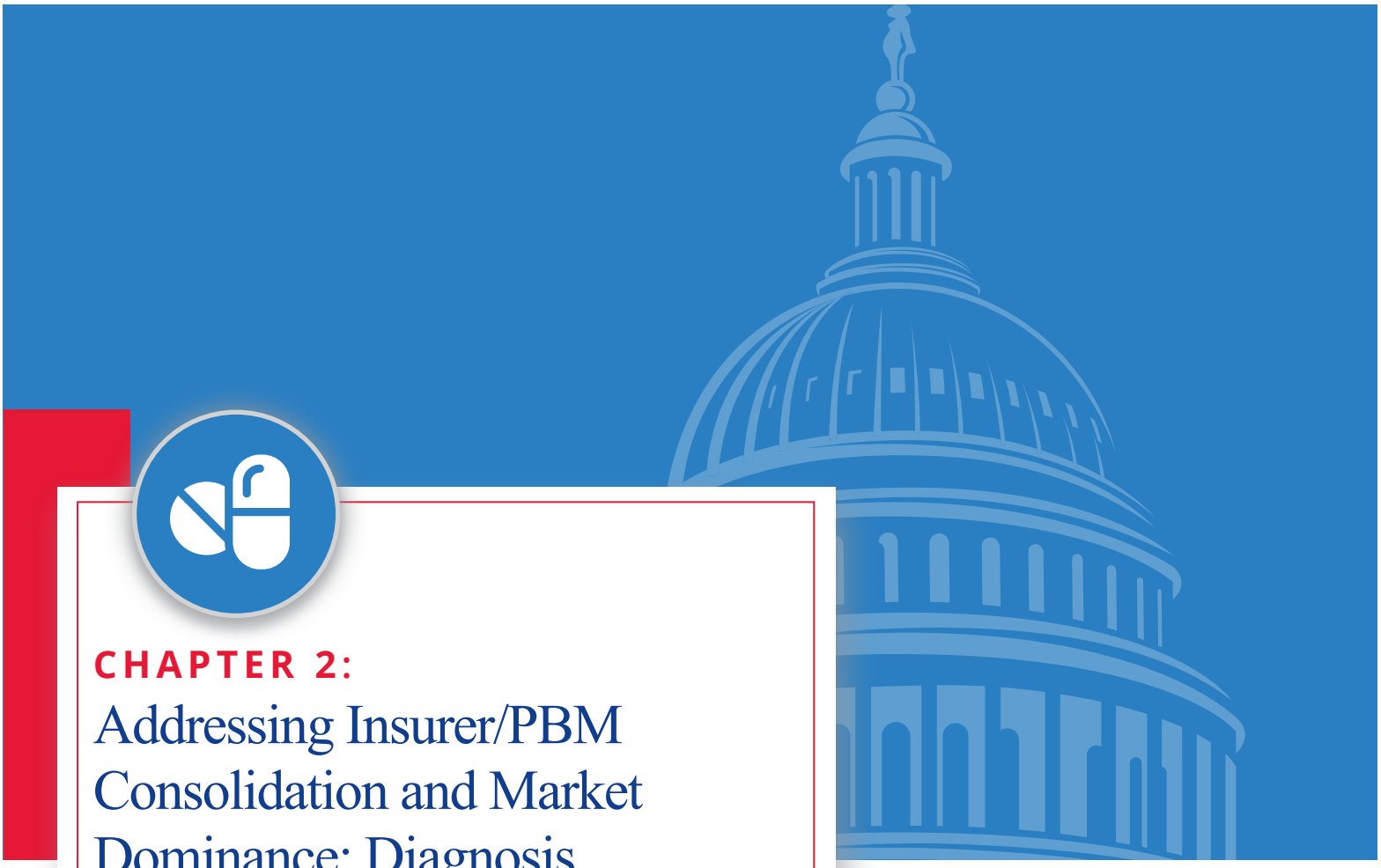
- Ban "all or nothing" contracts, in which a hospital requires physicians to accept unfavorable terms because rejecting the contract entirely could mean losing hospital privileges or access to a significant portion of their patient base.
- Require hospitals to maintain specialty-specific privileges (corresponding with the physician's area of practice) for independent oncologists and other physician specialists in good standing with the facility.
- Enhance patient choice by preventing inpatient and emergency department referral systems from automatically mandating or preferring hospital-owned care options in referral systems while shutting out independent physicians.
- Enhance patient choice by requiring that inpatient and emergency department referral systems equitably provide information on care options owned and not owned by the hospital.

Support Rural Providers

- Extend existing physician and nurse incentive programs, such as tuition forgiveness and loan repayment, to independent physician practices serving rural areas, similar to those offered to hospitals.
- Increase the geographic practice cost index (GPCI) for rural areas to increase payment to rural practices, without reducing payment to those in urban areas.
- Adjust technical revenue payments, currently delivered per patient or individual fraction (for radiation oncology), to adequately cover the costs of acquiring and maintaining expensive equipment based on rurality.
- Allow physicians to own hospitals but require that they accept Medicaid patients at all locations.

Expand Site-Neutral Payment Policies

- Reduce payments to HOPDs to the ambulatory surgery center (ASC) payment rate for certain services, as referenced by the MedPAC 2022 Report to Congress.[23]
- Seek opportunities to expand site-neutral payment policy within Medicare, for both Medicare Fee-For-Service (FFS) and Medicare Advantage (MA), as well as for Medicaid.



CHAPTER 2:

Addressing Insurer/PBM Consolidation and Market Dominance: Diagnosis, Prescription, and Treatment

ADDRESSING INSURER/PBM CONSOLIDATION AND MARKET DOMINANCE: DIAGNOSIS

Trend: PBMs have become extremely powerful intermediaries in the health care system. The PBM industry is highly concentrated and vertically integrated. Integration in the insurance/PBM industry has resulted in the top three PBMs effectively controlling 80 percent of the prescription drug market.[24] Not only have PBMs merged, and continue to do so, but they are also part of insurance corporations that have in turn merged to increase their market dominance and leverage over patients, employers, and pharmaceutical manufacturers. As a result, insurance markets have grown increasingly concentrated, limiting patient choice and inflating costs.[25] [26] The modern PBM business model incentivizes PBMs to promote those drugs—often the most expensive drugs—that maximize their profits.[27] In the process, this has fueled an arms race between mega hospital systems and insurers/PBMs, each vying for greater market leverage by consolidating.[28] Patients and independent medical practices are left to shoulder escalating costs and complex administrative burdens, while the "corporate practice of medicine" increasingly becomes the norm, denying physician and patient treatment choices.

Patient Impact: Increasingly, insurers/PBMs are prioritizing their profits over appropriate clinical decisions and patient wellbeing, dictating what treatment will be given and how and where it will be administered, and causing delays in treatment.[29] [30] This is particularly detrimental in cancer care, where the opportunity for effective intervention is narrow. Delays in treatment can lead to disease progression, diminished treatment efficacy, and ultimately, worse patient outcomes, even death. Treatment options are increasingly dictated by insurer/PBM profit incentives, not by what is clinically best for the patient.

