Sample Issue

August 16, 2022

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340B Drug Pricing Program, Purchases by Covered Entities, 2021

Entity type	Total 2021 purchases at 340B discounted prices	Share of total 2021 purchases	Change in total purchases vs. 2020
Hospital			
• Disproportionate Share Hospitals	$34,288,472,705	78.1%	+15.1%
• Children's Hospitals	$1,330,248,212	3.0%	+14.1%
• Rural Referral Centers	$1,174,151,155	2.7%	+34.8%
• Critical Access Hospitals	$620,923,559	1.4%	+18.6%
• Sole Community Hospitals	$451,594,319	1.0%	+11.2%
• Free-standing Cancer Centers	$304,098,033	0.7%	+35.6%
Subtotal	$38,169,487,983	86.9%	+15.7%
Federal Grantee			
• Consolidated Health Center Programs	$2,215,221,250	5.0%	+12.3%
• Ryan White HIV/AIDS Program Grantees	$2,180,003,882	5.0%	+8.2%
• Sexually Transmitted Disease Clinics	$871,036,833	2.0%	+54.2%
• Comprehensive Hemophilia Treatment Center	$192,106,843	0.4%	-10.1%
• All other	$284,557,390	0.6%	+20.6%
Subtotal	$5,742,926,198	13.1%	+14.8%
Total	$43,912,414,181	100.0%	+15.6%

Source: Drug Channels Institute analysis of data from Health Resources and Services Administration. Purchases exclude sales made directly to healthcare institutions by manufacturers and some sales by specialty distributors. Data for purchases at discounted prices show value of purchases at or below the discounted 340B ceiling prices.

Published on *Drug Channels* (www.DrugChannels.net) on August 15, 2022.

DRUG CHANNELS INSTITUTE

DSH hospitals accounted for 78.1% of all 340B program purchases in 2021, according to federal data obtained by Drug Channels Institute under the Freedom of Information Act.

Federal Data Show 340B Sales Hit $43.9 Billion in 2021, Drug Industry Consultant Reports

In **Federal, Regulatory, Research/Reports** August 16, 2022 **Tom Mirga**

Total sales in the 340B drug pricing program reached $43.9 billion in 2021, a 15.6% increase over 2020 sales and more than 3.5 times above total sales in 2015 ($12.1 billion), according to federal data obtained by Drug Channels Institute under the Freedom of Information Act.

The institute is led by drug industry consultant Adam Fein, creator of the influential Drug Channels blog and a leading critic of hospitals that participate in 340B. For several years Fein has obtained the government's most up-to-date 340B sales figures under FOIA and reported them in his blog. The U.S. Health Resources and Services Administration reports the same or slightly adjusted data months later in its annual budget requests to Congress. The figures come from Apexus, the 340B prime vendor, and do not include manufacturer direct sales to entities.

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Fein this year asked HRSA to break out 340B sales data by covered entity type. HRSA reported that hospital entities accounted for 86.9% of 340B sales in 2021 and grantee entities for 13.1%.

Among hospital entities, disproportionate share hospitals (DSH) were the largest purchasers of 340B priced drugs last year ($34.2 billion, 78.1% of all 340B program sales), followed by children's hospitals ($1.3 billion, 3.0%), rural referral centers ($1.7 billion, 2.7%), critical access hospitals ($620 million, 1.4%), sole community hospitals ($451 million, 1.0%), and free-standing cancer hospitals ($304 million, 0.7%).

DSH hospitals' share of total 340B program sales grew from just over half (52.0%) in 2015 to just over three quarters (78.1%) last year, the data show.

Among grantee entities, consolidated health center programs were the largest 340B program purchasers in 2021 ($2.2 billion, 5.0% of all 340B program sales), followed closely by Ryan White HIV/AIDS program grantees ($2.1 billion, also 5.0%). Sexually transmitted disease clinics ranked third ($871 million, 2.0%). All other grantee types collectively accounted for about 1.0% of 340B sales.

340B sales to some types of entities declined from 2020 to 2021, including comprehensive hemophilia treatment centers (from $213 million to $192 million) and family planning clinics (from $83.8 million to $74.9 million).

340B sales through the ADAP rebate option were $125,873 in 2015, dropped to just $724 in 2017, climbed back to $31,728 in 2020, then fell again last year to $23,336.

