



July 28, 2023

The Honorable John Thune  
U.S. Senate  
511 Dirksen Senate Office Building  
Washington, D.C. 20510

The Honorable Tammy Baldwin  
U.S. Senate  
141 Hart Senate Office Building  
Washington, D.C. 20510

The Honorable Debbie Stabenow  
U.S. Senate  
731 Hart Senate Office Building  
Washington, D.C. 20510

The Honorable Jerry Moran  
U.S. Senate  
521 Dirksen Senate Office Building  
Washington, D.C. 20510

The Honorable Shelley Moore Capito  
U.S. Senate  
172 Russell Senate Office Building  
Washington, D.C. 20510

The Honorable Benjamin L. Cardin  
U.S. Senate  
509 Hart Senate Office Building  
Washington, D.C. 20510

**Subject: 340B Program — Request for Information**

Dear Senators Thune, Stabenow, Capito, Baldwin, Moran, and Cardin:

On behalf of our more than 400 member hospitals and health systems — some of which are 340B eligible hospitals — the California Hospital Association (CHA) is pleased to respond to your request for information related to the 340B program.

California's hospitals are struggling financially because of inadequate governmental payment rates and rapidly increasing costs — particularly for clinical labor. The financial pressure that continues to build is such that nationally renowned consulting firm Kaufman Hall [estimates](#) that one in five California hospitals are at risk of closure. As evidence of this pressure, so far in 2023 one California 340B hospital (Madera Community Hospital) has closed and another (Beverly Hospital) has declared bankruptcy. Even more concerning, many other 340B hospitals are in severe financial distress and perilously close to reducing services, declaring bankruptcy, or shuttering outright.

[Data](#) from the National Bureau of Economic Research shows that hospital closures — particularly rural closures — increase inpatient mortality by 8.7%, with Medicaid patients and racial minorities bearing the brunt of negative outcomes — 11.3% and 12.6% increases in mortality, respectively. These are people's lives, not abstract data points. Sadly, at least three individuals' deaths have already been attributed to Madera Community Hospital's closing.

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Over the last 30 years, the 340B program has been a bulwark against the increasing financial pressures for rural and safety-net hospitals. Consistent with Congress' objectives, the 340B program has successfully allowed health care providers to stretch scarce federal resources to better serve their patients and communities. The savings 340B hospitals achieve through purchasing certain outpatient drugs at a discount allow them to provide a range of programs and services that directly benefit their patients. Examples include medication therapy management, diabetes education and counseling, behavioral health services, opioid treatment services, and the provision of free or discounted drugs. It is important to note that 340B supports these programs and services at no cost to taxpayers.

These are services that — without the savings from the 340B program — hospitals may have been forced to eliminate to remain financially viable. This is due, in part, to the low reimbursements from governmental payers — who cover many of the patients who utilize these services — which are contributing to ever-mounting financial pressure for hospitals. The recent Supreme Court 340B decision underscored the key tenet of the program, noting that it enables hospitals and health care systems to “perform valuable services for low-income and rural communities.” *Am. Hosp. Ass’n v. Becerra*, 596 U.S. \_\_\_ (2022) (slip op., at 13).

I share this information to underscore the importance of the 340B program in maintaining access to health care for individuals who live in rural and underserved communities. Without this important program, many safety-net hospitals would be forced to curtail vital programs or close outright. Below please find answers to the questions posed in the request for information.

Your work to preserve access to care in rural and underserved communities by providing stability to the 340B program is vitally important, and CHA looks forward to working with you. If you have any questions, please do not hesitate to contact me at (202) 488-4494 or [arourke@calhospital.org](mailto:arourke@calhospital.org).

Sincerely,

/s/

Anne O’Rourke

Senior Vice President, Federal Relations

## **340B Program — Request for Information**

### **Question 1: What specific policies should be considered to ensure HRSA can oversee the 340B program with adequate resources? What policies should be considered to ensure HRSA has the appropriate authority to enforce the statutory requirements and regulations of the 340B program?**

The Health Resources and Services Administration (HRSA) currently has ample authority, provided by Congress, to oversee the program and ensure program integrity. In fact, in the Affordable Care Act, Congress provided HRSA with a key oversight tool through the administrative dispute resolution (ADR) process. As required by federal law, the ADR process establishes a formal way for the agency to resolve disputed claims by 340B providers and drug manufacturers. Unfortunately, this ADR process has been challenged in court and has never been implemented in the way Congress intended. CHA believes that HRSA should be given a chance to implement this ADR process before any new enforcement authorities are considered.

