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The Cruel Mystery

LUPUS®
FOUNDATION OF AMERICA

Arthritis Foundation®

Impact of the 340B Program on Rheumatoid Arthritis and Lupus Therapies

Summary of Research

Conducted by the Berkley Research Group for

Arthritis Foundation and

Lupus Foundation of America

Spring 2025

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Introduction

The 340B program was started in 1992 to help offset the costs of providing pharmaceutical drugs to low-income patients. Over the past 15 years, the program has grown considerably, now accounting for over $60 billion annually. As such, scrutiny has grown about the scope and potential abuses within the program. Both federal and state legislators have introduced, and in some cases passed, proposals addressing the 340B program, but to-date no comprehensive reforms have materialized. The exponential growth of the program in recent years has raised questions about how that growth impacts patients. Are 340B discounts reaching the patients they are intended to serve? What is the impact on patients in rural and underserved areas? Are patients who are receiving 340B drugs also facing medical debt?

A major obstacle to patient engagement in 340B is the lack of data on the impact of the program in specific therapeutic areas. As such, the Arthritis Foundation and Lupus Foundation of America partnered to commission research on the impact of 340B on rheumatoid arthritis and lupus. The scope of the research was limited to Medicare Part B and D, in addition to examining 3 state Medicaid programs: CA, OK, and AL.

This summary paper provides an overview and discussion of the data; questions for further study; and recommendations for action steps.

Methodology

We were interested in exploring three essential questions:

1. The amount of 340B revenue for rheumatoid arthritis and lupus drugs received by hospitals on an annual basis in the Medicare program
2. The amount of 304B revenue in select state Medicaid programs
3. Whether the incentives driving growth in the 340B program result in higher patient out-of-pocket costs

Using Medicare Part B/D and Medicaid claims data, the Berkley Research Groups (BRG) quantified total reimbursement received in 2022 by 340B-enrolled hospitals for drug treatments related to arthritis and lupus (identified in partnership with Arthritis Foundation and Lupus Foundation staff). BRG estimated the 340B price for each treatment based on publicly available data points. 340B drug margin was calculated as the difference between reimbursement and the 340B price.

Identifying patients with an arthritis or lupus diagnosis in Medicare Parts B and D claims data, BRG examined:

- The percentage of patients whose copay exceeded the 340B price at which the hospital acquired the drug
- The cost of arthritis and lupus treatments prescribed or administered at 340B and non-340B hospitals to determine if 340B hospitals are using more costly drugs to treat patients

To select the three Medicaid states, BRG required the following data fields:

- **Medical claims**: billing NPI, reimbursed amount
- **Pharmacy claims**: prescriber, pharmacy identifier, reimbursed amount

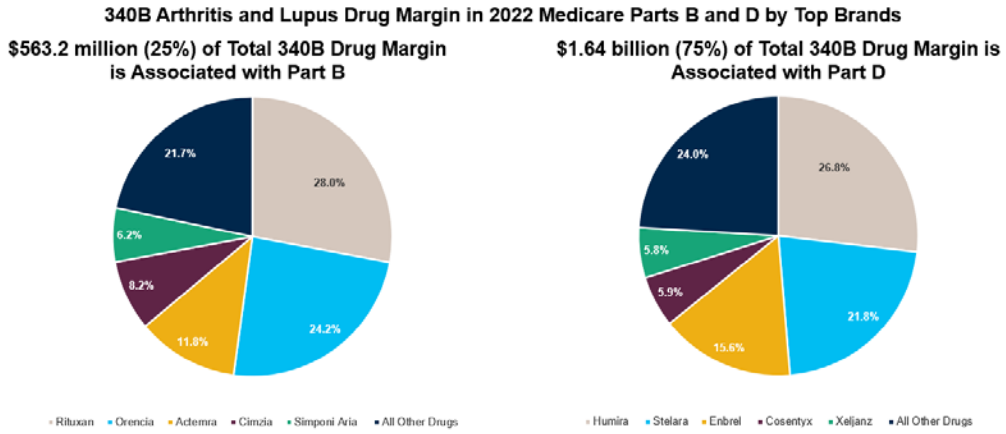
The states of Alabama and Oklahoma were selected due to their comprehensive pharmacy claims data (99% of claims had all necessary fields) and reasonably complete medical claims data (73% and 38% of claims were complete), while California was selected due to having a large population of arthritis and lupus patients. Only 6% of California medical claims have all required fields, meaning the analysis of 340B margin for California largely excludes medical benefit claims.