"340B advocates have been screaming that 'drug companies are cutting 340B,' but the data tell a very different story," Fein commented in his blog about the 2021 sales figures. "Congress has just passed the Inflation Reduction Act, which will sharply reduce pharmaceutical manufacturers' revenues. It's long past time for legislators to revisit the out-of-control and unregulated 340B program."

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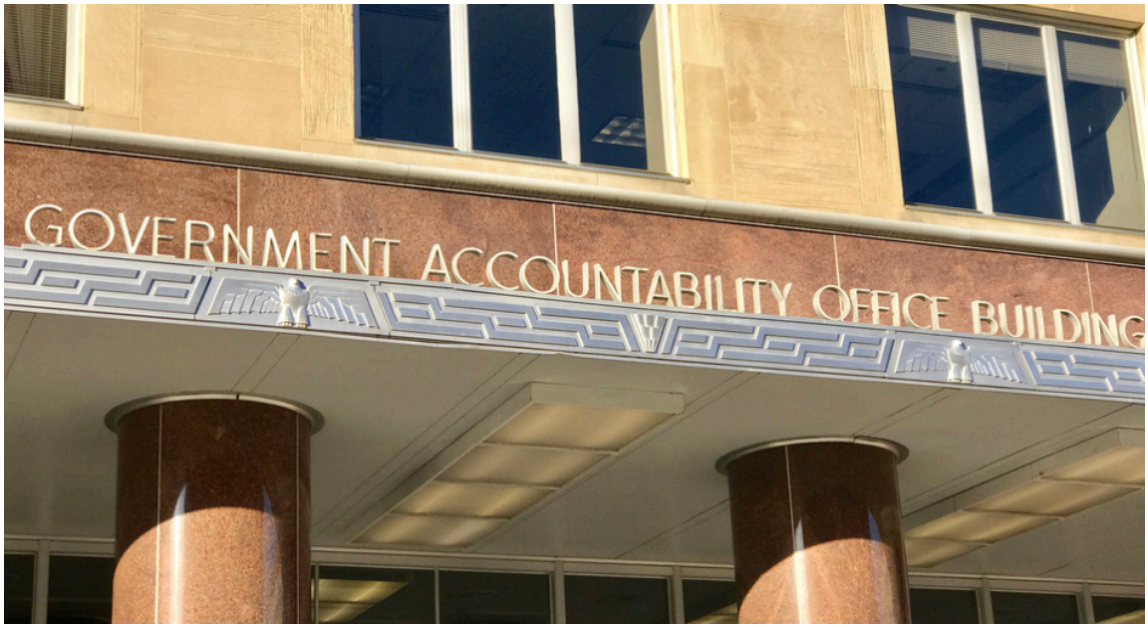

GAO is studying a new law that enables hospitals to maintain or regain their 340B eligibility despite having fallen below the minimum required Medicare disproportionate share (DSH) adjustment percentage due to COVID 19-related changes in patient mix.

At Request of Senior GOP Lawmakers, GAO Studying Law That Gave Relief to Hospitals Forced Out of 340B Due to COVID-19

In **Federal, Research/Reports** August 16, 2022 **Ted Slafsky and Sarah True**

The Government Accountability Office (GAO), Congress's watchdog agency, is conducting a study of a new law that enables hospitals to maintain or regain their 340B eligibility despite having fallen below the minimum required Medicare disproportionate share (DSH) adjustment percentage due to COVID 19-related changes in patient mix, says Michelle Rosenberg, GAO's Director of Health Care. Sen. Richard Burr (R-N.C.) and Rep. Cathy McMorris Rodgers (R-Wash.) requested the study, Rosenberg says.

Burr is the ranking Republican on the Senate Health, Education, Labor, and Pensions Committee and McMorris Rodgers is the top Republican on the House Energy and Commerce Committee. These committees have direct jurisdiction over the 340B program. The request to GAO could signal renewed interest in oversight and potential changes to the 340B program if the House and Senate flip to Republican control.

The study is currently underway and in its early stages, says Rosenberg. She says Burr and McMorris Rodgers asked GAO to look at the particular hospitals that received an exception to the DSH adjustment percentage requirement as well as HRSA's oversight of those hospitals. She says the exact scope and methodology for the study "have not been set" because the agency is still early in the research process and there is no estimated release date for the study at this time.