Among other things, the ADR process is intended to adjudicate disputes that arise when a drug manufacturer overcharges a 340B provider for covered 340B drugs. There is no more egregious example of this than the actions drug manufacturers have taken to limit or deny 340B pricing through arrangements with community and specialty pharmacies. For the last three years, in clear violation of the law and with no abatement on the horizon, several of the largest drug manufacturers have restricted, and in many instances denied, 340B hospitals' access to the statutorily required 340B prices for drugs purchased through established arrangements with community and specialty pharmacies. By intentionally denying or limiting access to the 340B price, these drug manufacturers are forcing hospitals to pay a higher price to acquire these drugs (e.g., wholesale acquisition cost price), representing an overcharge by these drug manufacturers for these covered drugs. According to an [AHA survey](#), these unlawful actions by drug manufacturers have resulted in 340B critical access hospitals experiencing average annualized losses of over \$500,000 and 340B disproportionate share hospitals (DSH) experiencing annualized losses of nearly \$3 million. However, the amount that an individual hospital experiences can be much greater. These overcharges jeopardize access that comes from allowing both 340B hospitals and pharmacies to coordinate care and ensure that drugs needed by their patients are available at their local pharmacies. In addition, as noted above, the loss of savings, as a result of these actions, reduces the resources that hospitals have to fulfill the intent of the program of increasing access to care.

The only beneficiaries of these restrictions are drug manufacturers who simply pocket the additional revenue to add to their already sky-high profits. Indeed, in 2021, 19 of the companies that introduced these restrictions made more than \$660 million in profits. Unsurprisingly, these companies are *not* using their additional earnings to expand access to care or lower drug prices. As more restrictions on contract pharmacies have been put in place, drug manufacturers have only *increased* the launch prices of new drugs and existing drugs. These drug manufacturers must be held accountable to the legal requirements in the 340B statute, which the ADR process was created to enforce.

Regrettably, for 13 years, the ADR process has not been fully implemented by the agency. It is imperative that HRSA finalize its most recent 340B ADR proposed rule and allow 340B hospitals and other participating covered entities the ability to bring forth disputed claims for administrative review before the panel. Drug companies should not be allowed to circumvent the law and indefinitely delay the implementation of this rule. CHA strongly urges HRSA to finalize the ADR rule and believes that HRSA

should explicitly state in its final rule that the ADR process is an available forum for affected 340B hospitals to seek redress from the restrictions targeted at community and specialty pharmacies.

At the same time, CHA continues to vigorously support the agency's efforts *outside* of the ADR process, including those by the Office of Inspector General (OIG), to enforce the law and penalize drug manufacturers who intentionally break it. In particular, CHA supports HRSA's actions to enforce drug companies' compliance with section 340B(a)(1) of the Public Health Service Act, which requires those companies to sell, without restriction, 340B-covered outpatient drugs at the 340B price to covered entities with contract pharmacy arrangements. Ultimately, given the scope of drug manufacturers' wrongdoing with respect to contract and specialty pharmacy arrangements, a whole-of-agency effort is needed. Congress has afforded HRSA, OIG, *and the ADR process* the authority necessary to preserve the integrity of the 340B program.

However, while HRSA has the *authority* to oversee the program, we recommend ensuring that it also has *the tools* that it needs to conduct that oversight. HRSA currently audits over 200 340B hospitals annually to ensure program integrity. In stark contrast, HRSA conducts *only six* audits of drug manufacturers. As the contract pharmacy issue underscores, greater oversight of drug manufacturers is needed. HRSA should be provided with the resources necessary to conduct audits of drug manufacturers to ensure greater oversight of manufacturers and audit parity.

## **Question 2: What specific policies should be considered to establish consistency and certainty in contract pharmacy arrangements for covered entities?**

Beginning in the summer of 2020, six pharmaceutical manufacturers implemented policies to limit covered entities' use of contract pharmacies to distribute discounted medications. These policies prompted concerns from the covered entity community that these restrictions would significantly limit access to 340B savings and, consequently, programs and services available to 340B patients. In response to these actions, in December 2020, the U.S. Department of Health and Human Services (HHS) issued an [advisory opinion](#) informing drug manufacturers that they are required to offer covered outpatient drugs at no more than the 340B ceiling price, even if said drugs are distributed via a contract pharmacy. Despite this guidance from the federal government, the six manufacturers persisted in their restrictions and did not adhere to the HHS advisory opinion. In May 2021, HRSA issued [violation letters](#) to these companies notifying them that their practices violate the law, and that they may be charged civil monetary penalties for overcharges.