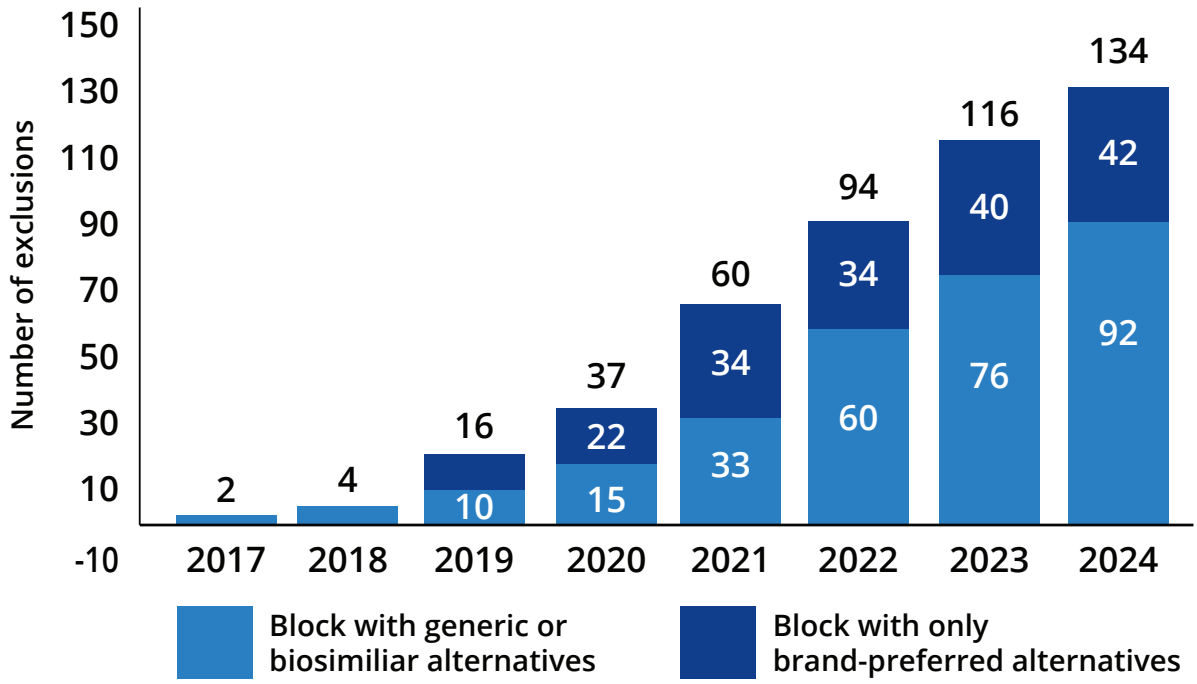
PBM administrative layers have also increased patients' out-of-pocket costs, creating significant financial burdens that make it difficult for patients to afford essential treatments.[31] [32] Despite negotiating rebates and discounts with drug manufacturers, PBMs rarely pass these savings on to patients and employers, leaving them with inflated costs. Utilization management practices, such as prior authorization, "fail-first" step therapy, and restrictive formularies, limit access to optimal, affordable medications and delay or deny critical patient care.[33] Consolidation among PBMs and their market leverage to dictate drug reimbursement has pressured independent pharmacies, creating "pharmacy deserts" across the country, especially in rural areas.[34] Access to needed medication to maintain health or address acute problems becomes impeded by the proximity to the nearest pharmacy.

The Facts: Insurers/PBMs Create Patient Access Challenges in Cancer Care

Formulary Exclusions Are Increasingly Common in Oncology

As new oncology treatments come to market, formulary exclusions and other access barriers have become more common in oncology.[i] A 2024 IQVIA analysis found that across the top national commercial formularies, there were 134 formulary decisions to exclude oncology products in 2024 (Figure 2). Within Medicare, the "six protected class" requirements provide some guardrails for oncology treatment coverage in the pharmacy benefit, but access challenges through utilization management remain.

Figure 2: Number of National Formulary Exclusions by Year, Top National Payers, Oncology Products, Commercial, 2017-2024[i]



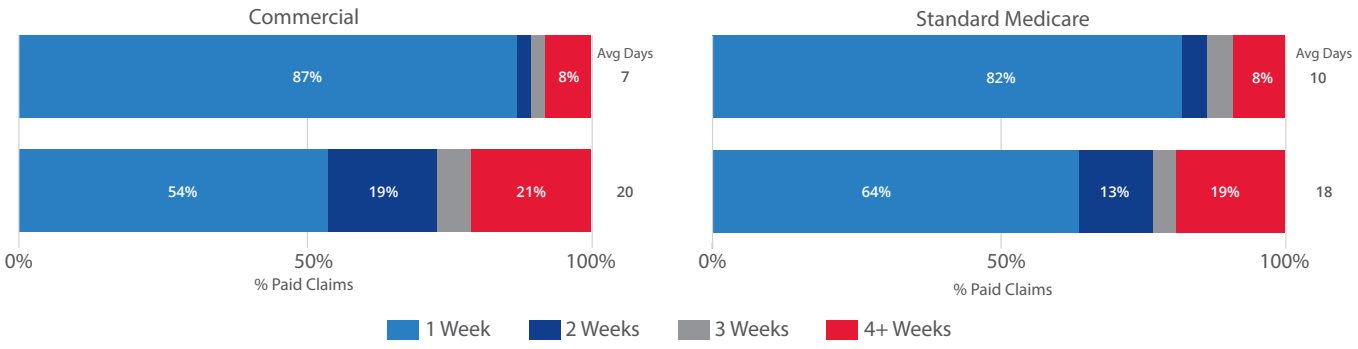
The Facts: Insurers/PBMs Create Patient Access Challenges in Cancer Care (continued)

The Burden of Prior Authorization Impacts People with Cancer, Caregivers, Doctors, and Staff, and Can Lead to Delayed or Denied Treatment

In addition to formulary exclusions, insurers/PBMs use prior authorization, step therapy, or other formulary requirements to control access. The number of diagnostic and therapeutic procedures requiring prior authorization has increased in recent years in staggering numbers. In 2023, 93 percent of physicians surveyed by the AMA found that prior authorization had a "somewhat or significant negative impact" on patient clinical outcomes. Nearly one in four physicians (24 percent) reported that prior authorization led to a serious adverse event for a patient in their care.[ii]

Among commercial and traditional Medicare patients, those with an initially rejected claim status had an average of 20-day delay and 18-day delay in accessing treatment, respectively. Around one in five patients had to wait over four weeks for their insurer to approve their prescription (Figure 3).[i]

Figure 3: Time to Treatment by Initial Claim Status, Branded Oral Oncology Therapy, 2020-2023[i]



The time spent and personnel required to adjudicate and be rightly reimbursed for these "authorized" claims is increasingly a financial and staffing drain on practice resources.[iii] For the patients who are denied prior authorization approval, access to immediate treatment is delayed and/or denied, and the physician typically begins an opaque and cumbersome process that can go on for several weeks as the medication or treatment plan is continually denied. This often leaves patients confused, frustrated, and hopeless at a time when they are particularly vulnerable. Furthermore, it is unclear what purpose prior authorization serves when treatments are prescribed following recognized pathways or clinical care guidelines.

