The Intersection of 340B and Cancer Care

Introduction

As policymakers consider changes to the 340B program, there is increasing interest in whether and how the drug discounts potentially affect the delivery of cancer care. ACS CAN worked with the Berkeley Research Group (BRG) to examine the intersection of the 340B program and oncology. This paper explores the contribution of oncology drugs to overall 340B income, the impact on site of care for cancer treatment, the prevalence of 340B hospital-owned satellite clinics focused on cancer care, the influence of hospitals' 340B status on their choice of cancer therapies, and the impact of 340B on cancer patients.

History of 340B

The 340B drug discount program was established in 1992 and permits certain types of hospitals and federally funded clinics, collectively referred to as "covered entities," to access pharmaceuticals at significantly discounted prices. Covered entities receive reimbursement from patients and insurers when these discounted pharmaceuticals are administered or dispensed. As examined in this study, reimbursement for 340B drugs generally exceeds the discounted price, often by a wide margin which can have an impact on cancer patients. The difference between reimbursement and the discounted 340B price represents the covered entity's income ("340B margin"). Some covered entities are subject to requirements regarding their use of 340B income, while others are not. For instance, hospitals, which account for 87 percent of 340B purchases in general[1] (and close to 100 percent of 340B purchases of oncology products[2]) are generally not subject to such requirements.

The 340B program has been expanded in several ways since its inception. In 1994, the Health Resources and Services Administration (HRSA), which oversees the 340B program, permitted hospitals to enroll outpatient sites located outside of the main hospital building, known as "child sites." In 1996, HRSA allowed certain covered entities to dispense 340B drugs through one pharmacy outside of the covered entity, known as a "contract pharmacy." This provision was expanded in 2010 when covered entities were permitted to dispense 340B drugs through an unlimited number of contract pharmacies. Also, in 2010, the Affordable Care Act (ACA) expanded the 340B program to include four new types of hospitals: Critical Access Hospitals, Freestanding Cancer Hospitals, Rural Referral Centers, and Sole Community Hospitals.

Over time, as the design of the 340B program expanded, total purchases at the discounted 340B price also grew. Since 2010, 340B purchases have grown on average by 18 percent per year, reaching $66 billion in 2023. As reported by the Congressional Budget Office (CBO) in June of 2024, "only a portion of the growth in 340B spending can be explained by market-wide trends or by disproportionate growth in spending on [certain] classes of drugs."[3]

According to CBO reporting, cancer treatments account for 41 percent of 340B purchases, more than any other individual therapeutic area.[4] Of the top ten drugs in terms of 340B purchases, five are indicated for cancer

[1] https://www.hrsa.gov/opa/updates/2023-340b-covered-entity-purchases
[2] https://www.cbo.gov/system/files/2024-06/60339-340B-Drug-Pricing-Program.pdf
[3] https://www.cbo.gov/system/files/2024-06/60339-340B-Drug-Pricing-Program.pdf
[4] https://www.cbo.gov/system/files/2024-06/60339-340B-Drug-Pricing-Program.pdf

treatment. The 340B program has influenced cancer care, with multiple studies indicating a shift in cancer care site of care toward hospital outpatient departments.[5] Oncologists represent significant financial opportunities for 340B hospitals (one oncologist represents at least $1 million in annual 340B profits, according to an often-cited statistic), making oncology practices frequent targets for acquisitions.[6] Other studies have also found a link between hospital 340B participation and the use of costlier drugs[7] which can have a direct impact on patient out-of-pocket costs.

Oncology Drugs and 340B Margin

As described above, covered entities benefit from the 340B program through the 340B margin, the difference between reimbursement paid to the provider or pharmacy and the discounted 340B price. A patient's insurer generally establishes the reimbursement level that a provider receives. Patients often bear some or all of this amount in the form of a deductible, copayment, or coinsurance. The 340B price, meanwhile, is calculated based on a statutory formula that considers a drug's time on market, price increases over time, discounts to commercial payers, and other factors. Because of the nature of this pricing formula, the 340B "discount" (the difference between the list price and the 340B price) can vary significantly from drug to drug. For some drugs, the 340B discount can approach 100 percent due to a phenomenon known as "penny pricing."[8] In certain instances where a drug has experienced significant price increases and is available at a significant discount to commercial payers, the statutory 340B pricing formula can result in a $0 or negative 340B price. Government regulations dictate that in these instances, the 340B price will be set at a floor of $0.01 per unit.

Little data is publicly available on the 340B margin earned by hospitals, much less the share of that margin that is attributable to different therapeutic areas. For certain payer types, however, claims data can reveal the reimbursement paid to providers for claims likely to have been filled using 340B-priced drugs.
For this study, we focus on two payer types for which recent claims data are available: Medicare Part B and Medicare Part D. Medicare is a federal insurer that covers individuals over 65 as well as persons who qualify for Social Security disability. Given that the median age of individuals receiving a cancer diagnosis is 66 years, Medicare is a significant payer for patients receiving cancer care. Within Medicare, Part B covers outpatient services, including drugs like chemotherapy that are administered to patients by a healthcare provider. Part D covers medications dispensed to patients at pharmacies, including oral cancer therapies.

Appendix A describes the methodology used to identify Medicare claims likely to have been filled using 340B-priced drugs, as well as to determine reimbursement for those claims. The other driver of 340B margin is the 340B price. While this price is confidential, Appendix A describes the process used to estimate the 340B price based on publicly available data points. For each 340B claim identified, reimbursement was compared to the estimated 340B price to arrive at a 340B margin. In some instances, this margin may be shared by the 340B hospital with other parties, including contract pharmacies or software vendors.

