January 27, 2023

Michelle Herzog
Deputy Director
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
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SUBJECT: HRSA-2021-000X; 340B Drug Pricing Program; Administrative Dispute Resolution; Federal Register (Vol. 87, No. 229, November 30, 2022)

Dear Deputy Director Herzog:

On behalf of our more than 400 member hospitals and health systems, including more than 170 340B-covered entities, the California Hospital Association (CHA) is pleased to submit comments on the Health Resources and Services Administration's (HRSA) recently proposed 340B administrative dispute resolution (ADR) proposed rule.

California's hospitals continue to struggle with myriad financial challenges triggered by the COVID-19 public health emergency. As a result of increasing costs per adjusted discharge, which are outstripping payment updates, 51% of California's hospitals had negative margins in 2021. We anticipate the number of hospitals experiencing negative margins in 2022 will be even greater.

Median expenses per discharge for California hospitals rose 15% in 2021, outpacing the 11% national average. These increases were largely driven by higher labor costs (+16%), pharmaceuticals (+41%), and medical supplies (+19%).[1] Pharmaceuticals make up a significant portion of a hospital's cost structure. Even before the recent bout of inflation, these pharmaceutical costs experienced unchecked growth. Between 2015 and 2017, total hospital and health system spending on drugs increased — on average — by 18.5% per admission. This includes a jump of 28.7% per outpatient adjusted admission, following a record 38.7% increase in prescription drug spending in the inpatient setting from 2013 to 2015.[2] Hospital efforts to contain this growth are hamstrung, given that for many of these compounds there are no clinically effective substitutes.

[1] Expense increases based on per adjusted discharge.
[2] https://www.aha.org/drug-prices/home

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In contrast, pharmaceutical manufacturers continue to enjoy strong profitability. As illustrated in the table below, the 10 largest manufacturers had combined revenues of $567 billion, with profits of $127 billion (22.55% profit margin). This profitability continues to be driven by aggressive increases in product pricing that harm both consumers — particularly those most at risk for inequitable outcomes — and the hospitals that serve them.

2021 Revenue, R&D Spend, Net Income, and Profit Margin[3]
10 Largest Global Pharmaceutical Manufacturers by Revenue

	Revenue $, Million	R&D Spend $, Million	R&D Spend as a % of Revenue	Net Income $, million	Profit Margin	Provides 340B Discount at Community Pharmacies?
Pfizer	81,288	13,829	17.01%	21,393	26.32%	NO
AbbVie	56,197	7,084	12.61%	11,760	20.93%	NO
Novartis	51,626	9,540	18.48%	24,018	46.52%	NO
J&J	93,775	14,714	15.69%	20,878	22.26%	NO
Roche[1]	70,844	10,672	15.06%	16,068	22.68%	
BMS	46,385	11,354	24.48%	7,014	15.12%	NO
Merck & Company	48,704	12,245	25.14%	13,049	26.79%	NO
Sanofi[2]	40,041	6,036	15.07%	6,599	16.48%	NO
AstraZeneca	37,417	9,736	26.02%	1,056	2.82%	NO
GSK[3]	41,156	6,368	15.47%	6,148	14.94%	NO
Total	**567,433**	**101,578**	**17.90%**	**127,982**	**22.55%**	

Sources:
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https://www.gsk.com/media/7465/financial-statements.pdf
https://www.beckershospitalreview.com/pharmacy/16-drugmakers-restricting-340b-discounts.html

Notes:
1) Converted to U.S. dollars from Swiss Francs using xe.com on 1/4/23
2) Converted to U.S. dollars from Euros using xe.com on 1/4/23
3) Converted to U.S. dollars from Great British Pounds using xe.com on 1/4/23

As a result of ongoing, unsustainable margins, not-for-profit hospitals across the country are forced to eliminate service lines that have negative margins. These closures disproportionately impact rural and safety-net hospitals — limiting access to labor and delivery, inpatient pediatric, and emergency department (ED) services.[4] If negative margins persist, more hospitals and health systems will be forced to discontinue services that are financially unsustainable or risk insolvency.

[3] Figures may not sum due to rounding errors.
[4] https://www.beckershospitalreview.com/care-coordination/18-hospitals-scaling-back-care.html?

Beyond simply reducing access to some services, sustained negative margins can result in hospital closures. Historically, hospital closures have most frequently occurred in rural areas. A hospital payer mix that includes high rates of uninsured patients and those covered by governmental payers (e.g., safety-net hospitals) are frequently cited as key drivers of the closure of rural hospitals.[5] Between January 2013 and February 2020, over 100 rural hospitals closed;[6] three of those facilities were in California. Another 631 rural hospitals (13 in California) are deemed at risk of closure.[7] One of these facilities is on the brink of filing for bankruptcy.[8]

This is unacceptable. Residents who live in areas affected by a rural hospital closure are more likely to live in poverty (13.3% vs. 9.3%). Medicare beneficiaries who live in areas that have experienced a rural hospital closure are more likely to suffer from one or more of the 10 most common chronic conditions.