It is unknown when Burr and McMorris Rodgers made the request. Staff for both members did not respond to multiple requests for comment.

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In March 2022, President Biden signed into law an appropriations bill with language to help some hospitals forced out of the 340B program during the COVID-19 pandemic to re-enroll. It is also intended to help others that similarly may lose their eligibility through the end of this year.

The 340B provision, which had broad bipartisan support, helps hospitals whose admission patterns were disrupted by the COVID-19 pandemic to the point that their Medicare disproportionate share (DSH) adjustment percentages fell below the levels needed to remain in 340B.

Hospitals nationwide suspended elective care for varying lengths of time to conserve resources for COVID patients, and this led to differences in demographics, insurance types, and clinical care of patients treated in 340B-eligible hospitals during these time periods when compared to the norm, 340B hospital advocates point out. Under the new law, hospitals could regain eligibility starting on the day that the law was enacted through the end of this year.

April 14 was the deadline for such hospitals that want to reenroll in 340B to attest to HRSA that the public health emergency (PHE) disrupted their admission patterns to the point that their Medicare disproportionate share (DSH) adjustment percentage fell below the level needed to qualify for 340B drug pricing.

Hospitals must fill out a three-page attestation form describing "any actions taken by or other impact on the hospital in response to or as a result of the COVID-19 PHE that may have impacted the hospital's ability to meet the applicable required DSH percentage for participation in the 340B program."

HRSA said in March that after the spending bill was passed it contacted 94 hospitals terminated from 340B during the pandemic for any reason to alert them about potential reinstatement.

On April 15, a HRSA spokesperson said that 48 hospitals had submitted attestations for reinstatement under the new law. HRSA declined to identify the hospitals. It is unknown if other eligible hospitals were unaware of or decided not to take advantage of the reinstatement option.

There is no guarantee that hospitals that apply for reinstatement to 340B will be let back in, no questions asked. HRSA told the 94 hospitals it contacted last month that "requests will be evaluated on a case-by-case basis."

To the disappointment of 340B hospitals, the bill stopped short of allowing them to recover lost revenue from 340B discounts they would have received while ineligible—an amount reaching millions of dollars, some hospitals said. Still, the inclusion of some relief was considered a victory by hospital groups who had spent months lobbying for these protections.

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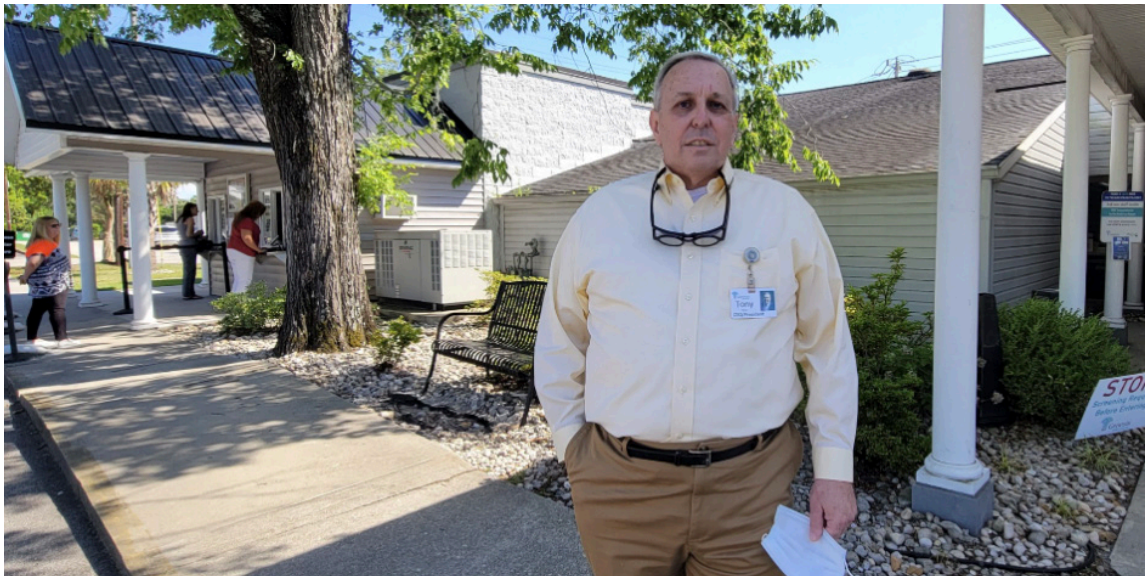

Tony Megna, CEO of one of the profitable health centers investigated by Kaiser Health News, said, "We ask, why is there an implication that surplus funds come at the expense of our mission?" | Phil Galewitz / KHN

Health Centers Criticize Kaiser Health News Story About Profit Margins

In **Other Industry, Research/Reports** August 16, 2022 **Tom Mirga**

Community health center advocates have strongly criticized a new Kaiser Health News (KHN) investigative report that found that some health centers have large profit margins.