Across all hospitals, $21 billion in 340B margin was identified within Medicare Parts B and D. Of this amount, $8 billion (37 percent) was associated with cancer therapies. For cancer therapies, the margin earned by 340B hospitals in 2022 equates to 45 percent of total reimbursement collected for those therapies. This margin percentage is more than ten times that earned by non-340B providers. For Part B drugs, Medicare reimburses at the average sales price plus 4.3 percent (accounting for the impact of sequestration). This implies a profit margin of only four percent for the average non-340B provider (4.3%/104.3%). For Part D drugs, reimbursement is typically near a drug's list price. Typical margin for brand drugs at a non-340B pharmacy is between three and four percent.[9]

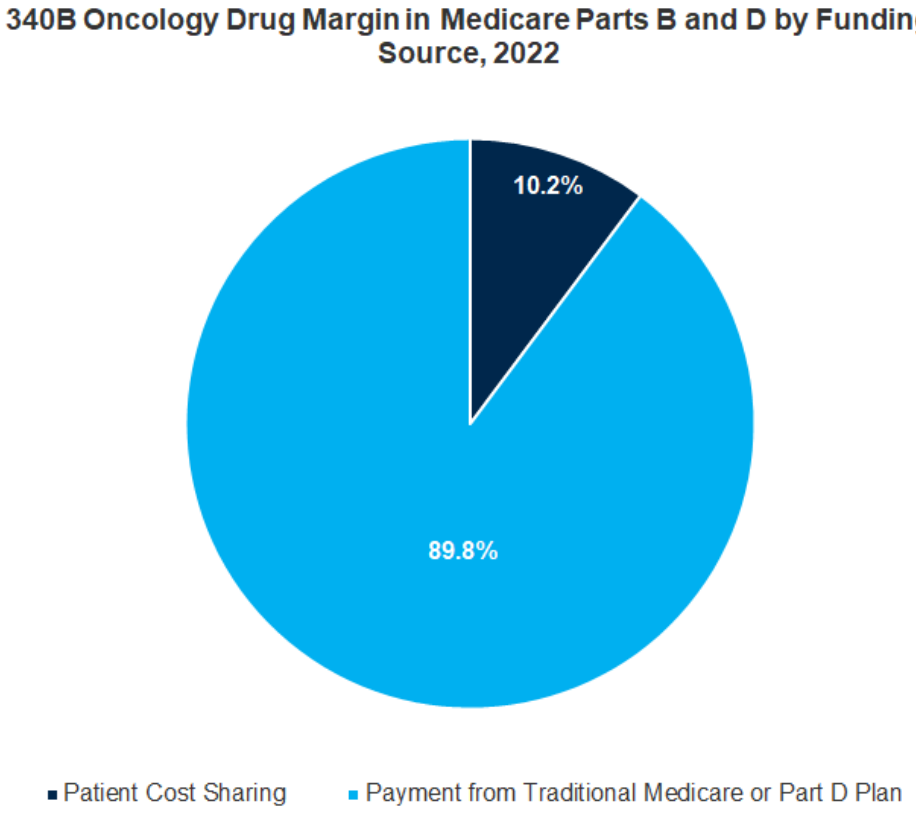
---

[5] https://onlinelibrary.wiley.com/doi/10.1111/1475-6773.12823; https://www.milliman.com/-/media/milliman/importedfiles/uploadedfiles/insight/2016/trends-in-cancer-care.ashx
[6] https://www.nytimes.com/2013/02/13/business/dispute-develops-over-340b-discount-drug-program.html
[7] https://jamanetwork.com/journals/jama-health-forum/fullarticle/2806517
[8] https://www.hrsa.gov/sites/default/files/hrsa/opa/federal-register-1-5-2017.pdf
[9] https://healthpolicy.usc.edu/wp-content/uploads/2017/06/The-Flow-of-Money-Through-the-Pharmaceutical-Distribution-System_Final_Spreadsheet.pdf

Patient Impact

The reimbursement that hospitals receive under Medicare comes in part from the Medicare program (either directly in the case of Part B or via a private plan in the case of Part D) and in part from patients via copayments, coinsurance, and deductible payments. Under Medicare Part B, patients are generally responsible for 20 percent of the total amount paid to a provider, though many elect to invest in a supplemental ("Medigap") plan to cover these costs.[10] Cost sharing is more complex within Medicare Part D and can vary based the patient's plan, the specific drug that he or she is taking, and the cumulative cost of all drugs taken by the patient within the year.

In 2022, claims data reveal that patient cost sharing payments accounted for approximately 10 percent of the reimbursement paid to 340B hospitals for oncology drugs under Medicare Parts B/D. This implies that 10 percent of 340B oncology drug margin, or approximately $800 million, is funded by patients.[11] The other 90 percent, while coming directly from Medicare or a private plan, is also partially funded by patients through their premium payments. The higher the cost of the drug used, the greater the amount cancer patients pay in cost sharing like deductibles and coinsurance. For cancer patients – whose costs are already high these additional out-of-pocket obligations puts them further at risk of medical debt.

