COA PRESCRIPTION FOR HEALTH CARE REFORM: APPENDIX

What follows is additional information on topics covered in the *COA Prescription for Health Care Reform*.

Explosion of 340B and Lack of Hospital Charity Care

Background: Over the last decade, the scope of the 340B program has expanded dramatically. A CBO analysis reveals 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.[1] A lack of program oversight and enforcement has created opportunities for hospitals and vertically integrated pharmacies to exploit the program's well-intentioned framework, contributing to its substantial growth.

In recent years, the 340B program has seen explosive growth, with no indication of slowing down. In a report, HRSA highlighted that under the 340B program, drug purchases at discounted 340B prices reached a record of $66.3 billion in 2023, representing a 24 percent year-over-year increase.[2] 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. Five of the top 10 340B drugs are oncology drugs. Growing evidence shows that many hospitals abuse 340B, acquiring drugs at huge discounts and generating much greater net cost recovery than is possible at independent practices.

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.[3] The 340B program has several fundamental flaws which create unintended consequences that are harmful for the health care system by increasing prices, incentivizing consolidation, and, ironically, are harmful to patient access and affordability.

Low to No Charity Care Among a Concerning Proportion of 340B Hospitals: Hospitals use the 340B program to generate profits by keeping the difference between the discounted drug prices and their costs. There is little evidence that these 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 the discount.[4] A 2019 analysis of charity care data reported by hospitals in FY 2017 Medicare cost reports reveal that many of the hospitals enrolled in the 340B program are continuing to fall short of Congress' expectations when it comes to providing care to vulnerable patients.[5] While there are some 340B hospitals that provide appropriate levels of charity care, for nearly one-third (29 percent) of 340B DSH hospitals charity care represents less than one percent of total patient costs

Driver of Consolidation: 340B is a significant contributor to hospital expansion and consolidation. Hospitals' pursuit of profits from expensive cancer drugs through the 340B program has led to their acquisitions of independent community oncology practices, as hospitals are incentivized to expand access to potential 340B patients through acquisition and consolidation. COA's 2020 *Practice Impact Report* revealed that from 2018 to 2020, 74.5 percent of the acquisitions of community oncology practices were by hospitals benefiting from 340B. This trend has disproportionately fueled consolidation in the cancer treatment market, leading to closures and reduced patient access. Since 2008, a total of 1,748 community

oncology practices have either closed, merged, or faced financial difficulties after being acquired by hospitals.[6] Although 340B was intended to help low-income patients, the program ironically incentivizes hospital expansion into wealthier neighborhoods, in which DSH hospitals acquire practices (child sites). In these areas, 340B institutions can generate greater returns by delivering drugs to a largely insured population.[7] Countless hospital examples offer case studies into this pattern.

Parkview Hospital in Indiana, for example, acquired six rival hospitals over the last decade, allowing Parkview to control referral flows to their own specialists and facilities, even if those patients could get the same services elsewhere for less. Despite being a nonprofit entity, Parkview raised prices that have strained local economies, squeezed employers, and increased health care premiums. Parkview's consolidation reflects a larger pattern in U.S. health care, where hospitals merge to dominate regional markets, which raises prices and limits competition.[8]

PBM Penetration and Growth of Contract Pharmacies: A provision in the 2010 Affordable Care Act allowed 340B covered entities to contract with an unlimited number of pharmacies to provide 340B discounted drugs rather than with a single pharmacy per covered entity. Large retail pharmacies and pharmacies owned or affiliated with PBMs represent a large and growing number of contract pharmacies. An Avalere analysis found that in 2023, 69 percent of 340B contract pharmacies were PBM owned/affiliated.[9]

Patient Impact: The shift of cancer care out of independent community oncology practices and into hospital-based outpatient cancer treatment sites is costly for both patients and the health care system. As more oncology-related encounters are shifted out of the independent community oncology practices and into hospital outpatient departments, costs to patients and payers increase dramatically.[10] In addition, Medicare Part B spending is higher at 340B DSH hospitals compared to non-340B hospitals, suggesting that there is a strong financial incentive at hospitals participating in the 340B program to prescribe more drugs or more expensive drugs to Medicare beneficiaries. Unnecessary spending has negative implications, not just for the Medicare program, but for Medicare beneficiaries as well, who are financially liable for larger copayments as a result of receiving more drugs or more expensive drugs. [11]