Sources:

i. *Thiesan, Jeff, et al. "Access Challenges in the Cancer Patient Journey: How barriers to oral oncology affect patient initiation and persistency." IQVIA. August 2024.* https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2024/iqvia-access-challenges-in-oncology-report-white-paper-2024.pdf

ii. *American Medical Association. "2023 AMA prior authorization physician survey; Care Delays Associated with PA Treatment Abandonment due to PA." 2023.* https://www.ama-assn.org/system/files/prior-authorization-survey.pdf

iii. *Community Oncology Alliance. "Position Statement on Prior Authorization." 22 April 2021.* https://mycoa.communityoncology.org/education-publications/position-statements/coa-position-statement-prior-authorization

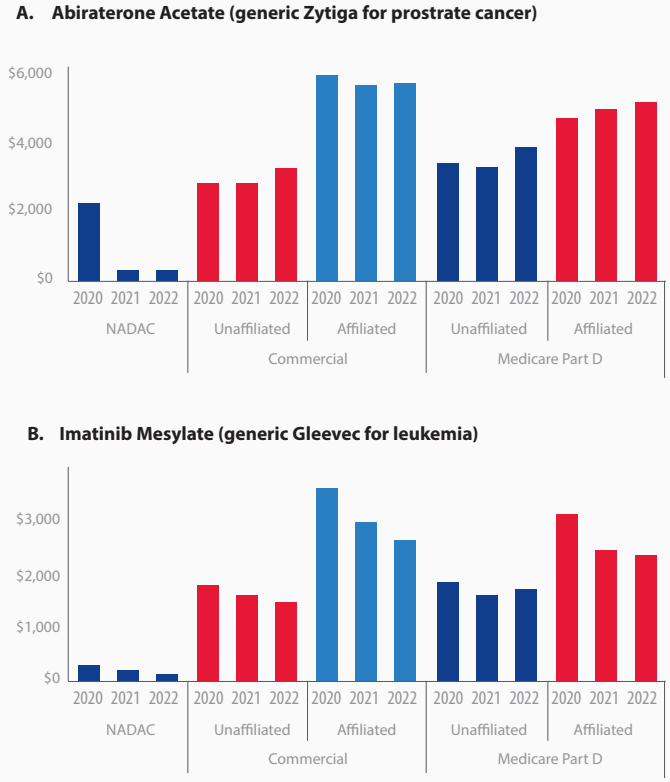
The Facts: Insurers/PBMs "Game the System" to Fuel Consolidation and Control Market Share

Lower Reimbursement and Exclusions from Insurance Networks Threatens Independent Pharmacies and Fuels Consolidation

Vertically integrated PBMs have the ability and incentive to prefer their own affiliated pharmacies, creating conflicts of interest that disadvantage unaffiliated pharmacies and increase prescription drug costs.[i ii] The PBM market has become highly concentrated in recent years, and the largest PBMs are also vertically integrated with the nation's largest health insurers and specialty and retail pharmacies. The top three PBMs—CVS Caremark, Express Scripts, and Optum Rx—processed nearly 80 percent of the approximately 6.6 billion prescriptions dispensed by U.S. pharmacies in 2023, while the top six PBMs processed more than 90 percent.[ii]

Low reimbursement rates by PBMs, as well as PBMs' exclusions of certain pharmacies from their preferred networks, affect pharmacies' profitability and lead to disparate closure rates. A Health Affairs study looked at closure rates of independent pharmacies relative to chain pharmacies from 2010 through 2021 and how the impact of those closures varied across geographic and demographic factors.[i] The research found that independent pharmacies were much more likely than chains to be in predominantly Black and Latino neighborhoods, as well as in neighborhoods with poverty rates of 20 percent or more. Independent pharmacies were nearly two times more likely than chain pharmacies to be in neighborhoods with higher uninsured rates and over twice as likely than chain pharmacies to be critical access pharmacies (the sole pharmacy in the neighborhood). Overall, the risk for closure among independent pharmacies was more than twice that of chain pharmacies.[i]

Figure 4: Gross Pharmacy Reimbursement Rates for a One-Month Supply of Two Specialty Generics Paid to PBM-Affiliated and Unaffiliated Pharmacies by Commercial and Medicare Part D Plans and Members Managed by the Big Three PBMs, and NADAC, 2020-2022 [ii]



The first interim Federal Trade Commission (FTC) staff report on PBM practices took a case study of two oncology products and compared reimbursement across markets (commercial, Medicare) and PBM affiliation. The comparison in reimbursement found that PBM-affiliated pharmacies also received significantly higher gross reimbursement rates than unaffiliated pharmacies for the two case study drugs. In 2022, commercial health plans paid affiliated pharmacies roughly 80 to 90 percent more than unaffiliated pharmacies for abiraterone acetate (generic Zytiga) and imatinib mesylate (generic Gleevec), while Part D plans paid affiliated pharmacies over 30 percent more than unaffiliated pharmacies for both drugs.[ii] A second interim FTC report documented that the top three PBMs excessively mark up generic cancer drugs and other critical therapies dispensed from their affiliated pharmacies. Additionally, the FTC analysis found that the PBMs paid their pharmacies more than unaffiliated independent pharmacies. [iii]

Sources:

i. *Guadamuz, Jenny S, et al. "More US Pharmacies Closed than Opened in 2018–21; Independent Pharmacies, Those in Black, Latinx Communities Most at Risk." Health Affairs. December 2024.* https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2024.00192

ii. *Federal Trade Commission. "Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies." July 2024.* https://www.ftc.gov/reports/pharmacy-benefit-managers-report

iii. *Federal Trade Commission. "Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers." January 2025.* https://www.ftc.gov/reports/specialty-generic-drugs-growing-profit-center-vertically-integrated-pharmacy-benefit-managers

ADDRESSING INSURER/PBM CONSOLIDATION AND MARKET DOMINANCE: PRESCRIPTION AND TREATMENT

The 119th Congress must prioritize PBM reform and stop the insurer/PBM middlemen from gaming the system, increasing costs, and hurting patients.

Require PBM Transparency

- Require PBMs to report on gross and net drug price, formulary construction, and related information including, but not limited to, drug rebates, spread pricing arrangements, formulary placement rationale, and information about benefit designs that encourage the use of pharmacies affiliated with PBMs to independent (non-corporate-affiliated) Medicare Part D plan sponsors.
- Mandate that specialty pharmacy performance or quality programs use evidence-based and relevant measures. For example, oncology practice dispensing facilities or pharmacies should not be measured on cardiovascular drug adherence.
- Mandate that the PBM drug dispensing fee must cover the cost of dispensing the medication.
- Require PBMs to publicly disclose the Maximum Allowable Cost (MAC) source used to calculate generic drug reimbursements.

Prohibit Insurers/PBMs from Owning Pharmacies

- Prohibit parent companies of insurers and/or PBMs from owning any type of pharmacy business.
  - Mandate that the Department of Health and Human Services (HHS), the FTC, and antitrust divisions of the Department of Justice (DOJ) use their authority to issue orders to violators to divest pharmacy business and relinquish revenue during the violation period.
  - Allow the FTC to distribute the funds to communities harmed by insurer/PBM ownership of pharmacies.
  - Report divestitures to the FTC and the Securities and Exchange Commission (SEC) to review all divestitures and actions to protect the financial viability, interest of the public, and competition.

Mandate PBM Rebate Reform

- Delink PBM rebates and fees as a percentage of prescription drug prices.
- Eliminate safe harbor protections for PBM rebates.
- Require that all PBMs institute "pass-through" pricing, in which (a) the amount a PBM charges a plan is equivalent to the amount the PBM pays the dispensing pharmacy, including dispensing fees; and (b) the amount paid to the PBM for a medication is passed through in its entirety to the pharmacy provider with no offset for reconciliation.

Prohibit Insurers/PBMs From Owning Physician Practices

- Prohibit insurers/PBMs from owning or controlling any type of physician practice.

Address Prior Authorization Challenges

- Ban "fail-first" step therapy and non-medical switching in cancer care if a drug is FDA approved, and a National Comprehensive Cancer Network (NCCN) Category 1 or 2A recommended cancer drug.
- Ensure a clear exception process for patients forced into "fail-first" step therapy and non-medical switching in cancer care.
- Require Medicare Part D (e.g., an oral cancer drug) and Part B (e.g., physician-administered drugs, radiation therapy) prior authorizations and appeals be reviewed by a physician of the identical specialty. For example, for medical or radiation oncology, a pediatrician cannot review an appeal of a cancer treatment.
- Mandate the timely review of all prior authorizations within 72 hours of submission.
- Require that all Part D plans establish electronic prior authorizations to expedite review and approval times.