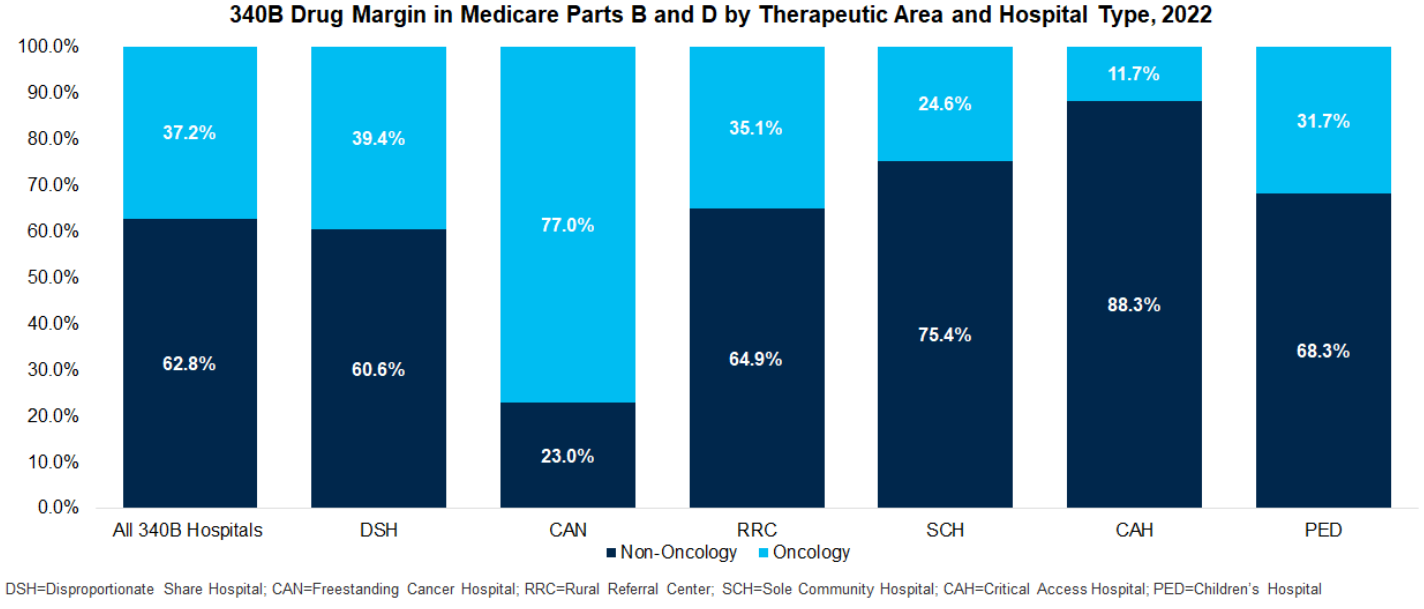


Margins by Hospital Type

The share of 340B margins accounted for by cancer therapies varies by 340B hospital type. Not surprisingly, the share is significantly higher at free-standing cancer hospitals. Cancer therapies account for a lower share of 340B margins at sole community and critical access hospitals, which are generally located in rural areas. For reference, cancer therapies represent approximately 20 percent of total spending on drugs by Medicare Parts B and D.[12] The larger presence of oncology drugs within 340B may be attributable to a variety of factors, including

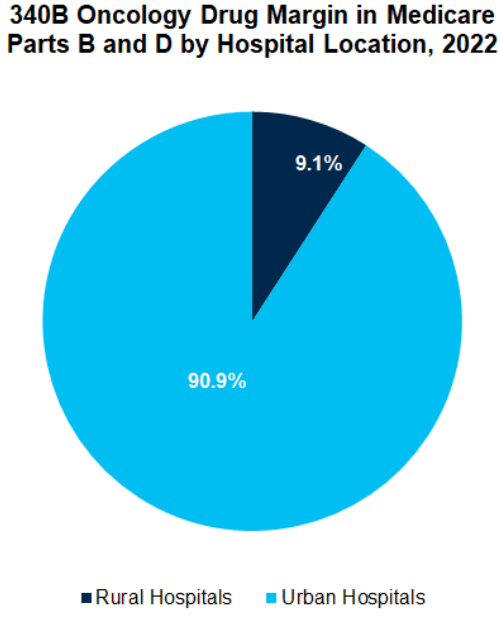
[10] https://www.medicare.gov/coverage/prescription-drugs-outpatient#:~:text=Doctors%2C%20other%20health%20care%20providers,Medicare%2Dapproved%20amount%20for%20these:
[11] Some of these payments may have been made by Medigap plans on behalf of patients.
[12] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2794172

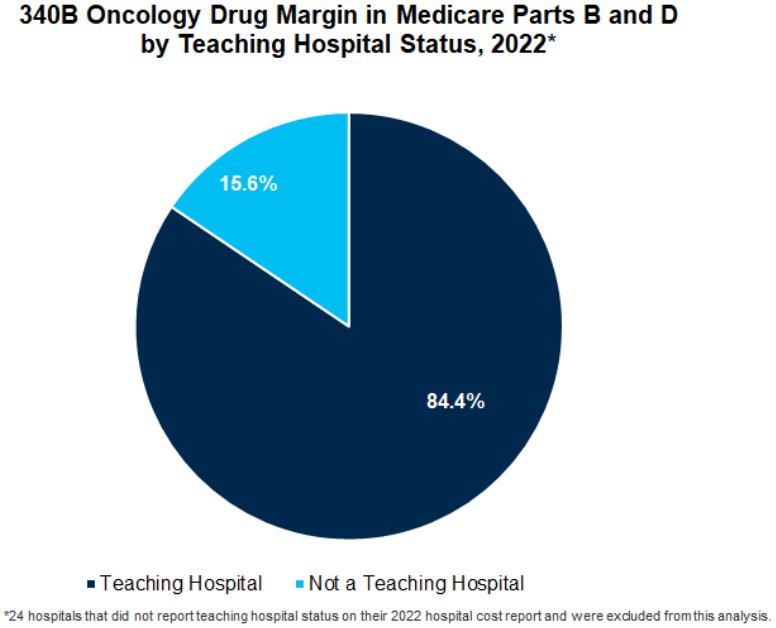
the greater ease with which 340B providers can "capture" prescriptions for provider-administered drugs (these are more common in oncology than other therapeutic areas) and the emphasis 340B providers have placed on expanding oncology care (discussed later in this study).



DSH=Disproportionate Share Hospital; CAN=Freestanding Cancer Hospital; RRC=Rural Referral Center; SCH=Sole Community Hospital; CAH=Critical Access Hospital; PED=Children's Hospital

Geographically, urban hospitals account for 91 percent of the cumulative 340B margin for cancer therapies.[13] Facilities that self-identify as teaching hospitals account for 84 percent of 340B margins. These findings suggest that the financial benefits of 340B as it relates to cancer care have largely accrued to urban academic medical centers rather than to facilities in rural areas, where disparities in access to oncology providers continue to impact cancer patients.[14]





*24 hospitals that did not report teaching hospital status on their 2022 hospital cost report and were excluded from this analysis.