Results

Medicare Parts B and D

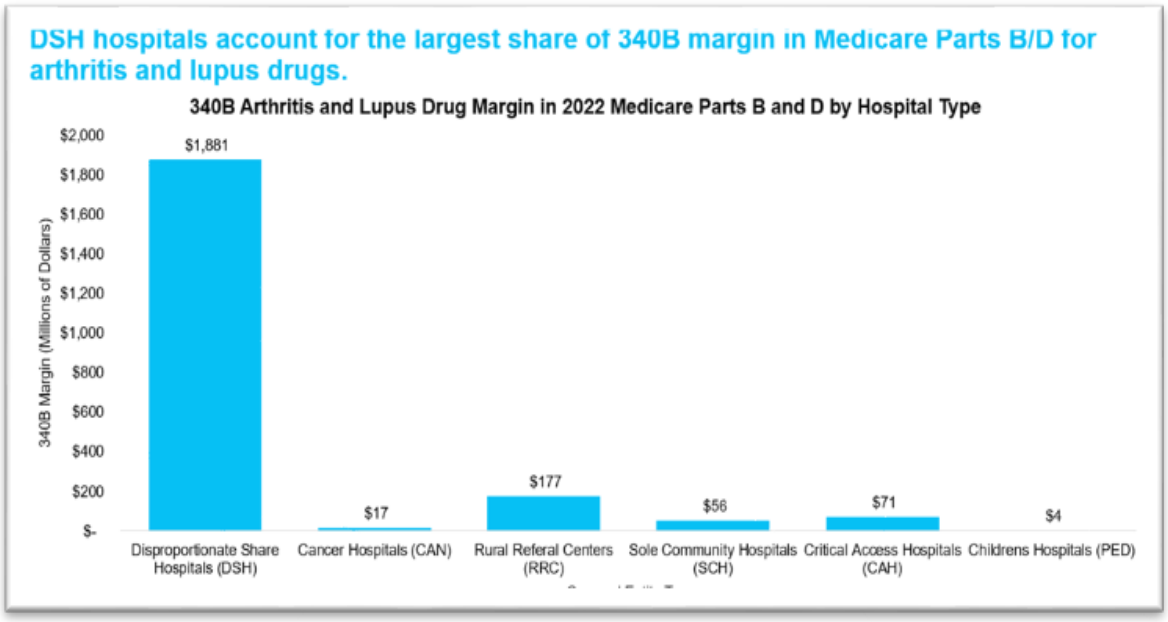
340 Margin in Parts B and D:

- 25% or $563.2 million 340B margin is associated with Part B, and 75% or $1.64 billion 340B margin is associated with Part D, totaling more than $2.2 billion in 340B margin in 2022 across those two programs
- $563.2 million (25%) of Total 340B Drug Margin is Associated with Part B; Humira is the largest share, at 26.8%
- $1.64 billion (75%) of Total 340B Drug Margin is Associated with Part D; Rituxan is the largest share, at 28%