The article found that nine of the nation's nearly 1,400 health centers reported profit margins above 20% in three or all of the last four years. The national average is 5%, KHN said.

The National Association of Community Health Centers (NACHC) said the story "paints a grossly inaccurate picture" of health centers' finances by focusing on "data representing fewer than 1% of health centers nationwide."

The story ran first on Friday online in The Washington Post and was KHN's lead story yesterday. The 340B program's role in generating health center revenue is a thread that runs through the article.

KHN is widely respected and lets others republish its content for free. The health center profit margin article likely will be read by many nationally.

It is the latest in a recent string of blows for health centers involving 340B. The story ran just days after Boehringer Ingelheim became the eighth drug maker to impose 340B pricing conditions on health centers when they contract with outside pharmacies. The story also came on the heels of a failed Republican attempt in the U.S. Senate to amend a major Democratic drug pricing, climate change, and taxation bill to require health centers to make insulin and injectable epinephrine available to patients at or below 340B price.

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"A Need for Greater Federal Scrutiny"

Two healthcare policy experts interviewed for the article—Johns Hopkins University professor Ge Bai and University of Oklahoma assistant professor Ganisher Davlyatov—told KHN that "the surpluses alone should not raise concerns if the health centers are planning to use the money for patients," the article said.

Bai and Davlyatov added, however, "that the high margins suggest a need for greater federal scrutiny of the industry and whether its money is being spent fast enough," the article continued.

"No one is tracking where all their money is going," said Davlyatov, who has led or collaborated on other research on health center chief executives' pay and its relationship to clinical performance and on where health centers choose to expand.

"The centers have to provide enough benefit to deserve their public tax exemption, and what we are seeing here is a huge amount of profits," said Bai, who led an April 2021 study from 340B published in Health Affairs that found that nonprofit hospitals spend less on charity care than government or for-profit hospitals.

The article said officials at the nine health centers "defended their strong surpluses, saying the money allows them to expand services without being dependent on federal funds and helps them save for big projects, such as constructing new buildings. They pointed out that their operations are overseen by boards of directors, at least 51% of whom must be patients, ostensibly so operations meet the community's needs."

U.S. Health Resources and Services Administration Associate (HRSA) Administrator James Macrae told KHN, "It's definitely something we will look at and what they are doing with those resources." Macrae, a long time HRSA senior official, heads the agency's Bureau of Primary Health Care, the unit that runs the federal health center program. "The expectation is they will take any profit and plow it back into the operations of the center," he said.

The KHN story said some of the health centers with large surpluses make most of their money from sales of 340B-purchased drugs. It said the drug discount program lets health centers buy medicines at deep discounts, bill insurers at a higher rate, and keep the difference. "Clinics can reduce the out-of-pocket costs for patients but are not required to," the article said.

NACHC's Response

NACHC called the article "grossly inaccurate" in an Aug. 12 letter to The Washington Post. The association gave 340B Report a copy of its letter.

The nine health centers singled out by KHN are less than 1% of the nearly 1,400 health centers nationally, NACHC said. "Framing an argument on a cherry-picked handful of health centers … may generate a compelling headline, but also skews the facts."

"Most health centers are operating on thin margins," NACHC said. "Health centers' financial reserves are not secreted away, but rather are regularly reported, publicly available for scrutiny and subjected to annual fiscal audits. In some cases, if allowable, these extra dollars go toward new site expansions, increased staffing, or expanded services to address identified unmet needs in an underserved community."

NACHC also said the article "amplifies misconceptions" about 340B. "By law, any and all health center savings resulting from that program must be re-invested in patient care," it said.