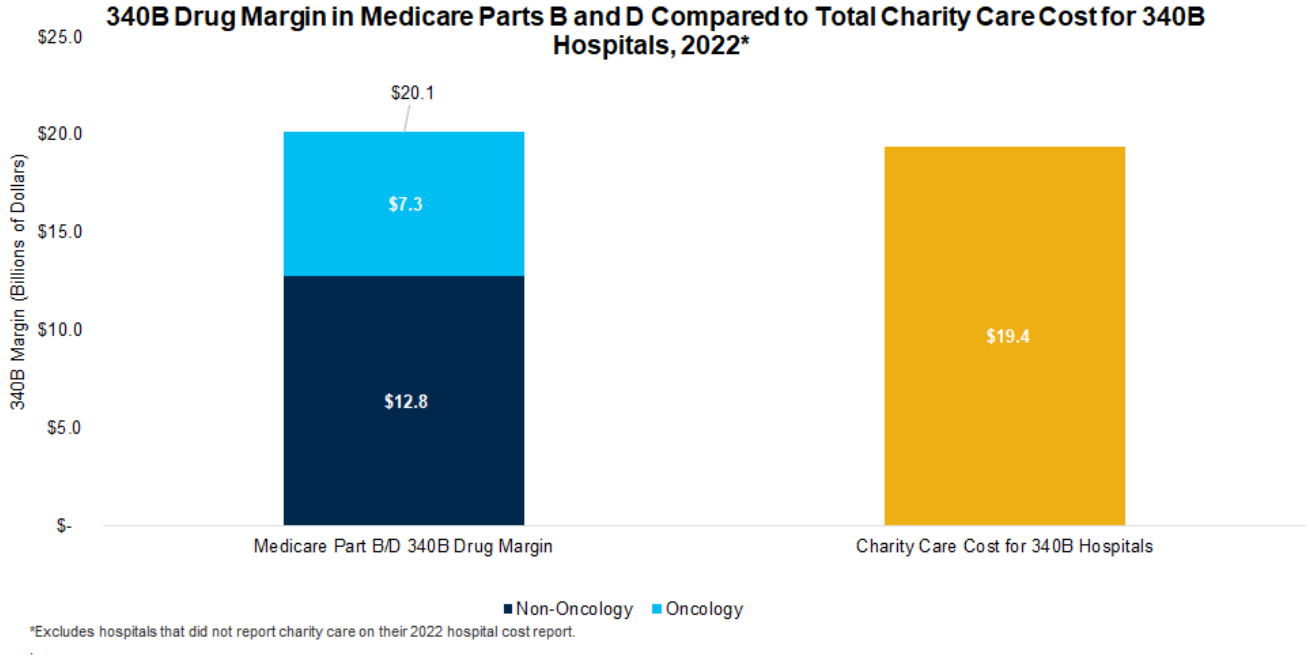
Hospitals are not subject to any federal reporting requirements on the amount of 340B drug margins that they earn or how these funds are used. 340B hospitals are required to be non-profits, meaning that net earnings may not "inure to the benefit of any private shareholder or individual," but federal law does not dictate specifically how

[13] Urban status defined according to the Office of Management and Budget (OMB) definition: the hospital must be located in a metropolitan or micropolitan statistical area.

[14] https://ascopubs.org/doi/10.1200/OP.20.00174

profits must be used.[15] Given that the intent of the 340B program is to support safety net providers and their patients, one use of 340B margin that is consistent with program intent would be to provide free or reduced-cost care to uninsured or underinsured patients. Costs for this type of support, known as "charity care," are reported annually by most 340B hospitals to the Centers for Medicaid and Medicare Services (CMS). For the 2,495 (94 percent) 340B hospitals that reported charity care to CMS for the fiscal year ending in 2022, the cost of providing that care amounted to $19 billion. This compares to $20 billion in 340B margins from Medicare Parts B and D - $7.3 billion of which was for cancer therapies. For context, prior research has found that Medicare (inclusive of Part C, which is not included in this study), accounts for one third of the spending on cancer care in the US.[16] Under the conservative assumption that the 340B margin on cancer therapies in Medicare Parts B/D is also one-third of the total, total margin on cancer therapies at 340B hospitals is approximately $22 billion, higher than total charity care costs for those same hospitals

The fact that 340B drug margins, for only two payer types, exceeds charity care costs implies that hospitals are using 340B margins for purposes other than providing free or reduced cost care. While those alternative uses could also be consistent with the intent of the 340B program, the lack of reporting makes this difficult to confirm.



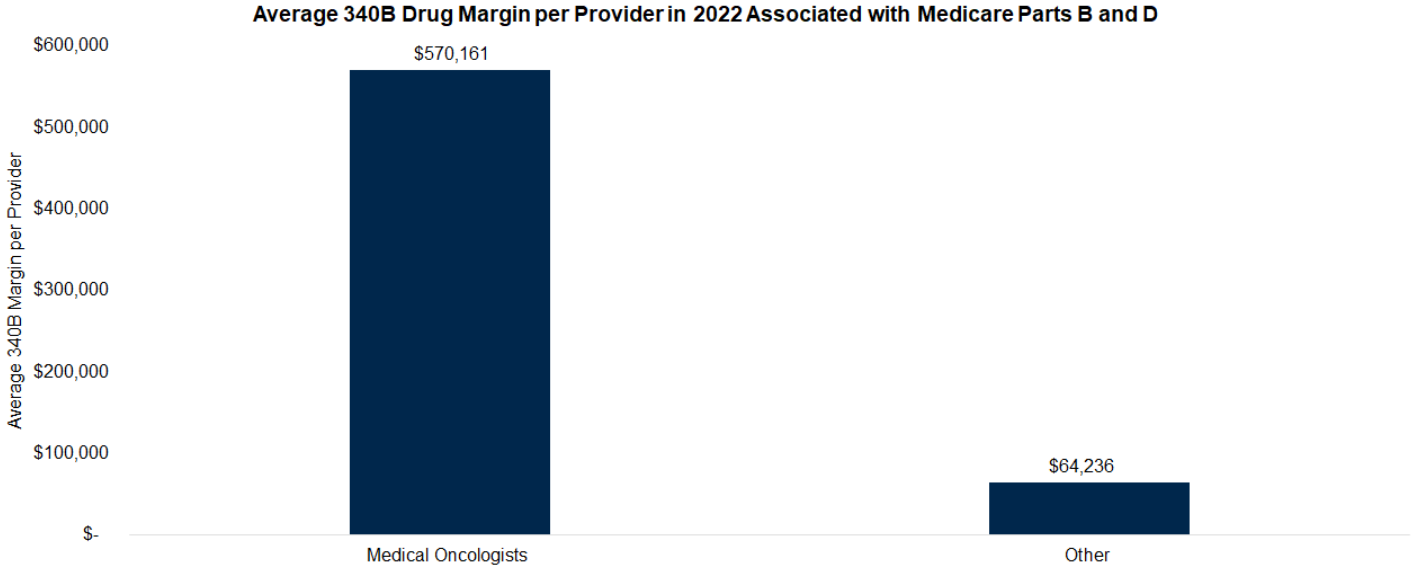
Hospital Consolidation

Over the past decades, there has been a well-documented shift in cancer care from the community setting to the hospital setting, with much of that hospital-based care occurring at 340B facilities. While multiple factors are likely to have influenced this shift, the 340B program has been cited as a driver.[17] With 340B hospitals at a significant financial advantage due to the discounts they receive, independent practices may struggle to remain independent. Meanwhile, the 340B margin opportunity associated with cancer therapies creates incentives for 340B hospitals to expand the oncology care that they provide through acquisitions of private practices or other growth strategies.