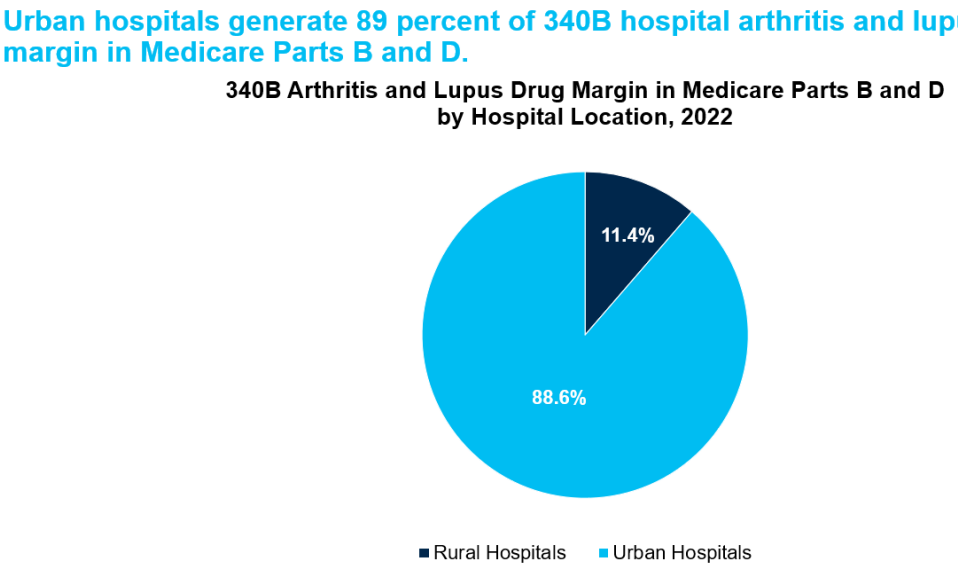


340B Margin Across Hospital Type

- Disproportionate Share Hospitals (DSH) accounted for the largest share of 340B margin, totaling $1.88 billion
- Rural Referral Centers had $177 million in 340B margin
- Critical Access Hospitals had $71 million in 340B margin
- Sole Community Hospitals had $56 million in 340B margin
- Cancer Hospitals had $17 million in 340B margin
- Children's Hospitals had $4 million in 340B margin



- Urban hospitals generate 89 percent of 340B hospital arthritis and lupus 340B drug margin in Medicare Parts B and D



- Teaching hospitals account for 87 percent of 340B hospital arthritis and lupus drug margin in Medicare Parts B and D

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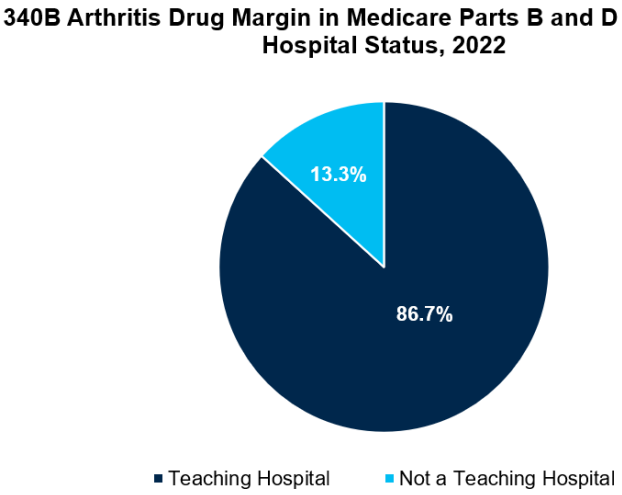

Charity Care and Bad Debt Comparisons

- Across all 340B hospitals, drug margin in Medicare Parts B/D for arthritis and lupus drugs is below total charity care cost and bad debt expenses:
    - The 340B margin was $2.2 billion for arthritis and lupus drugs, compared to $17.9 billion spend on charity care, and $27.7 billion in bad debt expenses