Mandate Formulary Transparency and Accountability

- Require Medicare Part D plans to provide a continuity-of-care period following any mid-year plan drug formulary changes.
- Require Part D plan sponsors to provide transparent, comprehensive information on plan prescription drug claims.
- Prohibit Part D plan sponsors from making mid-year formulary changes that remove drugs or place drugs on more restrictive tiers unless the removed drug has been withdrawn from the market.

- Require Part D plan sponsors to provide an up-to-date, maintained, publicly accessible online link to the plan drug formulary.
- Require Part D plan sponsors to provide a plain-language, written justification when denying a prior authorization due to non-formulary rejections along with clear and meaningful recourse options.

Create Patient-Oriented Solutions

- Ban copay accumulator or maximizer programs that prevent patient assistance from counting toward out-of-pocket costs.
- Mandate coverage policies following Value-Based Insurance Design (VBID) principles that ensure access to proper screening, imaging, treatment, and long-term care options, including payment for diseases found at screening.

Curb Insurance/PBM Consolidation

- Require PBMs to provide the same reimbursements to independent pharmacies and specialty dispensing facilities as they do to their own mail order and affiliated specialty pharmacies until insurer/PBM pharmacies are divested to comply with the prohibition against insurer/PBM ownership of pharmacies.
- Prevent PBMs from steering patients toward their corporately affiliated pharmacies until insurer/PBM pharmacies are divested to comply with the prohibition against insurer/PBM ownership of pharmacies.
- Require PBMs and their mail order pharmacies to operate under the state pharmacy laws where the patient lives, not where the filling facility is located, until insurer/PBM pharmacies are divested to comply with the prohibition against insurer/PBM ownership of pharmacies.
- Require Group Purchasing Organizations (GPOs) affiliated with insurers/PBMs to completely disclose all relevant financial information regarding rebates and administrative fees.
- Prohibit PBMs from requiring the mandatory use of their mail order pharmacies and discriminatory differential patient cost sharing for independent pharmacies, until insurer/PBM pharmacies are divested to comply with the prohibition against insurer/PBM ownership of pharmacies.

Implement Medicare Guardrails

- Ensure that MA plans have clear, enforceable guardrails to protect patient access.
- Ensure that MA plans are not using "ghost networks" that delay access to care.
- Require CMS to create a centralized data hub where MA plan sponsors would load provider contact information to ensure completeness and accuracy of their networks.
- Require MA plans to cover the same benefits as fully loaded A, B, Medigap, and D Medicare FFS plans.
- Prohibit Medigap plans from using pre-existing condition exclusions.
- Ensure that the Medicare Plan Finder is kept up to date and is a valuable resource for beneficiaries, particularly those with chronic conditions and who take multiple medications.

ADDRESSING INSURER/PBM CONSOLIDATION AND MARKET DOMINANCE: ONGOING TREATMENT

The 120th Congress and beyond must ensure that physicians are able to make clinical decisions and ensure that PBMs are held accountable to Employee Retiree Income Security Act (ERISA) fiduciary duties.

Create Federal Policies That Make Physicians, not Administrators, the Decision Makers

- Legislate a Corporate Practice of Medicine Doctrine (CPOM) at the federal level to ensure clinical decisions remain with licensed physicians, not corporations.

Amend ERISA to Require PBM's to Follow ERISA Fiduciary Duties

- Require PBMs to act as fiduciaries, which would mandate that PBMs act in the best interests of plan participants. As ERISA fiduciaries, PBMs could not engage in price-inflating behavior. Requiring PBMs to act as fiduciaries would align PBM practices with the best interests of plan sponsors and beneficiaries—for example, preventing a PBM from mandating patients receive an expensive originator biologic, which through rebating is more profitable to the PBM, rather than a less expensive biosimilar.

CHAPTER 3:

Fixing Physician Reimbursement and Workforce Shortages: Diagnosis, Prescription, and Treatment

FIXING PHYSICIAN REIMBURSEMENT AND WORKFORCE SHORTAGES: DIAGNOSIS

Trend: Outdated reimbursement models without inflation adjustments, continuous reimbursement cuts, and increasing bureaucratic barriers to patient care are accelerating physician burnout and driving many physicians out of independent practice. Since 2019, over 100,000 physicians have left private practice for hospital or corporate employment.[35] Regular reimbursement cuts to the MPFS, exacerbated by the ongoing Medicare sequester payment cut, have resulted in Medicare payments effectively lagging inflation by 28 percent over the last decade.[36] The result has been an unsustainable environment for many independent practices, leading to many closures and hospital mergers. Burnout is not only worsened by declining reimbursements but also by disputes with insurers/PBMs and excessive time spent on bureaucratic tasks such as prior authorization and data entry over clinical care.[37] [38]

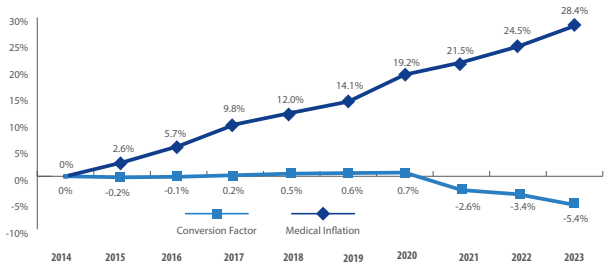
Patient Impact: Outdated Medicare policies have contributed to a wave of independent community oncology practice closures, forcing patients with cancer into larger health systems where treatment costs are markedly higher.[39] Lower reimbursement may result in fewer physicians caring for Medicare patients, resulting in longer wait times and delays in care, which are linked to poorer outcomes.[40] Rural areas are disproportionately affected and patients have increased travel burdens when clinics close. Satellite clinic closures create "medical care deserts" that significantly limit timely access to cancer care and exacerbate disparities in cancer care.[41] [42] For both patients and physicians, these closures disrupt the continuity and quality of care, making it increasingly difficult to deliver the timely, modern, patient-centered treatment essential for improved outcomes.[43]

The Facts: There is a Widening Gap Between Physician Reimbursement and the Cost of Providing Care

Physician Reimbursement Has Not Kept Pace With Inflation

The viability of independent physician practices is threatened by the continued decline in physician payment, which is true of all medical specialties, including primary care. In oncology, for example, an Avalere analysis found that from 2014 to 2023, the Medicare conversion factor decreased by a total of five percent, while the compounded increase of inflation over the same period was 28 percent.The gap between the rate of change of inflation and the conversion factor has resulted in dramatic physician underpayment over the last decade.[i]

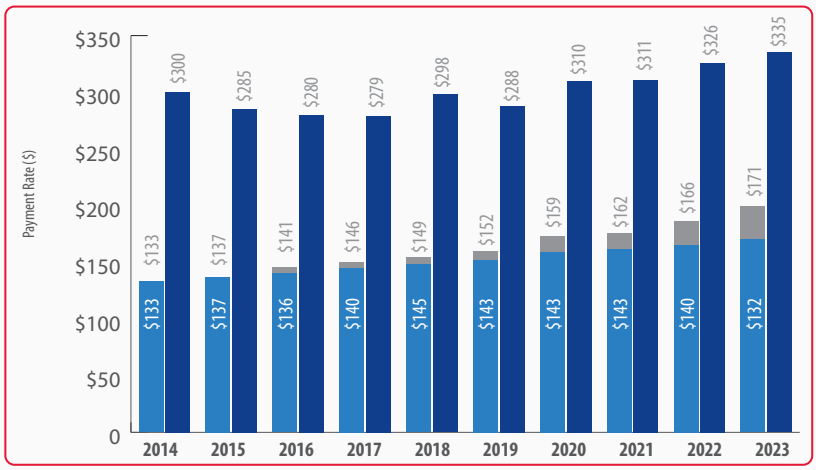
Figure 5: Physician Payment for Some Services Lags Behind Inflation[i]



Chemotherapy Reimbursement Diverges Over Time Based on Setting of Care

In 2023, physician payment for chemotherapy administration was nearly the same as 10 years ago ($133 in 2014 and $132 in 2023), while the hospital rate has increased by 11 percent during the same period. If chemotherapy administration reimbursement had kept pace with inflation in the physician office setting, it would have been $171 in 2023, and even still, this would only equal about half of the payment to hospitals ($333)[i]

Figure 6: Inflation Adjusted Physician and Hospital Payment for 1 Hour Chemo Intravenous Infusion (Code 96413), 2014-2023[i]



Note: Payment represents the non-facility physician rate; hospital outpatient represents OPPS APC rate. Avalere calculated the projected, inflation adjusted physician payment by applying the rate of change of medical inflation to the prior payment.