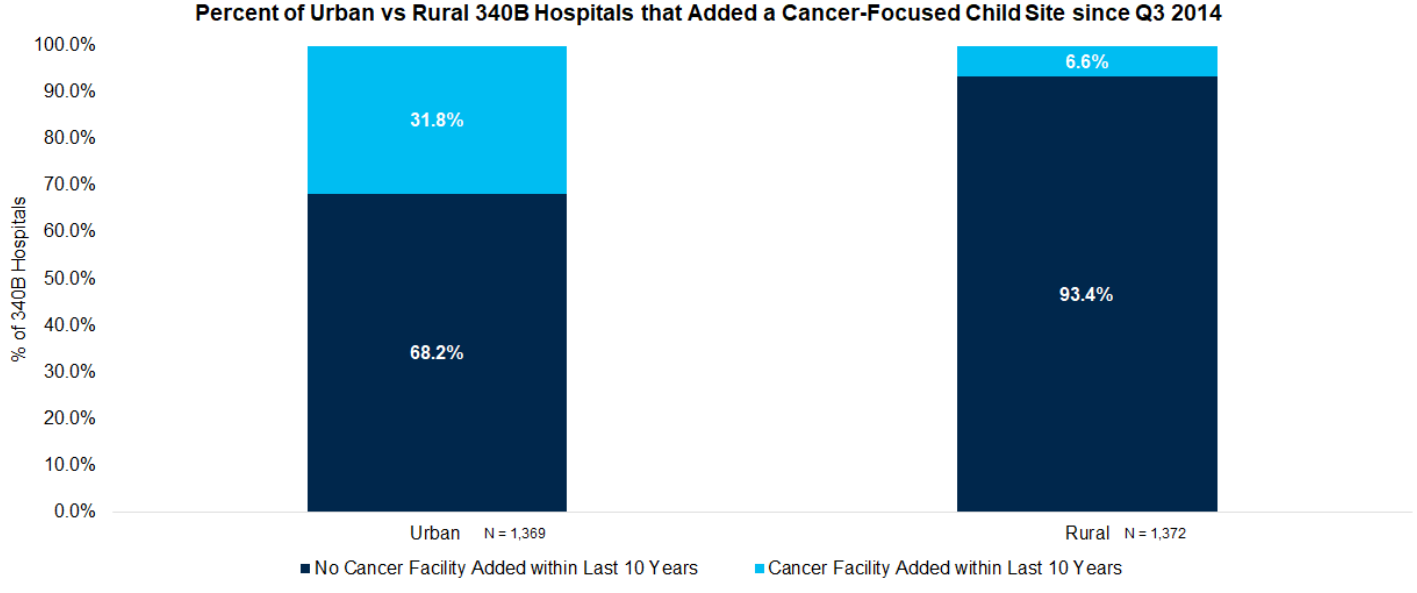
While the incentive for 340B hospitals to expand impacts multiple specialty areas, it is especially strong for medical oncology. Focusing solely on 340B-affiliated health care providers who administered or prescribed a brand drug to a Medicare Part B or D beneficiary in 2022, the average 340B margin per provider was $570,161

[15] https://www.irs.gov/charities-non-profits/charitable-hospitals-general-requirements-for-tax-exemption-under-section-501c3
[16] https://www.fightcancer.org/policy-resources/cancer-medicare-american-cancer-society-cancer-action-network-chartbook#:~:text=Medicare%20Expenditures%20for%20Cancer%20Care,-Cancer%20can%20be&text=Over%20one%2Dthird%20(33%25),attributed%20to%20the%20Medicare%20population.
[17] https://onlinelibrary.wiley.com/doi/10.1111/1475-6773.12823.

per medical oncologist compared to only $64,236 for other providers with other special types. This means that the financial benefit of hiring one medical oncologist is far greater for a 340B hospital than adding a general practitioner or other specialist type.

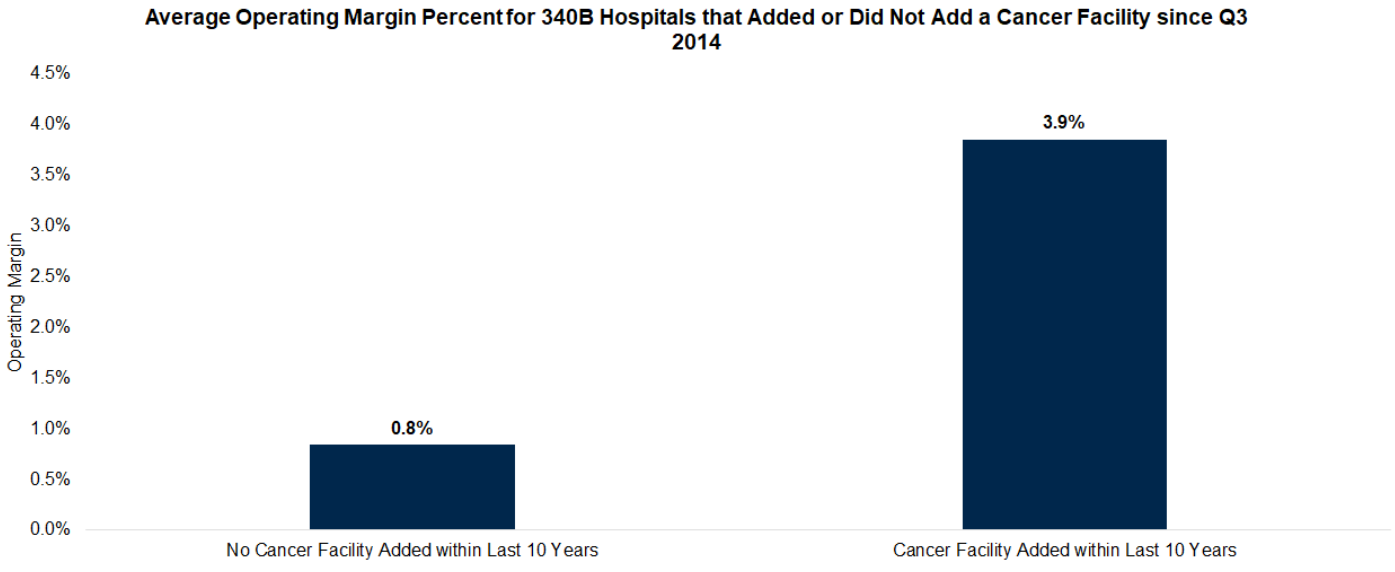


With these incentives in place, it is no surprise that 546 of the 340B hospitals have added a satellite clinic (child site) focused on cancer care within the last ten years.[18] These additions may indicate either the acquisition of an independent oncology practice or the establishment of a completely new facility. 340B hospitals located in urban areas are significantly more likely than those in rural areas to have added a cancer-focused child site during this period.