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Focus on Genesis Health Care

KHN's article begins and ends with South Carolina-based Genesis Health Care and its CEO and general counsel, Tony Megna. Genesis successfully contested its dismissal from 340B in 2018 over audit findings that it dispensed 340B drugs to ineligible patients. A federal appeals court held last month that Genesis has the right to seek a lower court order that could expand the 340B patient definition dramatically.

The article said Genesis "benefits financially" from participation in 340B and that drug sales provide the bulk of its revenue.

"Those sales helped Genesis record a $19 million surplus on $52 million in revenue—a margin of 37%—in 2021, according to its audited financial statement," the story said. "It was the fourth consecutive year the center's surpluses had topped 35%, the records showed."

"Most of Genesis' revenue comes from the 340B program," the article said.

"Genesis attributes its large margins to excellent management and says it needs the money to expand and modernize services while being less reliant on government funding," the article said. "Still, Genesis' hefty surplus stands out."

"Megna was paid nearly $877,000 in salary and bonuses in 2021, according to Genesis' latest IRS tax filing, an amount nearly four times the industry average," the article said. The chair-elect of the Genesis board told KHN "that part of that compensation made up for several years when Megna was inadvertently underpaid," the article said. KHN said Megna said his base salary is $503.000.

Three other health centers are profiled in the article. It does not say what their leaders are paid.

In response to a request for comment about the article, Megna said, "We ask, why is there an implication that surplus funds come at the expense of our mission? Many nonprofits have surpluses and/or substantial bank accounts. There is nothing wrong with good fiscal management. The wrong comes from spending the funds for something other than what supports our mission. Numerous required audits over the years have proven that Genesis does use funds appropriately."

"Rather than lauding the health centers that are successful, this article implies there is something nefarious about their success, which is not in line with good journalism," Megna said.

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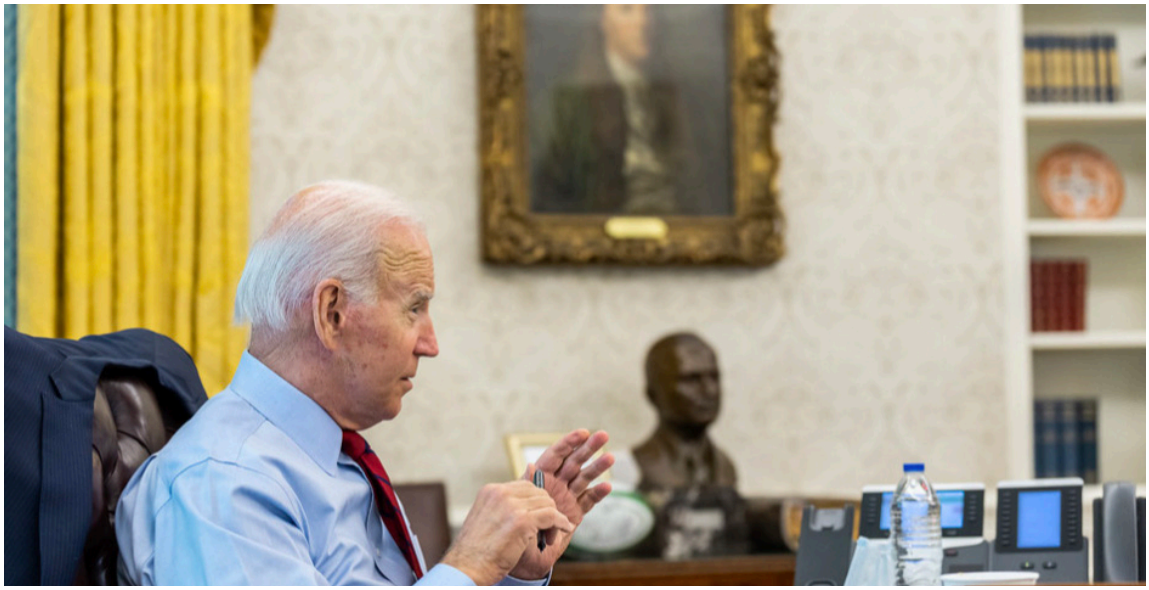

President Biden is scheduled to sign historic drug pricing legislation with implications for the 340B program later today.

Bill Giving Medicare Drug-Price Negotiating Power Set to Become Law

In **Federal, Legislative** August 16, 2022 **Laura Gilcrest**

President Joe Biden this afternoon is scheduled to sign legislation that for the first time will let Medicare negotiate the prices of certain costly prescription drugs and require drug makers to pay Medicare rebates when their prices outpace inflation.