The ever-widening gap between reimbursement rates and expenses threatens independent oncology practices' financial viability and ability to maintain high-quality patient care.

These dynamics have continued since 2023 and will continue to catalyze closures of independent community oncology practices, shifting more cancer care to the costly hospital setting. This threatens patient access to critical care and increases health care costs, for both patients and taxpayers.

Sources:

i. *Le, Caroline, et al. "Physician Payment for Some Services Lags behind Inflation." Avalere. 11 September 2023. https://avalere.com/insights/physician-payment-for-some-services-lags-behind-inflation*

FIXING PHYSICIAN REIMBURSEMENT AND WORKFORCE SHORTAGES: PRESCRIPTION AND TREATMENT

The 119th Congress must reverse the trend of falling physician reimbursement and address workforce shortages with sustainable policy solutions.

Fix Physician Reimbursement

- Stop the continuous annual reimbursement cuts to the MPFS by incorporating factors that reflect rising real practice costs and are not currently included in Relative Value Units (RVUs), such as administrative work.
- Implement an annual Medicare Economic Index (MEI) increase to physician payment to address inflation and ensure practice sustainability.
- Eliminate the Medicare sequester reduction for independent physician practices to prevent further financial strain.
- Mandate real-time payment processing from CMS FFS carriers and MA plans to improve cash flow and reduce administrative burdens.
- Provide stable, predictable, inflation-adjusted payments that align reimbursement with clinical guidelines through the advancement of physician-driven value-based payment models that reform reimbursement for capital-intensive medical specialties, such as radiation oncology.
- Remove the budget neutrality requirement or increase the threshold to $100 million. Congress should consider a different budget neutrality structure that accounts for the broader drivers of Medicare spending that exist across payment systems, both independent practices and hospitals.
- Note that paying for increasing physician reimbursement and indexing it to inflation can be offset by site-neutral payments and lowered 340B hospital reimbursement (exempting rural hospitals). What this does, in effect, is create ecosystem equilibrium between the less expensive physician practice setting and the more expensive hospital setting.

Address Workforce Shortages

- Increase the number of Medicare-supported residency positions to stem the looming physician workforce shortage crisis, particularly in oncology. Allow Medicare funding to follow residents and fellows to accredited, non-hospital-based clinic sites.
- Implement physician and nurse incentive programs for community practices, especially rural practices, such as tuition forgiveness and loan repayment.
- Decrease the requirements for physicians from accepted foreign medical schools to practice in the U.S. and increase the availability of Conrad 30 waivers as a strategy for mitigating the shortage of qualified doctors in Health Professional Shortage Areas (HPSA), Medically Underserved Areas (MUA), or Medically Underserved Populations (MUP).
- Require HHS to apply the updated definitions of "commercially reasonable" and "fair market value" as established in the CMS Final Rule "Medicare Program: Modernizing and Clarifying the Physician Self-Referral Regulations."[44] These key definitions, which are foundational to compliance with the Federal Physician Self-Referral Law (commonly referred to as the "Stark Law"), are not being applied during the review of certain hiring practices by hospitals. If these definitions are not properly applied, hospitals will continue to violate the Stark Law because payments to employed providers are not commercially reasonable and/or not consistent with fair market value. This will continue to fuel consolidation and increase costs to patients and the health care system.

Increase Rural Reimbursement Rates

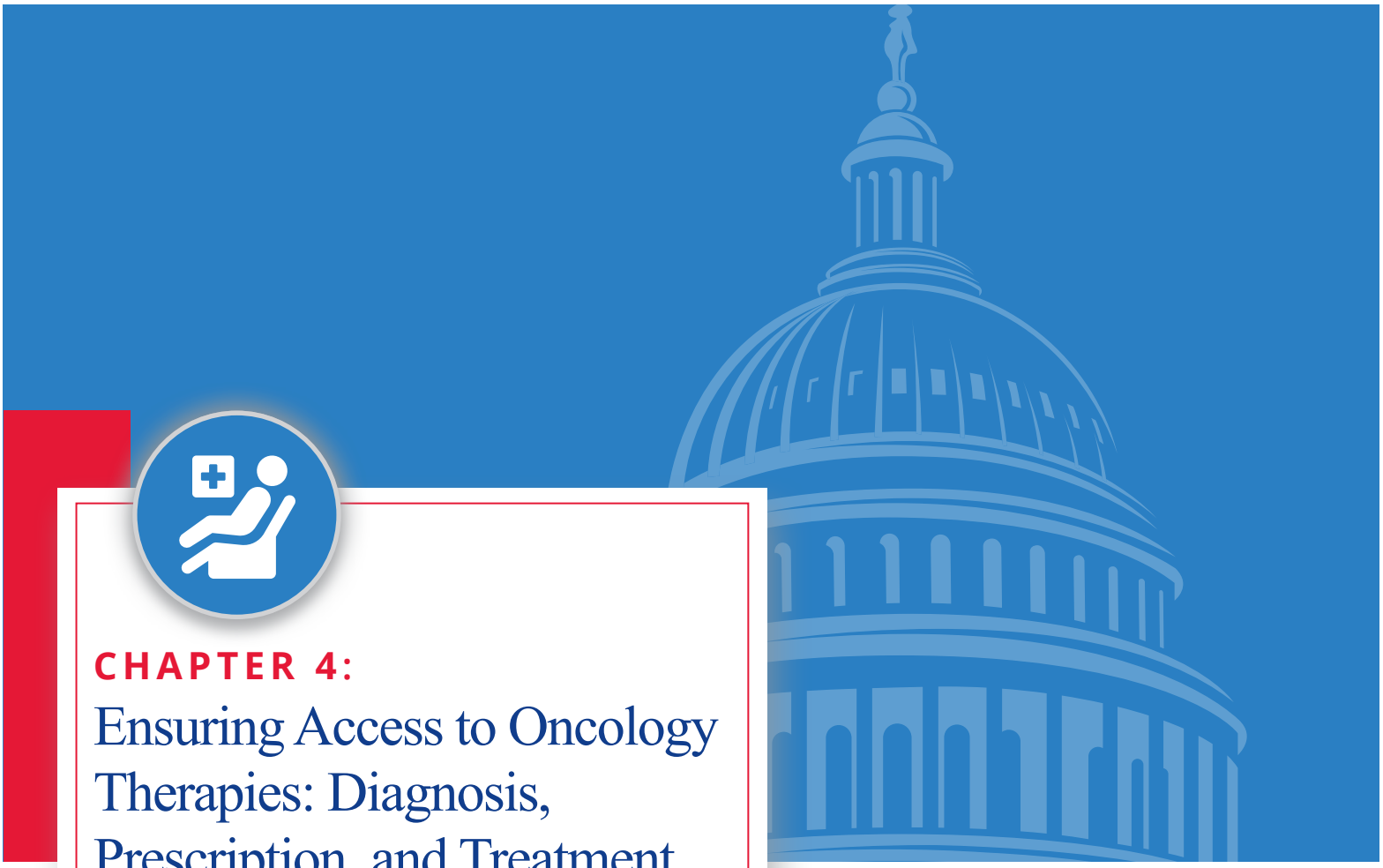
- Adjust payment models to compensate rural physicians and practices adequately, recognizing the unique challenges and higher costs of delivering care to patients and regions with fewer resources.
- Adjust technical revenue to reflect market usage to ensure the adequacy of payment for radiation and imaging services across both rural and underserved urban regions.