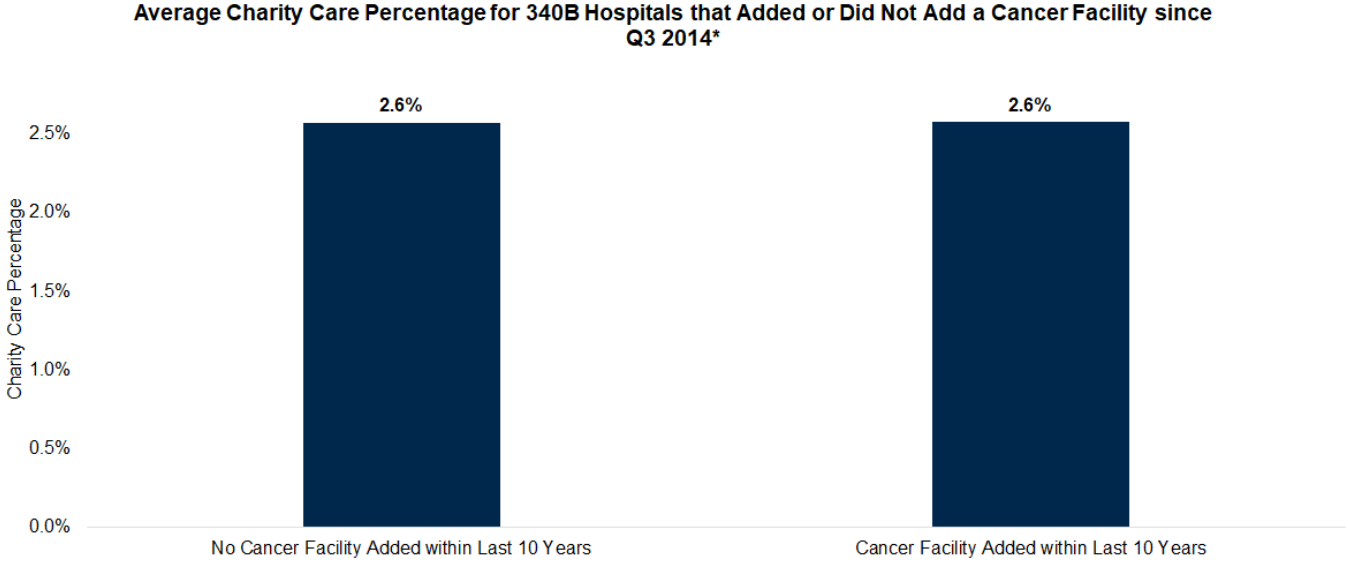


340B hospitals that added a cancer-focused child site are, on average, financially healthier than those that did not add a cancer-focused child site, with average operating margins of four percent compared to one percent. While this could indicate that financially healthier hospitals are more likely to invest in expanding oncology care, it could also reflect the significant 340B drug margin generated by cancer-focused child sites.

[18] Child sites focused on cancer care were identified based on review of their name as registered with the HRSA Office of Pharmacy Affairs.



While the 340B hospitals adding child sites focused on cancer care are financially stronger, they provide the same amount of charity care, as a percentage of their total costs, as hospitals without similar child sites. This could indicate that hospitals with fewer needy patients are most likely to expand cancer care. It could also indicate that the expansion of cancer care at 340B hospitals, despite generating additional 340B margin, is not translating to greater financial support for needy patients.



*For hospitals that did not report charity care on their most recent cost report, the next most recent year where charity care was reported was used.

Impact on Clinical Care

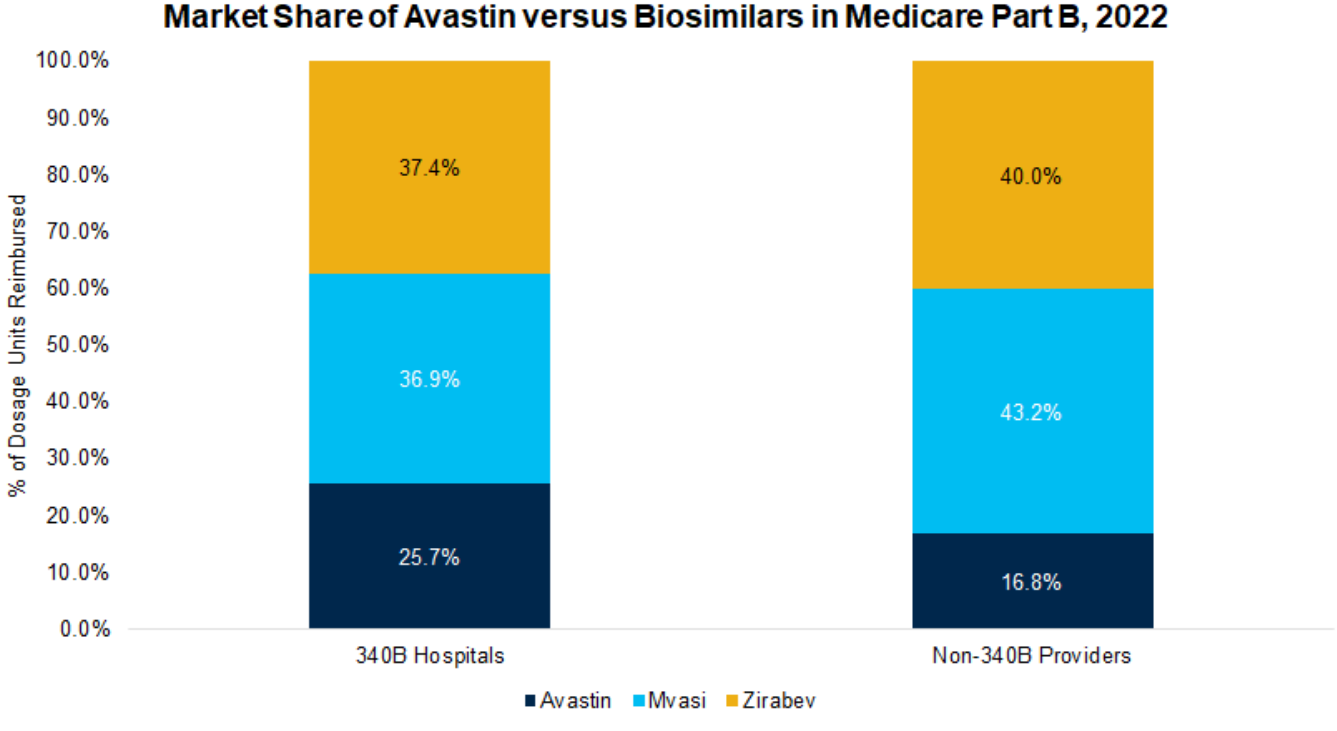
Just as the 340B program creates a financial incentive for hospitals to provide a greater volume of drugs, it also incentivizes hospitals to utilize more costly drugs.[19] 340B hospitals benefit financially from the difference between reimbursement and the 340B price, sometimes referred to as the "spread." This spread amount is almost always larger for drugs with higher list prices. While costlier drugs benefit the 340B hospital, they can increase the costs borne by patients, whether directly in the form of higher coinsurance or indirectly in the form of increased healthcare premiums. Within Medicare Part B, for example, patients are responsible for 20 percent of the cost of their claims. If a $500 drug is administered, this equates to a coinsurance of $100. If a $1,000 drug is used, the coinsurance increases to $200. The remaining 80 percent of the claim cost is paid by Medicare, using funds contributed by Medicare beneficiaries (in the form of premiums) and taxpayers. This means that the