House Democrats returned temporarily from recess Aug. 12 to approve the Inflation Reduction Act of 2022 in a 220-207 vote along party lines. Senate Democrats pushed their version of the bill through via the budget reconciliation process on Sunday, Aug. 7.

The bill's language cements price protections that 340B providers had pushed for, which enables 340B covered entities to access the lower of the 340B price or the "maximum fair price" negotiated by Medicare. However, the flip side is that, as Medicare bargains for lower prescription drug prices, that will result in smaller savings reimbursed to 340B providers.

The bill gradually increases the number of "negotiation-eligible" drugs cumulatively over time, with a total of 80 prescription drugs covered by Medicare's new bargaining authority by 2030.

Specifically, the U.S. Department of Health and Human Services (HHS) can initially negotiate the prices of 10 top-selling, single-source Part D drugs, with the prices taking effect in 2026. HHS can then select 15 additional Part D drugs for negotiation, with the prices effective in 2027, then an additional 15 Part B or D drugs, with prices taking effect in 2028.

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In the final phase, HHS can negotiate the prices on 20 additional Part B or D drugs, with prices effective in 2029, then 20 more drugs the year after.

The legislation sets criteria for selecting drugs that qualify for government negotiations, targeting Part B and D drugs that have cost Medicare the most money over the preceding 12 months. It also carves out exceptions, excluding drugs for which Medicare's total spending is less than or equal to 1% of total outlay under Part D, new formulations of an eligible drug, and orphan drugs.

The negotiating power would result in government savings of $288 billion over 10 years, according to a Congressional Budget Office estimate.

The legislation also requires manufacturers to pay rebates on Medicare drugs reimbursed under Part B or D when the average manufacturer price for a particular drug rises faster than inflation, with the rebate calculated based on the difference between the drug maker's price and the inflation rate for all sales of that drug to Medicare. The inflation penalty has been effective in tamping down prices in both the 340B and Medicaid rebate programs and the authors of the new Medicare law are hopeful that it will also play an important role in restraining prices for Medicare beneficiaries.

The bill includes language to protect a drug manufacturer from having to pay two inflation penalties on the same drug. This is done by excluding 340B purchases from the Part B and Part D rebate calculations.

The bill's other key drug pricing provisions:

- Cap Part D beneficiary total out-of-pocket spending at $2,000 per year
- Cap premium growth at 6% per year through 2029
- Cap insulin costs for Medicare patients at $35/month
- Eliminate cost sharing for adult vaccines covered in Medicare Part D
- Expand income eligibility for Medicare Part D low-income subsidies
- Repeals Trump Administration's drug rebate rule, requiring pharmacy benefits managers to pass on saving to patients at point-of-sale

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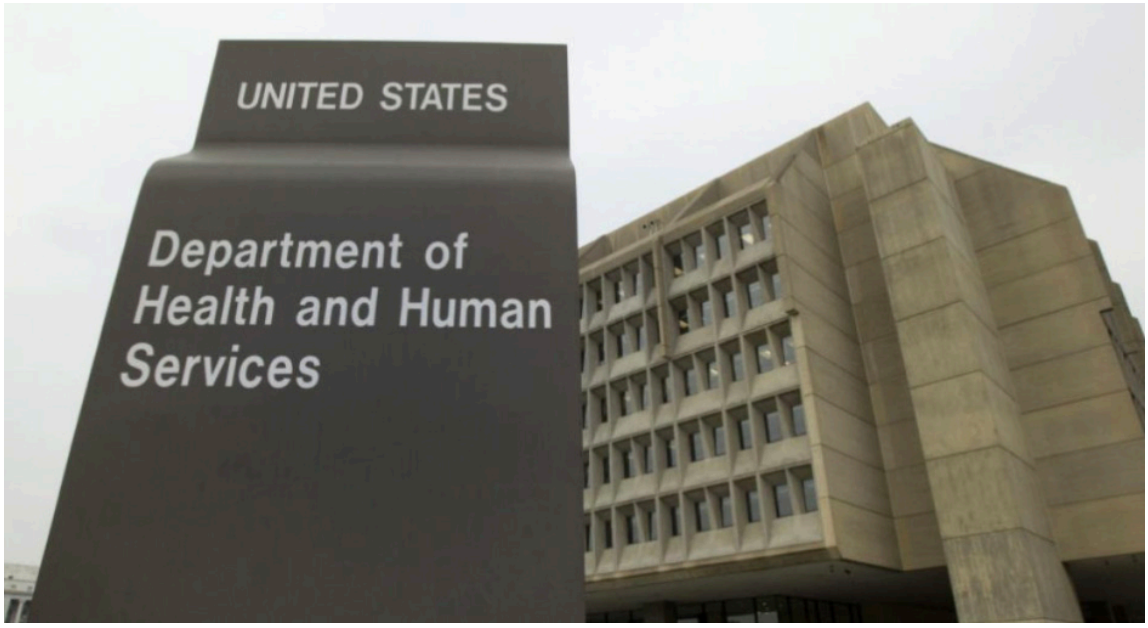