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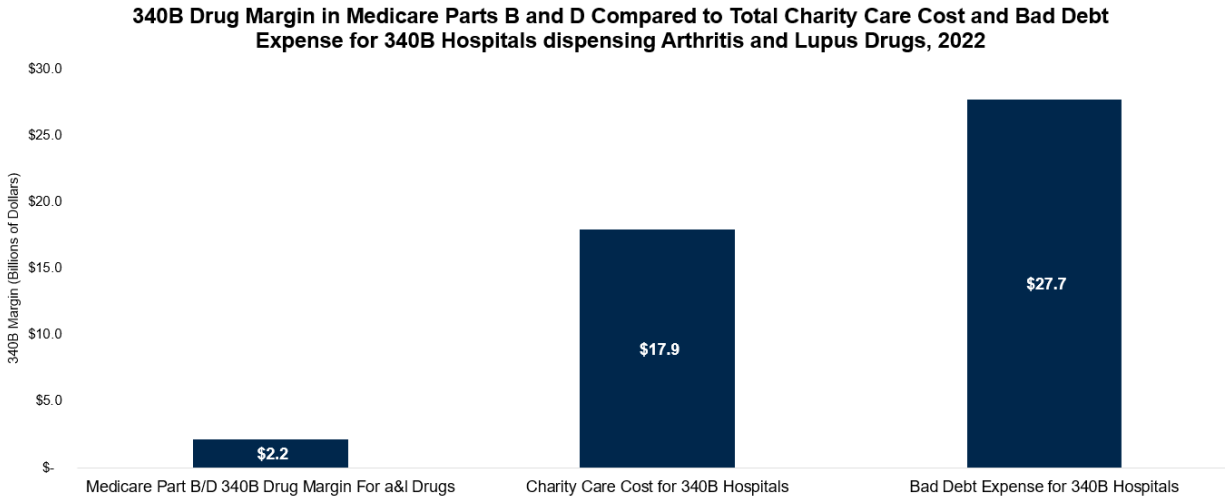
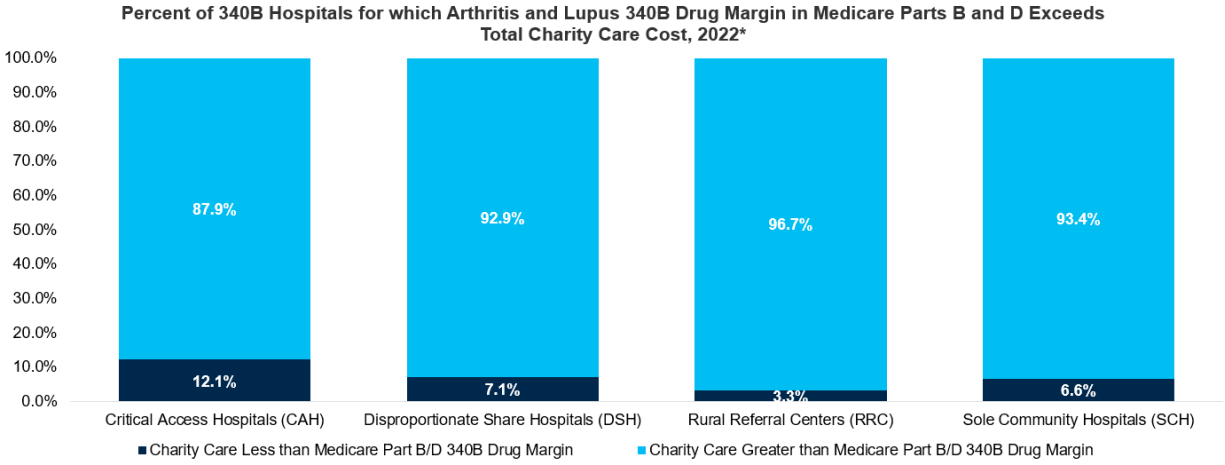


- Seven percent of DSH hospitals provide less charity care than their 340B drug margin from Medicare Parts B/D on arthritis/lupus drugs:
    - 12% of Critical Access Hospitals spent less on charity care than they received in 340B margin
    - 7.1% of DSH hospitals spent less on charity care than they received in 340B margin
    - 6.6% of Sole Community Hospitals spent less on charity care than they received in 340B margin
    - 3.3% of Rural Referral Centers spent less on charity care than they received in 340B margin

Seven percent of DSH hospitals provide less charity care than their 340B drug margin from Medicare Parts B/D on arthritis/lupus drugs, meaning profits from those drugs are being used elsewhere.