The closing of these facilities significantly reduces access to care for all patients. The distance patients are required to travel to access inpatient services increases by 20 miles; for services like treatment for substance use disorder, it increases by almost 40 miles.

Even more concerning, the trend of closures has expanded to safety-net hospitals.[9,10] Recent examples include Hahnemann University Hospital in Philadelphia, and Atlanta Medical Center (AMC) in Atlanta.[11] Beyond the loss of access for those in the surrounding community, the Hahnemann closure started a domino effect in the market, which nearly resulted in the closure of another hospital — Mercy Philadelphia Hospital.[12] However, a coalition of organizations stepped in to preserve some services.[13] While AMC recently ceased operations, the impact is already being felt by the community. Volumes at adjacent, already overcrowded hospitals are rising. Atlanta's remaining trauma center has seen a 30% increase in trauma patients. And EDs at nearby hospitals have been so overcrowded they were forced to divert ambulances to other hospitals further away.[14]

Closer to home, one of California's 340B hospitals — Madera Community Hospital[15] — recently filed for bankruptcy and ceased operations. People who relied on the hospital for emergency care must now travel as far away as Fresno, nearly 30 miles from the city of Madera. Farm workers who received health care at the hospital's rural clinic in Mendota (where the per capita income is less than $12,000) have lost access to basic medical services. This is the type of hospital and disadvantaged population that Congress intended the 340B program to support.

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[5] www.kff.org/report-section/a-look-at-rural-hospital-closures-and-implications-for-access-to-care-three-case-studies-issue-brief/
[6] https://www.gao.gov/products/gao-21-93
[7] https://www.beckershospitalreview.com/finance/631-rural-hospitals-at-risk-of-closure-by-state.html
[8] https://www.beckershospitalreview.com/finance/hazel-hawkins-explores-options-holds-off-filing-for-bankruptcy.html
[9] https://www.beckershospitalreview.com/finance/19-hospital-closures-bankruptcies-in-2022.html?
[10] https://www.beckershospitalreview.com/finance/ohio-hospital-closing-earlier-than-planned-due-to-patient-safety-concerns.html?
[11] www.beckershospitalreview.com/finance/wellstar-ceo-atlanta-medical-center-closed-after-exhaustive-search-for-partners.html?
[12] https://www.nejm.org/doi/full/10.1056/NEJMp2002953
[13] https://whyy.org/articles/penn-med-phmc-lead-coalition-to-save-mercy-philadelphia-hospital/
[14] https://www.beckershospitalreview.com/care-coordination/atlanta-hospital-reports-30-more-patients-4-days-after-wellstar-closure.html
[15] https://www.kvpr.org/local-news/2022-12-27/the-only-general-hospital-serving-rural-madera-county-will-close-ceo-announces

Unfortunately, this is just the tip of the iceberg. CHA is aware of other safety-net hospitals — including the state's largest district hospital[16] — experiencing severe financial distress. Without material margin improvement, more safety-net hospitals will be forced to discontinue operations. These closures would severely limit access to care for the disadvantaged populations they serve, exacerbating already inequitable outcomes.

Even in the best of times, the 340B program is indispensable to safety-net hospitals' ability to remain financially viable and provide medically necessary services to disadvantaged populations. The spread between the 340B acquisition price and the limited payment that safety-net hospitals receive from payers allows hospitals to fulfill the program's congressional intent by "stretch(ing) scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Unfortunately, many pharmaceutical manufacturers have elected to flout the 340B program's requirements. In some circumstances, they have denied safety-net hospitals discounts on covered drugs at a time when vulnerable populations need them most. Therefore, the ADR process, supported by the 340B program, is needed more than ever to maintain access to care at safety-net hospitals.

In general, we support the proposed rule and appreciate the thoughtful, reasonable approach HRSA took in drafting it. We greatly appreciate the myriad proposed steps taken by HRSA to reduce the costs associated with submitting a claim to the ADR process by moving away from a "trial-like" approach. Below, please find our specific comments.

Revise ADR Panel Role and Structure

Clarify Issues Considered by the ADR Panel: The proposed rule envisions that the role of the ADR panel would be to independently review and apply 340B law and policy to specific circumstances of potential overcharges, diversions, or duplicate discounts. **While CHA generally agrees with the scope of the ADR panel's writ, we ask that in the final rule HRSA clarifies that "overcharges" include instances where a manufacturer refuses — in violation of HRSA's interpretation[17,18] of the 340B statute — to provide access to the 340B discount in community (contract) pharmacies.** CHA notes that there are at least 16 manufacturers[19] that to date refuse to provide legally required 340B discounts to hospitals when covered drugs are provided in community pharmacies. As illustrated in the table on Page 2, this includes nine of the 10 largest manufacturers in the world. These organizations realized a combined profit of $110 billion on revenues of $496 billion (22.54% margin) in 2021.