FIXING PHYSICIAN REIMBURSEMENT AND WORKFORCE SHORTAGES: ONGOING TREATMENT

The 120th Congress and beyond must ensure that the physician workforce will be healthy and thriving for years to come in order to meet the needs of Americans.

Address Workforce Shortages

- Expand the number of Medicare-supported medical residency positions, particularly in critical specialties like oncology, internal medicine, and general surgery.
- Provide tax credits and financial incentives to independent physicians who establish practices in rural or underserved urban areas.



CHAPTER 4:
Ensuring Access to Oncology Therapies: Diagnosis, Prescription, and Treatment

ENSURING ACCESS TO ONCOLOGY THERAPIES: DIAGNOSIS

Trend: The oncology drug market is under immense pressure due to rising costs of innovative therapies, chronic shortages of essential GSIs, and the increasing influence of consolidated insurers/PBMs.[45] Market distortions, such as 340B and growing mandatory government rebates and discounts, contribute to higher launch prices for new products, exacerbate drug shortages, and threaten the viability of the biosimilar market intended to reduce costs. The oncology drug market is a harbinger of what other specialty drug markets now face or will face shortly.

For physician-administered therapies, the Medicare six percent add-on payment (i.e., ASP plus six percent) is essential to covering overhead, infrastructure and staff costs required to procure, store, handle, and safely administer complex oncology drugs.[46] This system has been under attack for years by policymakers. Due to sequestration, the add-on payment, in reality, is 4.3 percent and practices are not paid the full ASP plus six percent because the Medicare portion of the payment is cut by the two percent sequester. Practices rely on the add-on payment to offset otherwise unreimbursed costs that have increased significantly over time, especially since the pandemic-fueled increase in inflation of staff salaries and costs for materials.[47] [48] [49]

As noted in the physician reimbursement section above, physician payment for chemotherapy administration has essentially unchanged since 2014. Furthermore, codes for chemotherapy infusion services were established in 2005 and have not been updated since, despite significant increases in practice expense relating to these codes (e.g., electronic medical records, USP 800 compliant pharmacies, and increasing physician practice expense), payment has decreased with the other codes from the MPFS.[50] Net cost recovery from the drug reimbursement itself is no longer adequate to cover the increasing cost of administration and this will be made worse with the implementation of the IRA.[51]

Unfortunately, the IRA exacerbates these challenges and threatens the ability of independent practices to continue treating Medicare patients. This is because it ties reimbursement to the negotiated maximum fair price (MFP) plus six percent, rather than ASP plus six percent. This shift will drastically cut reimbursement to practices for Part B drugs, disproportionately impacting independent community oncology practices that do not have the drug profits from 340B and higher services payments that are available to hospitals. Furthermore, practices with in-house medically integrated dispensing pharmacies will face additional challenges from IRA Part D price negotiation due to administrative burdens and financial risk associated with retrospective MFP effectuation.[52]

There was a fundamental lack of understanding in developing the IRA that all indications of a drug, especially in cancer treatment, are not developed all at once on initial drug approval. Typically, an indication for a particular cancer is tied to a drug's initial launch, with additional indications developed and launched over time, with pediatric cancer indications developed later in a drug's lifecycle. The practical impact of this market reality is that as a drug without competition approaches the IRA negotiation point, pharmaceutical manufacturers may well stop any further research investments in the drug for additional indications. Given that pediatric indications are typically late in the drug lifecycle, the IRA could have an alarming adverse impact on the development of pediatric cancer drugs.

Independent community oncology practices are also contending with persistent shortages of essential GSIs, critical to many standard cancer treatment regimens and clinical trial protocols.[53] Persistent, unanticipated shortages compromise patient care and increase costs.[54]

In addition, the future of the biosimilar market is threatened by aggressive payer controls, restrictive formularies that favor more profitable products, and ongoing ASP price erosion.[55] Without policy adjustments to protect biosimilar pricing and ensure adequate coverage, this vital market segment risks destabilization, undermining the cost savings it was meant to deliver to patients and payers.[56]

Patient Impact: Rising drug costs, restrictive payer controls, and opaque PBM rebate practices lead to delayed treatments and higher out-of-pocket expenses for patients, forcing many to choose less effective, costlier alternatives.[57] Broader challenges, including chronic shortages of critical GSIs and the uncertain future of the biosimilars market further hinder efforts to lower costs and ensure access to high-quality cancer care.[58] Adding to these pressures is the prospect of Medicare price negotiation changes under the IRA, which will significantly reduce drug reimbursement and lead to more independent practice closures.

The Facts: Access to Cancer Care is Threatened by Medicare Drug Negotiation Under the IRA

IRA Medicare Drug Negotiation Will Slash Oncology Reimbursement

As an unintended consequence of the IRA, the erosion in ASP for negotiated drugs will lead to billions of dollars decrease in physician reimbursement for physician-administered oncology drugs, threatening the viability of independent community oncology practices.

Currently, Medicare reimburses physician-administered Part B drugs at ASP plus six percent, which is adjusted down to ASP plus 4.3 percent by sequestration. The add-on payment above the drug acquisition cost covers essential overhead costs for administering complex treatments. Because of the way that the IRA is operationalized, the add-on payment will be based on the new MFP negotiated by CMS, which will be significantly lower than the ASP, leading to steep cuts to provider reimbursements. As Medicare ASP is also tied to commercial market reimbursements, the spillover impact will compound the financial burden on providers.

An analysis by Avalere that analyzed the impact of negotiation on 10 drugs that are likely to be negotiated shows that physicians could lose at least $25 billion in add-on payments across both Medicare and the commercial market through the end of 2032 for the first 10 Part B drugs that may be negotiated under the IRA. The greatest impact will be felt by independent oncology practices that administer the four oncology/hematology drugs on the list. They are projected to see $12-19 billion in losses, which is a 39-64 percent decrease in Medicare add-on payments and a 13-21 percent reduction in commercial and MA add-on payments.[i]

Source:

i. *Sullivan, Milena, et al. "Commercial Spillover Impact of Part B Negotiations on Physicians." Avalere. 16 September 2024.* https://avalere.com/insights/commercial-spillover-impact-of-part-b-negotiations-on-physicians

The Facts: Access to New Pediatric and Rare Cancer Drugs is Threatened by Medicare Drug Negotiation Under the IRA

IRA Implications on Treatments for Pediatric and Rare Cancers

The IRA includes two provisions that raise serious concerns for patients with pediatric and rare cancers:

1. Under the IRA, small-molecule drugs are subject to government price negotiations nine years after their Food and Drug Administration (FDA) approval date. In contrast, biologics have a 13-year window.

   At a high level, the IRA sets up a framework that reduces the period during which manufacturers of small-molecule drugs can recoup their substantial research and development (R&D) investments at market-driven prices, compressing it from what was traditionally closer to the overall length of patent exclusivity to a shorter negotiation window. For any drug developer, this shortened exclusivity period can decrease the long-term expected return on investment, influencing which drugs get researched and ultimately brought to market. For pediatric cancers—a small, specialized segment of the oncology space—this chilling effect can be pronounced.