340B Increases Medicare Costs and Health Care Costs Overall: Medicare increased the costs of drugs to patients by increasing reimbursement to 340B hospitals. CMS ignored the Supreme Court ruling that the "first option" is to use survey data, which CMS has and has reported on. The 340B program may contribute to higher drug costs overall, as discounts are not passed on to patients who still pay based on list prices. 340B hospitals have higher Medicare drug spending compared to non-participating institutions. Additionally, 340B hospitals excessively markup oncology drugs in the commercial market and for patients with no or insufficient insurance.[12] [13]

Market Consolidation

Background: Hospital consolidation leads to higher prices for patients across different geographies and markets. The identical services provided in physician offices and the hospital setting are much more expensive in the hospital setting. Simultaneously, Medicare payment for physician services is declining and forcing independent practices out of business.

From 2000 to 2020, over 1,000 mergers took place among the ~5,000 hospitals in the U.S.[14] Large corporations, such as CVS and UnitedHealthcare, have continued to acquire small physician practices.[15]

The hospital mergers lead to job loss, higher prices for patients without increased quality of care, and exacerbate health disparities.

Rural Care is in Crisis: Rural hospital closures, decreasing reimbursements, declining operating margins, and staffing shortages have led to accelerated hospital closures in rural, underserved areas.[16] Between 2014 and 2022, 382 rural hospitals have stopped providing chemotherapy services.[17]

Workforce Impact: Hospital consolidation can be disastrous for health care workers and local economies even outside of the health care sector. A study by the Center for Equitable Growth modeled a hospital merger that raised its prices by five percent, leading to 203 jobs lost and $32 million in lost wages.[18] Furthermore, health care workers that remain in systems where jobs were lost may have to add on to their workload due to the staff shortages. Many hospital systems are already plagued with burnout, and allowing consolidation to continue could further exacerbate existing staff shortages.

Increased Costs to the System Without Improvements to Quality: A substantial body of research shows that consolidation has led to higher health care costs. Moreover, hospital mergers do not increase the quality of care. A study of 246 hospital mergers and acquisitions from 2009 through 2013 showed a decline in performance on patient-experience measures, no detectable changes in readmission or mortality rates, and inconclusive effects on other clinical process and quality measures. The study concludes that the findings provide no evidence of quality improvement attributable to changes in ownership.[19]

Patient Impact: Consolidation often leads to fewer independent hospitals and health care providers, which can decrease competition. This can result in higher prices for services and medications, as patients have fewer choices. Higher costs place a greater financial burden on patients, particularly those with cancer who may already be facing significant medical expenses and other burdens of disease.

Hospital mergers can exacerbate existing health disparities among rural and marginalized groups. When hospitals merge in rural areas, they are more likely to remove certain services including mental/substance abuse, neonatal, and surgical services.[20] Furthermore, consolidation has not kept rural hospitals financially viable and has not led to improvements in charity care.[21]

Consolidation and Lack of Transparency of Insurers/PBMs

PBMs are Increasingly Influencing Patient Care: The role of PBMs as "middlemen" among payers, pharmaceutical companies, and pharmacies goes beyond just drug negotiation. Increasingly, PBMs are fully administering the drug benefit, including creating formularies, making coverage decisions, and making utilization management decisions.

PBMs Subject Patients to Worse Care and Outcomes: Patients end up with suboptimal treatments and face delays and denials when treatment is delivered at the hands of the insurer/PBM, not the physician's practice. Medical care that should be coordinated becomes disjointed, and patients abandon treatment when faced with access barriers from payers. An IQVIA study found that formulary exclusions are increasing for oncology drugs across administration types (oral, IV, subcutaneous, intramuscular), and that following a payer rejection, 43 percent of commercial and 53 percent of Medicare patients never initiate therapy.[22] In addition, payer rejections were found to delay commercial and Medicare patients from initiating therapy by an average of three weeks.[23]

Anticompetitive Practices: The three largest PBMs use their dominant positions and integration with various stakeholders (insurers, pharmacies, providers, and manufacturers) to implement anticompetitive

policies. The three largest PBMs, CVS Caremark, Express Scripts, and OptumRx, control over 80 percent of the market. [24]

Cost and Transparency Issues: PBMs claim to save money through negotiation and drug programs, but evidence suggests that these practices often increase costs for patients and payers. Federal and state investigations have revealed that PBMs use opaque pricing schemes to overcharge hundreds of millions of dollars. [25]