Lawyers for HHS asked a federal district judge to let the department decide how to give 340B hospitals relief for Medicare Part B drug payment cuts that the Supreme Court has determined were illegal.

Let Us Decide How to Remedy Illegal Drug Payment Cut for 340B Hospitals, HHS Asks Judge

In **Federal, Judicial** August 16, 2022 **Tom Mirga**

Federal lawyers asked a judge on Friday to let federal health officials decide how to give 340B hospitals relief for illegal Medicare Part B drug payment cuts since 2018.

In papers filed in U.S. District Court for the District of Columbia on Aug. 12, lawyers for the U.S. Health and Human Services Department (HHS) opposed a group of 340B hospitals' motion for a court order forcing HHS to immediately start paying them at an average sales price plus 6% rate for 340B-purchased drugs, not the ASP minus 22.5% rate the hospitals have been paid since 2018.

The U.S. Supreme Court in June declared the cuts for 2018 and 2019 illegal. Hospital groups and health systems that won the case want the cuts for 2020, 2021, and 2022 declared illegal too. They also want immediate resumption of the ASP plus 6% payment rate and compensation plus interest for all alleged illegal underpayments.

"Abruptly increasing payments for drugs purchased through the 340B program for the remainder of 2022 would raise complicated questions" about decreasing payments for other items and services under the Medicare outpatient prospective payment system (OPPS), HHS pointed out.

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Under the OPPS statute, payment changes in the system must be budget neutral. When 340B hospitals' Part B payments were cut in 2018 and in every year since, non-drug payments among all hospitals in OPPS got a corresponding 3.2% increase. Hospital groups argue that HHS should be on the hook "for its own mistakes" and repay hospitals that were unlawfully underpaid from 2018 to the present without penalizing other hospitals. The cuts totaled about $1.6 billion a year.

The hospital plaintiffs' motion "entirely ignores the budget neutrality principles," HHS said in its new brief. HHS said giving it the first chance to come up with a solution is consistent with the heightened deference courts give it when it interprets a complex and highly technical program like Medicare. HHS also observed that when it published its OPPS proposed rule for 2023 it invited the public to comment "on the best way to craft any proposed, potential remedies" for the Part B cuts since 2018.

"The public comment period is ongoing and will end on September 13, 2022," HHS said. "The court should allow the agency to complete that administrative process and devise a solution for all of the calendar years at issue, given the potential for disruption in the immense and complex system that has been entrusted to the agency to operate."

FAH Amicus Brief

The Federation of American Hospitals (FAH), the trade association for for-profit hospitals, on Friday filed a friend of the court brief in the case.

"Any relief awarded to 340B hospitals in this action should not affect payments made or expected to be made to non-340B hospitals," FAH said. Retroactively recouping funds from non-340B hospitals is illegal and would cause chaos, the group said. It said many of its members would qualify for 340B drug discounts if they were eligible. FAH hospitals spend greater shares of total operating costs on charity care than 340B hospitals (4.4% versus 2.5%) and greater shares on uncompensated care (5.7% versus 3.5%), it said.

"The OPPS does not allow—let alone require—HHS to remedy its mistake by robbing Peter to pay Paul," FAH said. "And any remedy here should not inadvertently suggest that HHS has the ability to retroactively reallocate OPPS payments, which would be an unprecedented development in the history of Medicare reimbursement, given that the statute does not convey that power. HHS has the tools it needs to make plaintiffs whole—without touching OPPS reimbursements to non-340B hospitals."