   Pediatric cancer therapies often require additional, specialized clinical trials, which take more time and entail higher costs relative to adult trials. Drug sponsors must meet additional regulatory requirements (e.g., pediatric study plans), further extending the R&D timeline. If a company perceives that it will only have a short window to recoup investments before an MFP is established, it may deprioritize research in small-population diseases, such as rare pediatric cancers, where commercial returns are already modest relative to larger, adult indications.[i] In summary, when you shrink the time frame for return on investment, you create a disincentive to pursue smaller, riskier patient populations that urgently need new cancer and other treatments.

2. The IRA exempts certain orphan drugs used to treat only one rare disease or condition for which the only approved indication (or indications) is for such disease or condition.

   The IRA exempts certain orphan drugs used to treat only one rare disease or condition and for which the only approved indication (or indications) is for such disease or condition from the drug price negotiation program.[i] In addition, drugs with an annual Medicare cost of less than $200 million are exempt from negotiation, a provision that could shield some orphan products from negotiation. As a result, researchers may be disincentivized to pursue follow-on indications for orphan drugs, harming innovation and setting back patients.

Source:

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ENSURING ACCESS TO ONCOLOGY THERAPIES: PRESCRIPTION AND TREATMENT

The 119th Congress must address GSI drug shortages, ensure the stability of the biosimilars market, and mitigate the negative impacts of the IRA.

Address GSI Drug Shortages

- Exempt low-cost GSI drugs that are prone to be in short supply from 340B discounts, Medicaid rebates, and IRA inflation rebates.
- Change the basis of reimbursement for GSI drugs from ASP to Average Wholesale Price (AWP) as a more appropriate and stable pricing for low-cost GSIs.
- Create market incentives for manufacturers for GSIs with three or fewer active manufacturers.

Stabilize the Biosimilar Market

- Implement policies to address biosimilar pricing and coverage issues to stabilize and ensure a robust, healthy biosimilar market.
- Prohibit insurers and PBMs from restricting coverage to select biosimilars by banning the use of rebates on these products in Medicare.

Fix IRA's Unintended Consequences

- Legislate a technical fix to the IRA that removes providers and patients from the middle of price negotiations and is budget neutral by having drug manufacturers rebate the negotiated price difference directly to Medicare.
- Legislate a technical fix to the IRA to remove the MFP from ASP calculations to prevent spillover effects of MFP on non-Medicare populations.
- Address the IRA small molecule development disadvantage by extending the start time of negotiations to the same time frame as biologics.
- Incentivize pediatric cancer drug development by exempting pediatric cancer drugs from the Medicare drug price negotiations under the IRA.

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Preserving and Safeguarding the Role of Generics and Biosimilars in Cancer Treatment

Generic Drugs

Prescription drug shortages lead to increased costs for patients and the health care system. Drug shortages force patients to stop treatments, face delays, or receive potentially inferior treatments.[i] Generic drugs comprise most medications in shortage at any given time. A 2023 American Society of Health System Pharmacists (ASHP) analysis found that 56 percent of drugs in shortage in 2023 cost less than $1 per unit. GSIs, of particular importance in cancer treatment, represent an estimated 67 percent of shortages overall.[ii]

A fundamental challenge for generic drug manufacturers is the Medicare Part B drug reimbursement system, which is based on ASP, and also used by commercial payers. Additionally, 340B drug pricing discounts and Medicaid rebates erode drug prices, and the IRA's inflation penalty further puts downward pressure on GSI drug prices. These pressures mean, at best, there is little to no margin to invest in manufacturing upgrades, and at worst, there is no manufacturing redundancy as manufacturers leave the market, leading to shortages.

Biosimilars

Biosimilars can improve patient access to affordable cancer treatments and help prevent drug shortages. It is imperative that biosimilars are reimbursed at a fair rate to oncology practices to encourage their uptake.

Biosimilars can be a mechanism to lower drug spending in the U.S. Trastuzumab exemplifies the cost savings that biosimilars can produce. In less than three years, the prices of some of the versions of the drug declined by over 50 percent. However, due to financial incentives that make them less profitable than reference drugs, a Health Affairs study found that 340B hospital utilization of biosimilars dropped by 22.9 percent compared to other hospitals.[iii] With almost one-third of hospitals in the U.S. being 340B program participants, this has alarming implications for biosimilar uptake.

ENSURING ACCESS TO ONCOLOGY THERAPIES: ONGOING TREATMENT

The 120th Congress and beyond must incentivize domestic drug supply, address GSI drug shortages, establish payment parity for radiopharmaceuticals, and ensure diversity in clinical trials.

Incentivize Domestic Drug Supply

- Establish a quality program for manufacturers of GSI drugs that financially rewards quality and continuous drug supply by increasing payments. Conversely, penalize poor quality and gaps in drug availability.
- Provide direct financial incentives (e.g., tax incentives, incentive bonus payments) for manufacturers to produce quality GSI drugs domestically, with continuous supply.
- Use tax incentives to encourage the development of manufacturing plants in the U.S. to ensure a stable supply of GSI drugs, not dependent on other countries. ***This should be considered a national security priority.***

Address GSI Drug Shortages

- Ensure that policy solutions to address drug shortages do not put an undue burden on independent oncology practices and allow additional flexibilities for independent practices where appropriate (e.g., core standard requirements for drug purchasing).

Establish Payment Parity for Radiopharmaceuticals

- Mandate Medicare site-neutral payments for therapeutic radiopharmaceuticals. Under the HOPPS, therapeutic radiopharmaceuticals are considered a "drug" and are paid at ASP plus six percent when ASP data is available. The additional six percent is meant to reimburse for the complexity of the drugs, many of which are used to treat various types of cancer. However, radiopharmaceuticals furnished in the physician office are not paid at ASP and are instead paid by Medicare Administrative Contractors (MACs) under a variety of payment limits that vary geographically and, in the majority of MACs, are invoice-based pricing. As a result, freestanding radiation centers are most frequently paid significantly less than a HOPD and may not be able to justify offering radiopharmaceutical therapy because of the low reimbursement. This discrepancy is limiting access to care for patients with cancer in many communities.[59]

Ensure Clinical Trial Diversity

- Ensure that diverse patient groups are represented in clinical trials.
- Allow foundations to assist patients with the expenses associated with participating in clinical trials.

CHAPTER 5:
Modernizing Structural CMS Medicare Policies: Diagnosis, Prescription, and Treatment

MODERNIZING STRUCTURAL CMS MEDICARE POLICIES: DIAGNOSIS

Trend: Medicare's structure is woefully outdated and has not adapted to the evolving health care landscape, lagging behind shifts in care delivery, fueling hospital consolidation, and exacerbating the closure of independent practices. Rather than supporting competition, CMS payment policies have fueled consolidation by regularly increasing payments to hospitals while consistently cutting reimbursement to physician practices.[60] Simultaneously, costs have increased for both Medicare and its beneficiaries. Additionally, the siloed nature of Medicare's payment system is hopelessly outdated, hindering holistic global payment initiatives.

The Center for Medicare and Medicaid Innovation (CMMI) requires significant restructuring to ensure that Medicare policy aligns with the needs of patients and providers. Despite the focus on shifting to value-based health care and the proliferation of new CMMI payment models, the measurable impact on cost savings, quality improvement, and patient outcomes has been far less transformative than many had hoped thus far from CMMI.