[19] https://www.gao.gov/products/gao-15-442; https://www.milliman.com/-/media/milliman/pdfs/2022-articles/9-13-22_phrma-340b-commercial-analysis.ashx

use of costlier drugs has ramifications not only for those patients directly impacted but for all Medicare beneficiaries and US taxpayers more broadly.

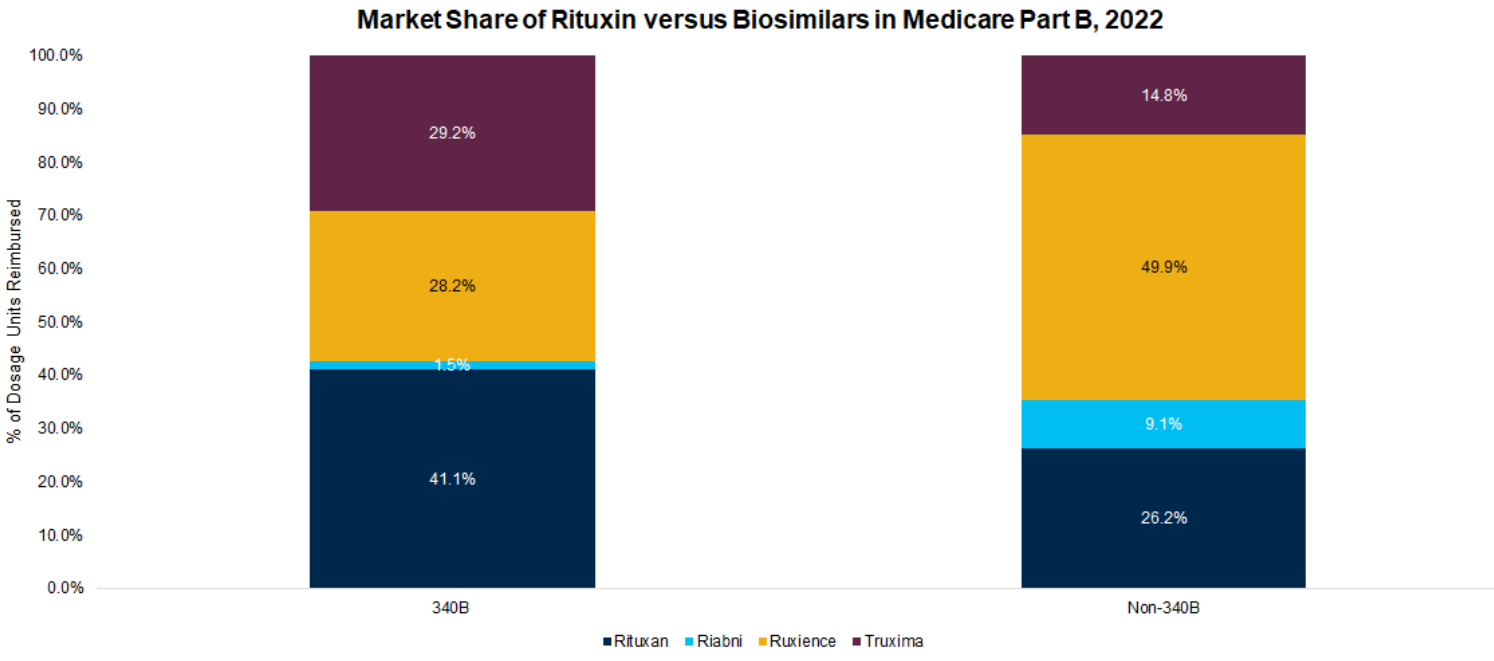
Within cancer care, different therapies are rarely perfect substitutions for one another, and a costly drug may be the only appropriate option for certain patients. The availability of biosimilars for certain common cancer therapies, however, creates a useful mechanism to evaluate whether financial incentives are influencing clinical decision making at 340B hospitals. Biosimilars are drugs that are very similar, though not identical, to biologics that are already on the market.[20] Similar to generics, biosimilars present a lower-cost option with the same treatment risks and benefits as a more costly drug.

Within the oncology space, several common treatments now have biosimilar competitors. Among other cancer therapies, the drugs Avastin and Rituxan, both of which are FDA approved to treat multiple types of cancer, have had approved biosimilar competitors for several years. In 2022, there were two biosimilars available for Avastin: Mvasi and Zirabev. According to CMS reporting for 2022, average Medicare spending per dosage unit (10 milligrams) was $34.40 for Mvasi and $43.28 for Zirabev.[21] These prices represent 48 percent and 35 percent discounts, respectively, from the spending per dosage unit for Avastin, at $66.78. Despite the higher cost to Medicare and to patients, use of Avastin remained significantly higher at 340B hospitals (26 percent of dosage units administered) compared to non-340B hospitals and non-hospital providers (17 percent of dosage units).