The impact on safety-net hospitals that have been illegally denied access to the 340B discount threatens access to patient care. A survey[20] of 550 hospitals conducted in early 2022 by *340B Health* found these restrictions by drug companies cause an estimated annual median loss of $2.2 million for larger, urban safety-net hospitals. Ten percent of those hospitals expect their annual losses to exceed $21 million. Among the smaller, rural safety-net hospitals, the median annual loss is $448,000, with 10% estimating losses of more than $1.3 million a year. Those losses have more than doubled since a similar survey[21] in

[16] https://www.beckershospitalreview.com/finance/california-hospital-ceo-asks-newsom-for-financial-aid.html
[17] https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf
[18] CHA is aware that this advisory opinion was subsequently withdrawn in 2021 due to ongoing legal challenges from manufacturers.
[19] https://www.beckershospitalreview.com/pharmacy/16-drugmakers-restricting-340b-discounts.html
[20] https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Report_FINAL_05-05-2022.pdf
[21] https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Findings_January_2022_FINAL.pdf

December 2021. Since March 2022, two more major drug companies have adopted similar policies that will further deepen those losses.

The U.S. Department of Health and Human Services (HHS) also proposes — as part of the ADR process — that if the panel determines a specific issue in a claim is the same or similar to an issue pending in federal court, the ADR panel will suspend review of the claim until the issue is no longer pending in federal court. **CHA strongly urges HRSA to reconsider this position and allow for review of claims that are pending in federal court. Given the time required to resolve cases in federal court, CHA is concerned that this approach will irreparably harm safety-net hospitals.** First, it will deny 340B entities the discounts they are likely entitled to receive. Second, it will encourage manufacturers to adopt behaviors that limit discounts to covered entities that are subject to litigation in federal court. We have already seen this unintended consequence of inaction. HRSA's inability to compel an initially small number of manufacturers to provide discounts to covered entities when 340B drugs are provided in a community pharmacy. That's resulted in a growing list of manufacturers refusing to provide a discount on 340B drugs that covered entities are entitled to by statute.

ADR Process – Complaint Resolution Time Frame: CHA is concerned that HRSA has not proposed a time frame for an ADR panel to hear and resolve a submitted dispute. **We strongly encourage the agency to provide a decision to covered entities and manufacturers that are subject to a dispute within 45 days of its submission.**

ADR Panelists: HRSA proposes that "no less than 10" subject matter experts (SMEs) from the Office of Pharmacy Affairs (OPA) will resolve matters that proceed through the ADR process. All members on the 340B ADR panel will undergo an additional screening prior to reviewing a specific claim. This will ensure that the 340B ADR panel member was not involved in previous agency actions (including previous 340B ADR panel decisions) concerning the specific issue of the ADR claim as it relates to the specific covered entity or manufacturer involved. **CHA strongly supports the use of OPA SMEs on the ADR panel.** The 340B program is complex. Therefore, it is important that individuals who understand the intricacies of the 340B program adjudicate these disputes in order to ensure a fair outcome.

CHA strongly encourages HRSA to expand the number of SMEs who will review disputes submitted to the ADR process to ensure that the complaint resolution time frame discussed above can be consistently met. Given the volume of likely claims and the potential for conflicts of interest, we are concerned an insufficient number of available panelists will result in delayed decisions.

Good Faith Efforts to Resolve Dispute: The proposed rule reinforces that covered entities and manufacturers must attempt to work together in good faith to resolve disputes. **CHA strongly supports this provision.** We appreciate that HRSA, in the proposed rule, reiterated the 340B statute requiring drug manufacturers to first audit the covered entity's alleged violation of the 340B statutory prohibitions on diversion and duplicate discounts prior to filing an ADR claim.

Reconsideration of Decisions: The proposed rule allows for a reconsideration process if either of the disputing parties is dissatisfied with the panel's decision. HRSA proposes the reconsideration would be conducted by the HRSA administrator (or their designee), and their review will be independent of the

panel's decision. **CHA strongly supports this provision and believes it is a marked improvement over the 2020 final rule.**

The proposed rule notes that any final agency decision is binding upon the parties involved in the dispute, unless invalidated by an order of a federal court. **CHA further appreciates that the proposed rule clearly preserves access to federal courts in instances where either of the disputing parties is dissatisfied with the reconsideration decision.**

Eliminate Minimum Threshold

To make the ADR process more accessible, the proposed rule would eliminate the $25,000 minimum threshold value of the disputed claims necessary for accessing the ADR process. **CHA strongly supports eliminating the minimum threshold.** We agree with HRSA that a minimum threshold serves as a barrier that has prevented covered entities from bringing overcharging issues to the ADR process, in effect creating a mechanism to allow pharmaceutical manufacturers to flout the 340B statute.

CHA appreciates the opportunity to comment on the 340B ADR proposed rule. If you have any questions, please do not hesitate to contact me at cmulvany@calhospital.org or (202) 270-2143.

Sincerely,

/s/
Chad Mulvany
Vice President, Federal Policy