Cost of Care Analysis

- In Medicare Part B, beneficiary cost-sharing exceeds the 340B price of an arthritis or lupus drug 16 percent of the time compared to 6 percent in Part D

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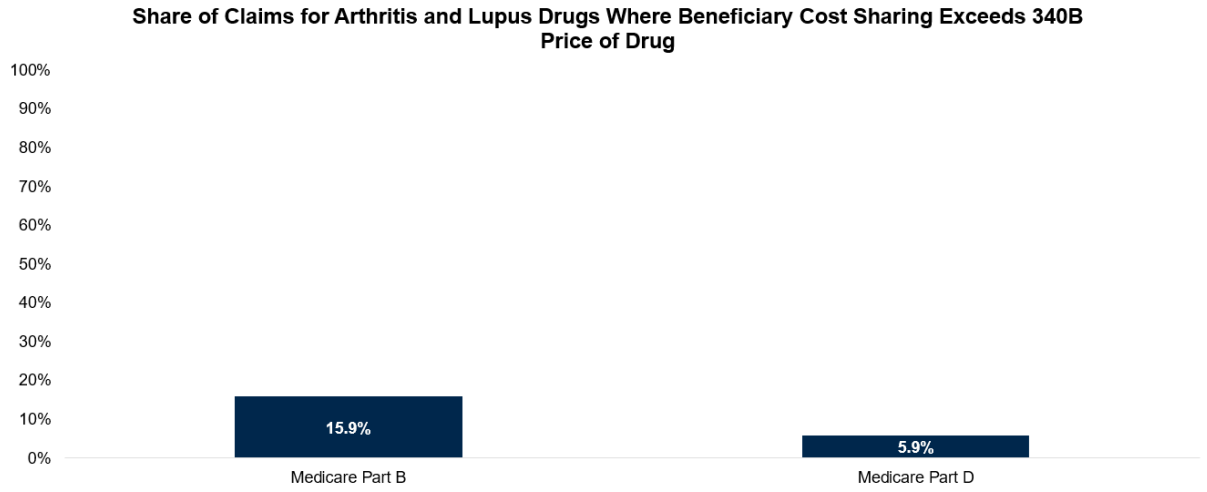

- The average annual cost per patient for arthritis or lupus treatments is higher at 340B hospitals than non-340B hospital/clinics in Medicare Part D but not Part B:
- In Part D, the average cost per patient was $60,407 at a 340B hospital compared to $56,885 at non-340B hospitals
- In Part B, the average cost per patient was $18,520 at 430B hospitals vs $20,575 at non-340B hospitals