For Rituxan, three biosimilars were available in 2022: Riabni, Ruxience, and Truxima. Reported Medicare spending per dosage unit across the biosimilars ranged from $46.65 for Ruxience to $53.88 for Riabni. This compares to spending of $82.21 per unit for Rituxan. As with Avastin, the market share for Rituxan is significantly higher at 340B hospitals (41 percent of dosage units) compared to non-340B hospitals (26 percent of dosage units).

[20] https://www.fda.gov/drugs/biosimilars/biosimilars-basics-patients
[21] https://data.cms.gov/tools/medicare-part-b-drug-spending-dashboard



Conclusion

Just as oncology influences the 340B program's scope and growth, the 340B program influences the delivery of cancer care in the US. The financial incentives associated with 340B directly impact what a cancer patient pays for their care – the higher the cost of the drug used, the greater the amount cancer patients pay in cost sharing like deductibles and coinsurance. The incentives that the 340B program creates for hospitals to use costlier medications adds to the costs born by cancer patients. And the findings from this study and others indicate that the 340B status of a hospital does not necessarily translate to greater amounts of charity care. While 340B hospitals may use the financial benefits of the program in other ways that benefit patients, lack of transparency makes this difficult to confirm.

340B financial incentives have also contributed to the consolidation of cancer care within the hospital setting. Today, urban academic medical centers are the primary beneficiaries of 340B drug margins from cancer treatments and are also more likely to establish or acquire new cancer care sites. While urban teaching hospitals may offer innovative treatments and high-quality care, this consolidation could have negative implications for some patients. First, hospitals tend to be a higher cost site of care compared to the community setting. Second, consolidation may exacerbate access issues in rural areas.

As policymakers consider changes to the 340B program, these issues will need to be addressed to ensure that cancer care is not unfairly impacted, and cancer patients are not burdened with additional out-of-pocket costs.

Appendix A: Methodology

This study utilizes Medicare Part B claims and Part D Prescription Drug Event (PDE) data for 2022, accessed through the Chronic Conditions Warehouse (CCW). Within the Part B claims data, drug claim lines were identified if they included a Healthcare Common Procedure Coding System (HCPCS) Code listed on one of the 2022 quarterly Average Sales Price (ASP) pricing files published by CMS, and flagged if they were a cancer therapy as identified by the National Cancer Institute.[22] The analysis excluded vaccine HCPCS codes, given that the 340B program generally excludes vaccines. The analysis also excluded HCPCS codes assigned to generic products. Because low-cost generics administered at hospitals are often reimbursed by Medicare through a bundled payment inclusive of other goods and services, calculating a reimbursement amount specific to these

[22] https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files; https://seer.cancer.gov/oncologytoolbox/canmed/ndconc/?p=40&paginate_by=10&s=-code

drugs is not always possible. Medicare Part B claims likely to have been filled using 340B-priced drugs were identified based on the Medicare Provider Number on the claim being enrolled in the 340B program on the date of service, according to the HRSA Office of Pharmacy Affairs Information System (OPAIS).[23] While 340B modifier codes were in use in 2022, they were not required for all provider types until 2024.[24] For this reason, this study relies on the 340B status of the provider at the time of the claim, rather than the presence of a 340B modifier, to identify claims likely to have been filled using 340B-priced drugs.

During part of 2022, certain 340B hospitals were subject to reduced reimbursement for drugs. Rather than being reimbursed at the typical rate (ASP plus 4.3 percent after accounting for sequestration), these hospitals were reimbursed at ASP minus 22.5 percent. This reimbursement reduction was reversed in late 2022, however, with 340B hospitals receiving a lump sum repayment in 2024.[25] Part B claims data available within the CCW reflects reduced reimbursement for impacted claims, even though this reduction was later reversed. For this reason, rather than relying on the actual reimbursement amount recorded on the claim, this study reprices claims at the typical reimbursement rate of ASP plus 4.3 percent.

For Medicare Part D, the data was limited to brand drugs, with cancer drugs flagged as described above. Again, generic drugs were excluded. Because of the limited 340B margin opportunity that fails to offset fixed vendor costs, generic prescriptions are often not identified as 340B eligible. This is especially common in the contract pharmacy setting.[26] From there, brand claims were limited to those with a prescriber who was affiliated with a 340B hospital in 2022 and a dispensing pharmacy that was either an in-house or contract pharmacy of that hospital at the time of the dispense. The pharmacy payment amount reported on the PDE record was used to calculate 340B drug margin.

The 340B price for brand drugs is calculated as the Average Manufacturer Price (AMP) less the Medicaid unit rebate amount (URA). This study relies on the Elsevier Gold Standard Drug Database to determine the WAC for each drug at launch and as of 2022. AMP is assumed to be 91 percent of WAC both at launch and in 2024, consistent with averages as reported by the Congressional Budget Office (CBO).[27] The Medicaid rebate per unit includes two components:

- **Basic Rebate**: The greater of AMP multiplied by 23.1 percent or AMP less "Best Price." Best price is defined as the lowest price available to any purchaser (with some exclusions) and is highly confidential. Given the proprietary nature of best price, this study relies on public disclosures of average rebates in Medicare Part D and information on the typical ratio between average rebate and best price to arrive at a proxy for best price.[28]
- **Additional Rebate**: A penalty for increasing a drug's AMP at a faster rate than the Consumer Price Index (CPI) has grown since the drug's launch. Inflation data (without seasonal adjustments) was collected from the Bureau of Labor and Statistics and used to establish the allowable increase in AMP for each drug. The additional rebate was calculated as the difference between the allowable AMP in 2022 versus the estimated 2022 AMP.

This report was supported in part by grants from Bristol Myers Squibb, Genentech, Novartis, and Pfizer. Thanks also to Eleanor Blalock, Mark Fleury, Anna Howard, Nisith Pandya, Pam Traxel, Robin Yabroff and Qin Zhang for their contributions.

[23] https://340bopais.hrsa.gov/home
[24] https://www.cms.gov/files/document/revised-part-b-inflation-rebate-340b-modifier-guidance.pdf
[25] https://jamanetwork.com/journals/jama-health-forum/fullarticle/2817845#:~:text=In%20Medicare%20Part%20B%2C%2020,totaling%20$9%20billion%20in%202024.
[26] https://pmc.ncbi.nlm.nih.gov/articles/PMC4545491/
[27] https://www.cbo.gov/publication/57007.
[28] https://www.gao.gov/products/gao-23-105270; https://www.cbo.gov/publication/57007.