In the intervening years since HHS first published its advisory opinion, the number of pharmaceutical manufacturers restricting contract pharmacy arrangements has grown to over 20. These restrictions have a tangible impact on 340B hospitals' ability to care for patients and communities. According to 340B Health's 2022 [annual survey](#), 56 percent of rural hospitals and 43 percent of DSH, rural referral center, and freestanding children's hospitals reported a decline in 340B savings resulting from these restrictions. Given the mounting financial pressures facing hospitals, including rising labor and supply costs, workforce shortages, insufficient reimbursement from payers, and increasing administrative burden, these restrictions may limit the programs and services that 340B hospitals can offer to low-income and under-resourced patients.

CHA recommends that Congress clarify and codify protections for contract pharmacy arrangements in federal 340B statute. We support legislation clarifying that Section 340B of the Public Health Service Act (42 U.S.C. 256b) requires pharmaceutical manufacturers to deliver discounted drugs to covered entities, irrespective of the method through which these drugs are dispensed. We support specifically prohibiting pharmaceutical manufacturers from imposing conditions on covered entities' use of contract pharmacies through methods such as requiring covered entities to submit additional claims data or other information for these dispenses. CHA supports efforts to address pharmaceutical companies' increasing proclivity to restrict 340B hospitals' use of contract pharmacies, thereby ensuring that the program can continue to benefit covered entities and the patients they serve.

**Question 3: What specific policies should be considered to ensure that the benefits of the 340B program accrue to covered entities for the benefit of patients they serve, not other parties?**

CHA is increasingly concerned about the role that insurers and pharmacy benefit managers (PBMs) are playing in managing access to outpatient prescription drugs for patients. Rather than supporting 340B hospitals and their patients, PBMs have engaged in a number of [harmful tactics](#) to reduce the scope and benefits of the program. Most importantly, PBMs have created terms and policies that discriminate against 340B hospitals by paying them less than non-340B hospitals for certain outpatient drugs in order to protect their rebate revenue from drug manufacturers. PBMs require 340B hospitals to accept [unfair terms and policies](#) to participate in their pharmacy networks, which are needed to give hospital patients greater access to those drugs. This practice, widely referred to as “discriminatory 340B pricing,” forces hospitals to accept lower and discriminatory reimbursement rates. Although the law intends to ensure patient access to drugs through PBM pharmacy networks, forcing hospitals to accept lower and discriminatory reimbursement rates threatens their ability to provide more comprehensive services to their patients. Some of the tactics we are concerned about include PBMs establishing barriers for pharmacies that contract with 340B hospitals to participate in their networks, disallowing PBM members from using 340B pharmacies, and even wholly excluding certain hospital-based pharmacies from their networks. While [some states](#)<sup>1</sup> have explicitly prohibited 340B discriminatory pricing by PBMs, this [practice](#) and other harmful policies remain prevalent in many parts of the country and continue to enrich PBMs at the expense of 340B hospitals.

Congress should hold PBMs accountable as they continue to engage in policies that siphon 340B savings away from 340B hospitals and into their pockets. Specifically, Congress should:

- Prohibit nationwide PBM policies that provide differential reimbursement to 340B providers and non-340B providers (discriminatory pricing).
- Prohibit PBMs from steering patients away from 340B pharmacies to pharmacies that they own, denying 340B entities the ability to earn savings.
- Prohibit PBMs from engaging in “white bagging” or “brown bagging” policies that [jeopardize patient safety](#) and undermine access to 340B discounts for providers and their patients.

We urge Congress to eliminate any possibility for drug companies to try to circumvent their responsibility and obligations under the 340B law by codifying the use of contract pharmacies as a lawful

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<sup>1</sup> California [Senate Bill 786](#), currently under consideration and [supported by CHA](#), proposes a ban on harmful manufacturer discriminatory pricing practices.

and critical part of the 340B program. The law should ensure that drug companies cannot condition, restrict, or deny 340B pricing for drugs regardless of the manner in which those drugs are dispensed or administered to patients.