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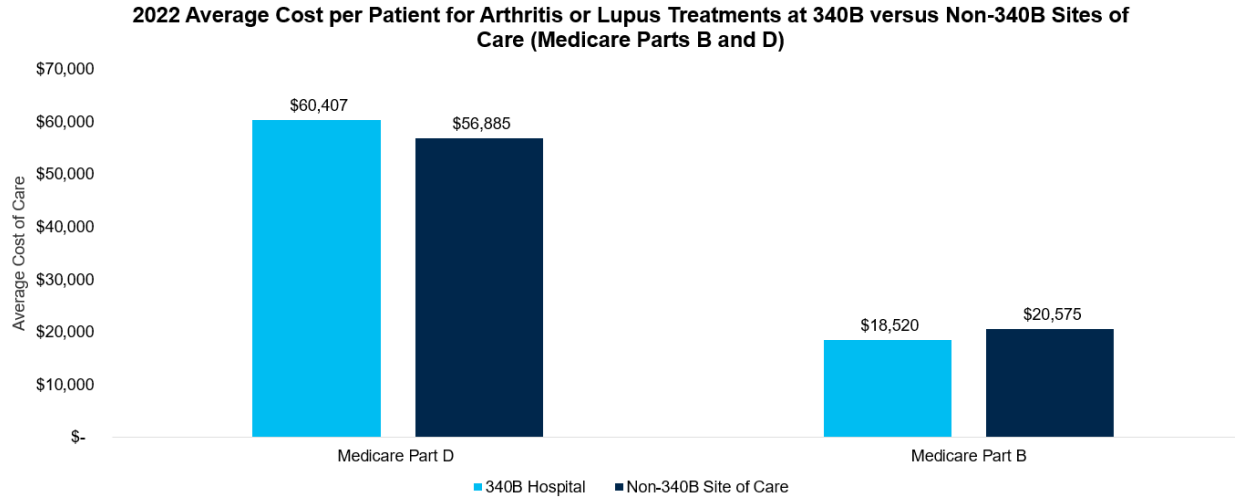
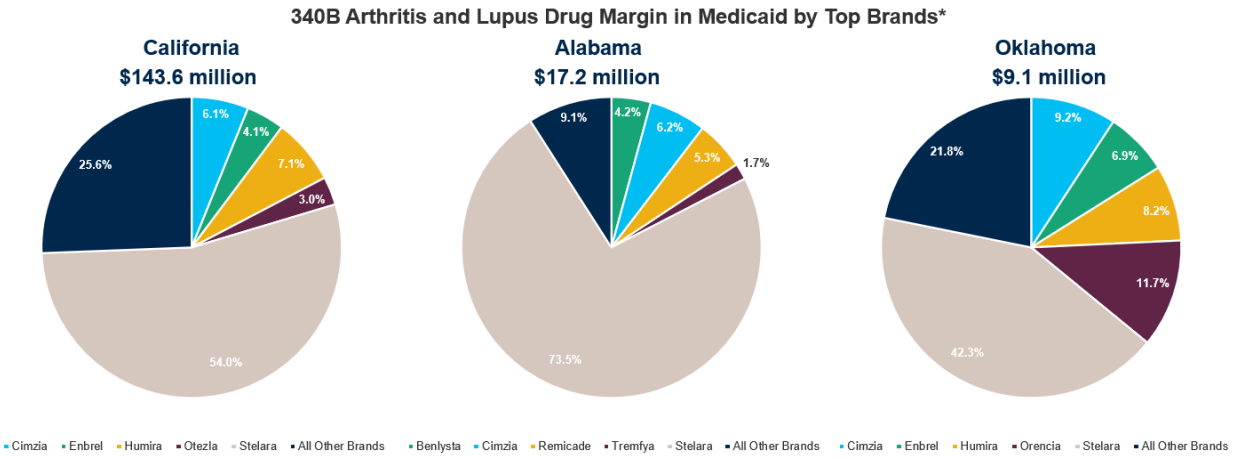