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The Frustrating Realities of 340B ESP Data Submission

July 26, 2022

Steps That Covered Entities Can Take to Ease the Pain

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For decades, the 340B drug pricing program has served an important purpose by helping hospitals and other covered entities receive discounted prices on drugs to offset care provided to vulnerable, underserved populations.

But over the past several years, drug companies have started pushing back on the 340B program by putting restrictions and conditions in place that have threatened to dismantle it altogether. These restrictions are causing significant financial losses for covered entities with contract pharmacy relationships.

One such condition has been for covered entities to submit their 340B contract pharmacy claims data to drug companies through a third-party contractor called ESP. The goal was to provide a secure and easy-to-use platform for 340B covered entities (CEs) and pharmaceutical manufacturers to work together to resolve duplicate discounts. Ideally, the CEs submit their claims data, ESP takes the data and submits it to the manufacturer, and pricing is restored to the covered entity. This has also given CEs the hope that manufacturer inquiries and audits would decrease (or go away altogether) for manufacturers that participate in ESP, given they are receiving all the necessary details related to the 340B dispense on the front end.

Since this structure was put in place, large numbers of CEs have begun submitting data to ESP in an effort to regain some of the past two years' lost revenue. The process was said to be simple, straightforward, and efficient —but the reality has been quite the opposite.

ESP Submission Challenges

Under the ESP setup, it is supposed to provide general information regarding the "restoration of 340B pricing within 10 business days," but this has been a gross understatement compared to the actual amount of time it has taken for CEs to see pricing restored. This is not the fault of only ESP, but all the parties necessary to restore pricing in a timely manner.

The entire process of pricing restoration is dependent on the wholesaler, manufacturer, and TPA communication, and it is often taking 12 weeks or more for CEs to see pricing restored. There is also tremendous effort involved in managing communication to keep the process moving forward.

Combine this with the fact that pricing is not restored all at once but rather manufacturer-by-manufacturer, and the process slows down even further. Meanwhile, CEs need to allocate additional resources to manage additional requests and track the delays. Manufacturer lookback dates also vary by manufacturer, making data retrieval and submission even more challenging.

Factors of ESP Submission Challenges

So what is ultimately causing these challenges? There are a number of factors at play.

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First is the volume of submissions, as so much data is being submitted that ESP simply cannot keep up with its proposed timeline. But this is partly due to the fact that there is little effort being made to escalate or fast-track communications, largely on the part of wholesalers and manufacturers. CEs are continually reaching out to wholesalers that do not show a congruent level of urgency.

The manufacturers and wholesalers are simply not as incentivized financially to speed up the process, which is undoubtedly a root cause of the issue.

What Covered Entities Can Do

While the team at Visante has witnessed dozens of success stories from CEs seeing pricing restored several months post-submission, it has not come without its challenges. It is important for CEs to appoint appropriate resources and time to allow the ongoing communication and research necessary for pricing to be restored in a timely manner.

While many contract pharmacy chains early on had not allowed their CE partners to share data with ESP, this has largely been reversed. However, there are still several chains that are not allowing CEs to share data with ESP, with the warning that doing so would be a violation of their existing contract and relationship. This leaves these 340B providers in a vulnerable position and continues to fragment their data submission process and the ability to regain lost revenue.

Visante continues to encourage TPAs to develop standard reporting for their CEs to use to allow for easier data extraction, analysis, and submission. While several vendors have made progress in this regard over the last several months, there are still several TPA vendors that are lagging, creating work around processes for CEs that are both time consuming and inefficient.

For CEs that have been without contract pharmacy revenue for some time and have recently made a decision to proceed with ESP, these wrinkles create an additional challenge after years of uncertainty and revenue loss.

How Visante Can Help

In the face of these challenges, many covered entities are left wondering how to communicate and whom to communicate with. Many lack the resources to perform the follow-up necessary to see their pricing restored.

Visante can provide resource support, working with all types of CE's, and can help open the lines of communication, extending the bandwidth of CEs' internal teams while leveraging industry connections to help make follow-up more effective.

Kristin Fox-Smith is Visante's Senior Vice President for the Hospital and Health System Services Division, and a 340B ACE. She can be reached at kfoxsmith@visanteinc.com.

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— Colleen Meiman, National Policy Advisor, Primary Care Associations

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