Rebate Manipulation: Large PBMs require drug manufacturers to pay rebates to secure favorable formulary positions. This practice makes it difficult for lower-priced alternatives, like generics or biosimilars, to be included on formularies, despite their cost-effectiveness. A first interim report by the FTC found that PBMs and brand drug manufacturers sometimes negotiate prescription drug rebates that are expressly conditioned on limiting access to potentially lower-cost generic alternatives in favor of highly profitable rebates.[26] A second interim FTC report documented that the top three PBMs excessively mark up generic cancer drugs and certain other critical therapies dispensed from their affiliated pharmacies. Additionally, the FTC analysis found that the PBMs paid their pharmacies more than unaffiliated independent pharmacies.[27]

Physician Reimbursement

Background: The MPFS only directly applies to FFS Medicare reimbursement but is functionally used as a template for MA, Medicaid, and commercial physician reimbursement.[28] Thus, the challenges and shortfalls of the MPFS on physician reimbursement have an outsized impact for independent physicians. Medicare as a payer has become less and less viable for providers. As a result, many physicians are faced with difficult decisions regarding the operations of their practices. Some physicians are forced to contemplate what hours they can be open and whether they have the funds to pay their staff. [29]

Inadequate Medicare Reimbursement: Radiation oncology Medicare reimbursement has dropped by more than 20 percent since 2013 and fails to align with clinical guidelines.[30] There is broad consensus among policymakers that the MPFS is not only outdated but provides misaligned incentives, such as discouraging patient evaluation and management. Outdated reimbursement and misaligned payment incentives lead to physician burnout, departure from the field, and accelerated hospital acquisition.

Increase in Costs for Physicians: The cost of physician office rent, increased labor and equipment costs, professional liability insurance, and administrative staff wages are not reflected in the Medicare payment rates**.** In 2022, the average premium for medical liability insurance increased by 8.1 percent according to a study by the AMA.[31] Physicians are struggling to account for these increased costs as the Medicare conversion factor continues to decrease while inflation continues to skyrocket. Physicians are being forced to join larger hospital groups, which commonly leads to more administrative burdens for physicians which increases physician burnout.

The differential payment across hospital versus physician office site of care is driving independent physicians out of business or into retirement. The price of infusion cancer treatment (both the price paid by the insurer and by the patient) in a hospital setting is significantly higher than in the physician office setting. In one study, plans paid 50 to 90 percent more for oncology drugs in the HOPD compared to physician office.[32] This creates access concerns for patients and problematic incentives for hospitals towards higher-cost sites of care.

Workforce Issues

Background: The physician workforce is plagued with shortages and burnout due to insufficient payment models, administrative burdens, and workforce stresses. Physician practices are plagued with a plethora of policies that place more burden on them to understand and treat patients within the rules and take away from their abilities to practice medicine. These issues culminate in driving physicians out of the workforce. Over one-third of physicians in the U.S. report that they are experiencing burnout.[33] [34]

Physician Shortages and Migration from Smaller Practices: The number of medical oncologists in smaller practices decreased from 2015-2022 and the number of medical oncologists in large practices saw a large increase.[35] This trend may continue to have a negative impact on physician burnout because physicians will be forced to take on the additional administrative burdens that working in large hospital systems coincides with, which is one of the main causes of burnout.

Outdated Medicare Reimbursement Does Not Reflect Today's Costs: The cost of physician office rent, increased labor and equipment costs, professional liability insurance, and administrative staff wages are not reflected in the Medicare payment rates**.** In 2022, the average premium for medical liability insurance increased by 8.1 percent according to a study done by the AMA.[36] Providers are struggling to account for these increased costs as the Medicare conversion factor continues to decrease while inflation continues to skyrocket. Physicians are being forced to join larger hospital groups, which commonly leads to more administrative burdens for physicians, which in turn increases physician burnout. The current MPFS exacerbates workforce issues that physicians are facing. The MPFS conversion factor continues to decrease, while inflation grossly outpaces physician payment. The cost of physician office rent, increased labor and equipment costs, professional liability insurance, and administrative staff wages are not reflected in the Medicare payment rates

Burnout: Burnout is driving physicians out of practice. Over one-third of U.S. physicians report that they experience burnout.[37] Burnout is linked to financial hardships, workforce stressors, and administrative burdens that make it more difficult to provide clinical care to patients.