Medicaid data for California, Alabama, and Oklahoma

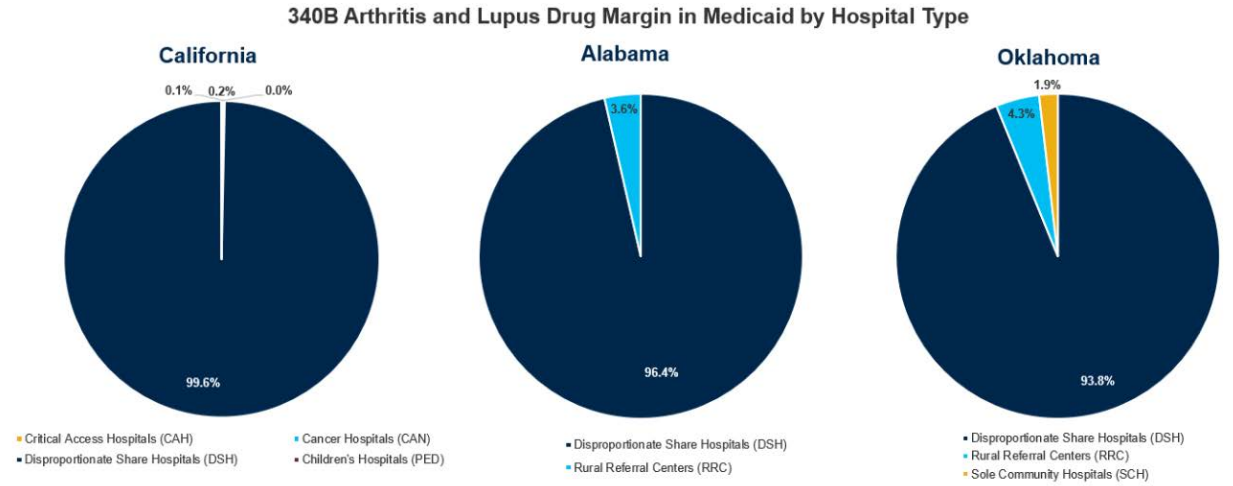
340B Margin in Medicaid across three states:

- Stelara is the largest share in the 3 states analyzed, at 54% (CA), 73.5% (AL), and 42.3% (AL)



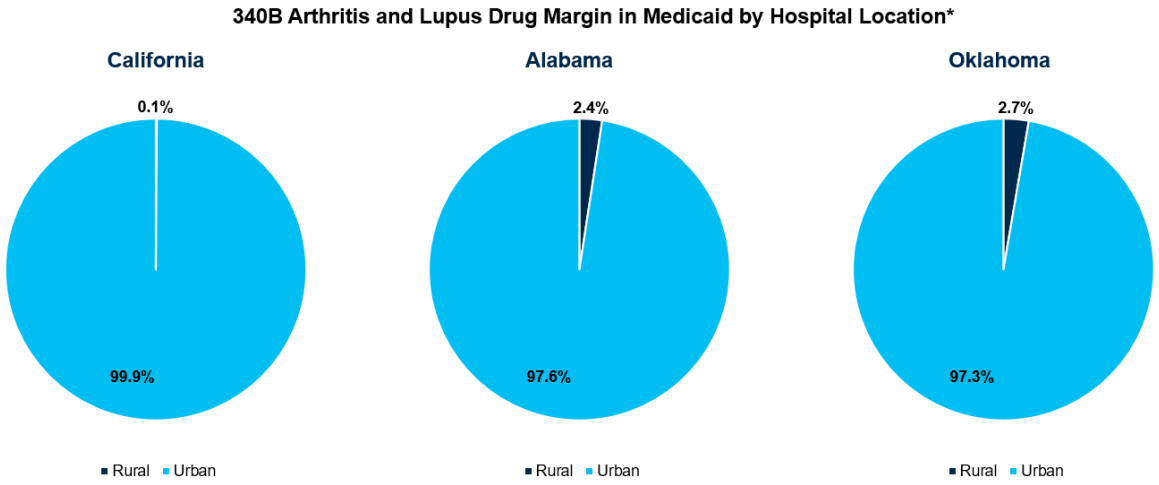
- DSH hospitals accounted for 99.6% margin in CA, 96.4% in AL, and 93.8% in OK

DSH hospitals account for the highest percentage of 340B margin from Medicaid in California, Alabama, and Oklahoma.



- Urban hospitals account for 99.9% of 340B arthritis and lupus drug margin in CA, 97.6% in AL, and 97.3% in OK

Across California, Alabama, and Oklahoma, urban hospitals account for almost all 340B hospital arthritis and lupus drug margin in Medicaid.