Additionally, CMS refuses to "police" Medicare Part D in any way whatsoever, choosing to hide behind the "non-interference clause" of the Medicare Modernization Act of 2003. This is allowing PBMs implementing Medicare Part D plans to force pharmacy providers to accept "low-ball" reimbursement, very often lower than the actual acquisition price of the drug.[61] This is fueling the closures of independent pharmacies, especially in rural areas, creating "pharmacy deserts" across the country.[62]

Patient Impact: Outdated Medicare policies and regulations severely impact patient care by reducing access and increasing costs. Disparate reimbursement rates for advanced medical treatments strain independent practices, leading to closures and forcing patients into larger, more expensive health systems.[63] This not only increases patient costs but also affects the quality and timeliness of care, leading to poorer outcomes and exacerbating health disparities.[64] Comprehensive policy reform is urgently needed to better support patients, independent physician practices, and long-term Medicare stability.

Of particular note, citing Stark restrictions, CMS has blocked independent community oncology practices from delivering an oral cancer drug to a patient via mail, courier, ground package delivery, through a caregiver, or even a family member. Only the patient, in person, can receive the prescription. This is life-threatening in cases where the patient is too ill to pick up their drugs in person or where the patient does not have reliable or affordable transportation, especially in rural areas. The House passed legislation in the 118th Congress that would overcome this absurd and life-threatening CMS restriction, but time ran out to pass the legislation in the Senate. ***This must be an immediate priority of the 119th Congress.***

MODERNIZING STRUCTURAL CMS MEDICARE POLICIES: PRESCRIPTION AND TREATMENT

The 119th Congress must protect physician practices' ability to deliver oral drugs to patients and improve Part D oversight by enforcing the Any Willing Provider (AWP) law. Furthermore, Congress must revise the IRA MFP effectuation process to remove independent physicians from IRA negotiations between pharmaceutical manufacturers and CMS.

Protect Physician Practices' Ability to Deliver Oral Drugs to Patients

- Stop CMS from considering it a Stark violation if a practice delivers a drug to a patient from a medically integrated dispensing facility or related practice pharmacy, including not allowing a family member or caregiver to pick up the drug for a patient.[65] [66] The House must immediately introduce the *Seniors Access to Critical Medications Act* (H.R. 5526 in the 118th Congress) and pass it and the same for the Senate. ***This is an important priority!***

Improve CMS Oversight of Medicare Part D

- Force CMS to "police" Part D in terms of enforcing AWP laws and ensuring that pharmacy reimbursement is "reasonable and relevant" according to statute.[67]
- Mandate that CMS enforce its own policies to provide meaningful oversight of Part D.

Fix Physician Payment

- Amend the *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA) to tie annual updates of the Medicare Conversion Factor (CF) to a reliable index, such as the Medicare Economic Index (MEI), to ensure the physician payments reflect true cost increases.
- Inflation adjustments, which account for the broader impacts of medical inflation and economic realities, should be coupled with a robust regular update in calculations for the direct inputs for practice expense relative value units, accounting for clinical wages and costs of medical supplies, equipment, etc.
- Note that the cost of amending MACRA and providing inflation updates can be more than paid for by the fixes to 340B and payment site neutrality previously discussed and recommended in this document.

Fix Unintended Consequences of the IRA

- Implement a technical fix to the IRA to remove independent physicians from the negotiations between pharmaceutical manufacturers and CMS/Medicare, using a rebate mechanism similar to Medicaid best price.

Critically Evaluate CMMI

- Mandate a critical evaluation of CMMI, including whether payment models that place participants, including independent physician practices, "at risk" are in the best interest of patients.
- Restructure CMMI so that it removes legal and bureaucratic impediments to real testing of phase I models, as is the congressional intent of the center.
- Put guardrails on CMMI's authority so that it is not used as a tool of the executive branch to change reimbursement and other policy bypassing Congress.

MODERNIZING STRUCTURAL CMS MEDICARE POLICIES: ONGOING TREATMENT

The 120th Congress and beyond must work towards building a health care system with streamlined metrics, ensuring adequate financial support for smaller practices, aligning incentives more robustly with quality outcomes, and supporting systems that incorporate the social and economic realities of cancer patients. Additionally, Congress needs to implement solutions that ensure stable, long-term policy and better data transparency.

Completely Restructure Medicare

- Completely restructure the Medicare "silos" to create a global payment system for Medicare that equitably balances payments between hospitals and independent physician-run medical practices, promoting competition and more sustainable patient care. The current Medicare "silos" are hopelessly outdated.

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WHAT AILS HEALTH CARE? CONSOLIDATION.

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Chapter 5: Modernizing Structural CMS Medicare Policies: Diagnosis, Prescription, and Treatment

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61 *Federal Trade Commission. "Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies." July 2024. https://www.ftc.gov/reports/pharmacy-benefit-managers-report*

62 *Ibid.*

63 *Rooke-Ley, Hayden, et al. "Value-Based Payment and Vanishing Small Independent Practices." JAMA. 22 August 2024. https://jamanetwork.com/journals/jama/article-abstract/2822764*

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65 *The Physician Self-Referral Law (the Stark Law) prohibits a physician from making a referral to an entity for the furnishing of designated health services (DHS) payable by Medicare if that physician (or immediate family member of the physician) has a financial relationship – including a direct or indirect ownership or investment interest or compensation arrangement. In 2023, CMS ruled that Stark Law violation for oncology practices to deliver an oral cancer drug to a patient or even to have a patient's family member or caregiver pick up the drug at our practice for the patient. As a result, CMS prohibits oncology practices from delivering an oral cancer drug to a patient or even to allow a patient's family member or caregiver pick up the drug at the practice for the patient. This interpretation of Stark law greatly impedes patient access to care. When mail order service is limited, it can put elderly patients and rural patients at a disadvantage because they are unable to get the treatment that they need. Effectuation of the Stark Law is not only archaic but places physician-run practices at a serious disadvantage to hospitals, which can refer to themselves in any manner, regardless of whether it is a clinical or financial detriment to the patient. Source: Community Oncology Alliance. "The Community Oncology Alliance Supports the Protecting Patient Access to Cancer and Complex Therapies Act (S. 2764, HR. 5391)." 18 September 2023. https://mycoa.communityoncology.org/news-updates/press-releases/the-community-oncology-alliance-supports-the-protecting-patient-access-to-cancer-and-complex-therapies-act-s-2764-h-r-5391*

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67 *Any Willing Provider (AWP) definition: AWP statutes, sometimes referred to as "Any Authorized Provider," are laws that require health insurance and specialty health carriers to allow health care providers to become members of the carriers' networks of providers if certain conditions are met. Such statutes prohibit insurance carriers from limiting membership within their provider networks based upon geography or other characteristics, so long as a provider is willing and able to meet the conditions of network membership set by the carrier. (Source: American Association of Payers, Administrators and Networks, "Public Policy Position: Any Willing Provider." 26 May 2017. https://aapan.org/wp-content/uploads/2020/03/AAPAN-Public-Policy-Position-Any-Willing-Provider-5.26.2017.pdf). In practice however, this has proven not to be the case (COA has filed a lawsuit against Caremark/CVS for violating AWP laws; (Source: Levitt, Jonathan, et al. "Re: Illegal "Slow Rolling" and "Pretextual Denials" of Applications by Dispensing Physicians Seeking Admission into CVS Caremark's Pharmacy Networks". 16 September 2020. https://communityoncology.org/wp-content/uploads/2020/09/Demand-Letter-to-CVS-Caremark-re-Physician-Dispensing.pdf). Without stronger enforcement from CMS, the PBMs will continue to limit beneficiary's access to the cancer drugs that they need.*

The Community Oncology Alliance (COA) is a nonprofit organization dedicated to advocating for community oncology practices and, most importantly, the patients they serve. COA is the only organization dedicated solely to community oncology where the majority of Americans with cancer are treated. The mission of COA is to ensure that patients with cancer receive quality, affordable, and accessible cancer care in their own communities. Learn more about COA at www.communityoncology.org.

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