Patient Impact: As physician shortages and physician burnout increases, it may be more difficult for patients to obtain the care that they need. If Medicare does not reform payments to help the physician workforce stay afloat and avoid burnout, there will be dire consequences for patients when it comes to accessing high quality care such as physician shortages.[38]

Generic Drug Shortages

A quality program for manufacturers of GSI drugs that financially rewards quality and continuous drug supply by increasing payments must be developed and implemented. Conversely, penalize manufacturers for poor quality and gaps in drug availability. It is imperative that these problems are addressed before there are drug shortages in the market.

Prescription drug shortages lead to worse outcomes and higher costs for patients and the health care system. Prescription drug shortages lead to increase costs for patients and the health care system, while leading to worse health outcomes.[39] As COA's Executive Director Ted Okon testified to Congress, there is a shortage of mainstay GSI drugs, such as carboplatin, cisplatin, and fluorouracil. These drugs are treatments for many cancers, including curable ones.[40] Due to these shortages, patients have had to stop treatments, face delays, or receive potentially inferior treatments.[41] Generic drugs comprise most medications in shortage at any given time. A 2023 ASHP analysis found that 56 percent of drugs in

shortage in 2023 cost less than $1 per unit. GSIs have proven particularly vulnerable, representing an estimated 67 percent of shortages overall.[42] The average drug shortage affects at least a half a million consumers; more than two thirds of those impacted were consumers ages 65 to 85 (32 percent), 55 to 64 (24 percent) and 45 to 54 (17 percent).[43] Analysis of the data showed a 16.6 percent increase in the price of drugs in shortage, driven mostly by an increase in the price of generics (14.6 percent). In some cases, the increase in the price of substitute drugs was at least three times higher than the price increase of the drug in shortage.[44]

As Okon testified to Congress in 2023, a fundamental challenge for generic drug manufacturers is the Medicare Part B drug reimbursement system, which is based on ASP, also used by commercial payers, which caps drug prices. Additionally, 340B drug pricing discounts and Medicare rebates erode drug prices, and IRA drug price inflation caps further put 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.[45]

Patient Access to Oncology Therapies

Background: PA requires that physicians and patients navigate a complex approval pathway. This approval process typically takes an inordinate amount of time and is extremely problematic for patients with cancer who require timely treatment.

Shifting Medicare Lives from Medicare FFS to MA: MA enrollment continues to increase, and patients face increased barriers to care from prior authorization and utilization management practices. Virtually all enrollees in MA (99 percent) are required to obtain prior authorization for some services—most commonly, higher cost services, such as inpatient hospital stays, skilled nursing facility stays, and chemotherapy.[46] Additionally, 83.2 percent of prior authorization appeals were successfully overturned in 2022, which lead to delays in care for patients that desperately needed it.[47]

Provider Impact: According to a survey done by the AMA, 95 percent of physicians surveyed agreed that prior authorization increased their feelings of burnout.[48]

Patient Impact: Prior authorization is detrimental to cancer care. In a 2023 study of oncology patients in the U.S., 22 percent of patients did not receive the care recommended by their treatment team because of PA.[49] Not only can this negatively impact health outcomes for patients, but it can also leave them riddled with anxiety, increase their administrative burden, and lead to an overall negative perception of the prior authorization process.[50]

CMS/Medicare Issues

CMS' payment system creates a plethora of challenges for independent community oncology practices. The payment methodologies severely lag behind inflation, leaving providers struggling to provide quality care for their patients.[51] The siloed nature of the Medicare payment system, as well as the low reimbursement for independent physician practices, will continue to drive independent physicians out of their practices. Under the current system, it is incredibly difficult for independent physicians to compete with larger hospital systems.[52] This can lead to greater difficulty in patients accessing the care that they need.[53]

CMMI: CMMI has become a waste of $10 billion allocated every 10 years and has failed to set a roadmap for true health care reform. It is stymied by lawyers and actuaries and has become a political

toybox for the executive branch to end run Congress.[54] According to a report by CBO, spending outpaced savings produced by the program by $5.4 billion. The report also concluded that CMMI is expected to increase spending by more than a billion dollars.[55] Despite the program being tasked with increasing quality of care through testing a variety of payment strategies and models for CMS to utilize, the program itself has been a direct contradiction of its own goals. There has been little to no evidence that CMMI has had any improvements on the quality of health care in the U.S. and has, instead, been wasting money that could have been better allocated to other programs.

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