Discussion

The data show there is a significant impact from the 340B program on rheumatoid arthritis and lupus medications. The over $2 billion in 340B revenue to Medicare does not include Medicare Advantage, Medicaid, or the commercial and individual insurance markets. We cannot accurately extrapolate the total 340B revenue for arthritis and lupus drugs across all markets, but we would anticipate that it would be a significant share of the over $60 billion aggregate 340B market. Many of the data points track with outside data and research on the program overall, including the higher shares of 340B revenue among DSH hospitals, the ratio of teaching hospitals to non-teaching hospitals, and the ratio of urban to rural entities.

An important caveat on the results of charity care and bad debt ratios is that the 340B dollars reflect only arthritis and lupus drugs while the charity care and bad debt numbers reflect all therapeutic areas, so this is not a 1:1 comparison. However, this makes it even more alarming that there is any percentage of hospitals that receive higher 340B revenue in two therapeutic areas than they fund in charity care. It is also concerning that cost-sharing is exceeded 16% of the time in Part B and 6% in Part D. This suggests these entities are charging patients more than the cost at which they purchased the 340B drugs.

As the drug with the largest market share for autoimmune arthritis in the year 2022, it is logical that Humira would be the largest driver of 340B revenue in Part D. One note of interest is that this data predates the launch of adalimumab biosimilars in the United States, and we will be curious to see if revenue percentages shift in subsequent years.

Another important consideration in the coming years is the impact of the One Big Beautiful Bill Act (OBBBA) on Medicaid enrollment. If cuts to Medicaid increase the rate of uninsured Americans, how might that impact the 340B program and what pressure might that put on hospitals to provide further charity care?

While the data provides a good overview of 340B revenue for arthritis and lupus medications, the lack of transparency requirements for the program leaves us with many questions about how patients are impacted by the program. Questions for future research and consideration include:

- Will current incentive structures impact 340B drug purchasing of biosimilars in the future? If entities can receive larger profits from purchasing higher-cost drugs, will Humira continue to dominate the market share of 340B revenue?
- How will the implementation of the Part D $2,000 cap impact the ratio of patients who are paying a higher cost-share than the 340B drug cost?
- What is the relationship between arthritis and lupus patients experiencing medical debt and 340B?
- How will implementation of OBBBA and potential Medicaid cuts impact the 340B program?

Conclusions and Recommendations

There is a clear case to make that there is a patient impact from the 340B program in our therapeutic areas. A lack of transparency in the program makes it difficult to understand the full extent of this impact. We were particularly alarmed that there are instances in which patients are paying higher out-of-pocket costs than the entity is paying to purchase the medication. At a minimum, there should be patient protections that prevent this from happening. It is also clear that there is a relationship between 340B and many other issues that impact patients both positive and negative, including availability of biosimilars, Medicare Part D cost caps, Prescription Drug Affordability Board activities, and industry consolidation, among others. Policymakers should proactively work with the patient community to craft guardrails on patient out-of-pocket costs and to understand the impact the 340B is having on patient access.

Below are four principles we recommend for consideration in any reform efforts:

1. **Increased Transparency.** Better transparency into how 340B revenue is being allocated and whether it is appropriately being utilized to support low-income and uninsured patients is a critical step in reforming the program.
2. **Reduced Patient Out-of-Pocket Costs**. 340B revenue should first and foremost be utilized to lower out-of-pocket costs for the most vulnerable patients, in keeping with the original intent of the program. Reform policies should ensure that low-income, underinsured, and uninsured patients are protected against burdensome out-of-pocket costs. Further, no patient should pay a higher out-of-pocket cost for their prescription than the hospital or facility is paying to acquire the drug, regardless of income status.
3. **Medical Debt Protections.** Guardrails should be in place to ensure entities receiving 340B revenue are not engaging in aggressive medical debt collection practices.
4. **Charity Care Guardrails.** Entities receiving 340B revenue should prioritize their charity care programs and ensure 340B discounts are being utilized to support charity care needs.