**Question 4: What specific policies should be considered to ensure that accurate and appropriate claims information is available to ensure duplicate discounts do not occur?**

CHA supports a national data claims clearinghouse as proposed in the bipartisan legislation introduced by House Representatives Abigail Spanberger (D-VA) and Dusty Johnson (R-SD). Their 340B Protect Act (H.R. 2534) represents long-needed legislation that would prevent PBMs and health insurance companies from siphoning off savings from the 340B program that were meant to help health care organizations that care for many uninsured and low-income patients. In addition, the legislation would authorize the Health and Human Services secretary to contract with a third-party entity to collect and review data from state Medicaid agencies and covered entities to prevent Medicaid duplicate discounts. It is vitally important that any national data claims clearinghouse, such as the one created by the Protect 340B Act, should:

- Be free of any conflicts of interest
- Limit data collection to Medicaid claims to mitigate against the prohibition of duplicative 340B discounts and Medicaid drug rebates on the same drug
- Limit any burden on 340B covered entities to collect such data and allow sufficient time for providers to set up the necessary processes and programs to report claims data
- Ensure data security in accordance with HIPAA standards so that claims information or personally identifiable information are not compromised

**Question 5: What specific policies should be considered to implement common sense, targeted program integrity measures that will improve the accountability of the 340B program and give health care stakeholders greater confidence in its oversight?**

HRSA has ample authority to oversee the 340B program and ensure program integrity. Specifically, HRSA conducts over 200 audits of 340B-covered entities every year, a majority of which are for hospitals. Since 2012, HRSA has conducted 1,720 audits of covered entities. These audits are rigorous and require hospitals to maintain several years of auditable records, as well as policies and procedures to mitigate against issues like the diversion of drugs to ineligible patients and duplicate discounts. Further, should there be any finding of noncompliance, hospitals work in good faith with the agency to take corrective action and rectify issues to become compliant with program rules. In addition, 340B hospitals take program integrity seriously and invest significant resources in conducting regular self-audits of their programs to ensure they are staying compliant with all program rules and requirements.

In certain instances, drug manufacturers are also permitted to conduct audits of 340B hospitals in coordination with HRSA, but hospitals have no ability to audit drug manufacturers. There are many instances when drug companies have violated program rules and requirements by overcharging hospitals, denying 340B pricing for certain drugs, and arbitrarily placing drugs in limited distribution. Congress should mandate that HRSA provide hospitals and other covered entities with the same ability to audit drug manufacturers.

As noted above, while HRSA performs over 200 audits of 340B-covered entities each year, it only conducts on average less than six audits annually for drug manufacturers. Since fiscal year 2015, HRSA has conducted only 31 audits of drug manufacturers, which is a meager 4% of all drug manufacturers participating in the program. The obvious [disparity](#) between the oversight that HRSA exercises over covered entities and drug manufacturers is concerning. Therefore, Congress should mandate that the agency bring more parity to its oversight of the 340B program, by increasing the number of annual audits of drug companies.

**Question 6: What specific policies should be considered to ensure transparency to show how 340B health care providers' savings are used to support services that benefit patients' health?**

340B hospitals report a variety of information to demonstrate their commitment to providing care to underserved populations. Hospitals report uncompensated care, charity care, and other benefits provided to the communities they serve through both the Medicare cost reports and the IRS 990 form required for tax-exempt organizations. In fact, the most recently available IRS 990 data show that 340B hospitals alone provided nearly [\\$68 billion](#) in community benefits. HRSA requires separate reporting during its annual 340B hospital certification process, including Medicare cost report information. And many of California's 340B hospitals are voluntarily committing to the [AHA Good Stewardship Principles](#) that focus on 340B hospitals sharing how 340B savings benefit their patients and communities.

At the same time, drug companies are not required to report any information about how they set their prices, by how much and when they decide to increase their prices, or when they have implemented a policy that restricts covered entities' access to 340B pricing. That type of information would be important in understanding drug companies' pricing decisions. It would also help us understand how we can mitigate arbitrary and egregious price increases for drugs that are critical and lifesaving for patients, as well as ensure the government is aware of drug manufacturer actions that may unilaterally (and illegally) shrink the program. We urge Congress to increase oversight of drug companies to ensure they do not continue to obfuscate their pricing practices, undermining the law and their obligations to provide 340B discounts.