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Advancing Health in America

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March 26, 2024

The Honorable John Thune
United States Senate
511 Dirksen Senate Office Building
Building Washington, D.C. 20510

The Honorable Debbie Stabenow
United States Senate
731 Hart Senate Office
Washington, D.C. 20510

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

The Honorable Tammy Baldwin
United States Senate
141 Hart Senate Office
Washington, D.C. 20510

The Honorable Jerry Moran
United States Senate
521 Dirksen Senate Office Building
Building Washington, D.C. 20510

The Honorable Benjamin L. Cardin
United States Senate
509 Hart Senate Office
Washington, D.C. 20510

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

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, including our nearly 2,000 member hospitals that participate in the 340B Drug Pricing Program (340B program), the American Hospital Association (AHA) welcomes the opportunity to provide feedback on the Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future of (SUSTAIN) 340B Act bipartisan discussion draft and accompanying request for information on the critically important 340B Drug Pricing Program.

For over 30 years, the 340B program has successfully allowed health care providers to stretch scarce federal resources to better serve the needs of their patients and communities, consistent with Congress' objectives. The savings 340B hospitals achieve through purchasing certain outpatient drugs at a discount enable them to provide a range of programs and services that directly benefit their patients. The 2022 Supreme Court decision regarding the 340B program underscored this key tenet of the program, noting that the program 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).[1] These savings are used to fund services like medication therapy management, diabetes education and counseling, behavioral health services, opioid treatment services, and the provision of free or discounted drugs; each

[1] https://www.supremecourt.gov/opinions/21pdf/20-1114_09m1.pdf

340B hospital tailors its offerings to the unique needs of its patients. Notably, the spending on these programs often exceeds 340B savings, demonstrating the outsized commitment 340B hospitals have to the communities they serve. A recent study found that between 2017 and 2020, the growth in community benefits provided by 340B hospitals far outweighed the growth in their program savings.[2]

The 340B program is especially important in the face of rising drug prices and persistent financial challenges for hospitals and health systems. A recent report by the Department of Health and Human Services (HHS) found that between January 2022 and January 2023 prices increased an average of 15.2% for over 4,200 drugs, many of which are used to treat cancer and other chronic conditions.[3] Compounding this problem is the fact that drug companies are introducing unusually expensive drugs onto the market at record high prices, crossing a median price of $300,000 in 2023. These high drug prices are increasing at an alarming rate: This extraordinary median drug price represents an increase of 35% from the prior year.[4] These drug prices and subsequent price increases — which are at the sole discretion of drug companies — crowd out the resources hospitals have available to care for their patients and communities. This only underscores why the 340B program is so vital for patients and providers.

Given these realities, the AHA appreciates your continued interest in protecting the 340B program and welcomes opportunity to provide feedback on the SUSTAIN 340B Act discussion draft. **We commend your efforts to clarify Congress' intent in creating the 340B program and to deliver 340B providers much needed relief from the egregious behavior of drug companies, insurers and pharmacy benefit managers. Their unlawful and pernicious practices have collectively undermined the 340B program and harmed patient care. At the same time, we have concerns regarding other aspects of this discussion draft that should be better aligned to reflect the operational realities that 340B hospitals face every day.** Therefore, our comments primarily focus on how Congress can ensure that the 340B program continues to benefit patients and communities, while protecting against any unnecessary harm or burden that would jeopardize patient care.

Our detailed feedback on the discussion draft provisions and responses to the request for information (RFI) questions follow. Please contact me if you have questions or feel free to have a member of your team contact, Aimee Kuhlman, AHA's vice president for advocacy and grassroots, at akuhlman@aha.org.

Sincerely,

Stacey Hughes
Executive Vice President

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[2] https://www.aha.org/guidesreports/2024-03-12-340b-drug-pricing-program
[3] https://aspe.hhs.gov/reports/changes-list-prices-prescription-drugs
[4] https://www.reuters.com/business/healthcare-pharmaceuticals/prices-new-us-drugs-rose-35-2023-more-than-previous-year-2024-02-23/

I. Contract Pharmacies

340B hospitals' partnerships with local and specialty pharmacies have long been recognized by the government as a key component of the 340B program. These arrangements allow patients access to their prescribed medications at their local community pharmacy or through local and mail-order specialty pharmacies. Nearly half of all Americans live within one mile of a pharmacy, while 73% live within two miles and 89% live within five miles[5]. The accessibility of community pharmacies to many Americans presents a convenient, familiar and dependable source of care. This is especially true for those living in rural communities or who lack easy access to transportation.

Contract pharmacies currently provide health care access for large numbers of underserved patients. Specifically, 80% of rural counties had a contract pharmacy with a 340B hospital, and contract pharmacies were located in 74% of counties with higher-than-average uninsured populations, 81% of counties with higher-than-average unemployment, and 82% of counties with high food insecurity.[6]

Despite the demonstrated benefits to patients, these arrangements have been criticized by — and increasingly *restricted* by — big drug companies. Nearly 30 drug companies, including many of the largest and most profitable drug companies in the world, have targeted 340B arrangements with community and specialty pharmacies by denying the discounted 340B pricing for outpatient drugs dispensed through these arrangements. These restrictions have come at a cost to hospitals of an average of nearly $3 million annually for 340B disproportionate share hospitals and an average of over $500,000 annually for critical access hospitals.[7] Another recent report estimated that these drug company actions have reduced 340B hospitals' savings by approximately $8.4 billion since the restrictions were first imposed.[8]

For these reasons, **we strongly support your efforts to recognize contract pharmacies as an integral part of the 340B program and prohibit drug companies from restricting access to 340B drugs through contract pharmacies.**

With that vital goal in mind, we have a few suggestions that we believe will further strengthen this section.

Strong and unambiguous language is needed to protect 340B contract pharmacies. While the current language lists two specific conditions/restrictions that are prohibited and leaves it up to the HHS Secretary to impose additional prohibitions, we believe the language should expressly bar drug companies from imposing *any and all* restrictions or conditions on the distribution or access to 340B-priced drugs. Drug companies have shown that they will exploit any ambiguity in federal law to avoid paying 340B discounts. We believe that clear

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[5] Berenbrok LA, Tang S, Gabriel N, et al. Access to community pharmacies: A nationwide geographic information systems cross-sectional analysis. J Am Pharm Assoc (2003). 2022;62(6):1816-1822.e2. doi:10.1016/j.japh.2022.07.003
[6] www.aha.org/system/files/media/file/2024/02/340B-Contract-Pharmacies-Infographic-20240212.pdf
[7] https://www.aha.org/news/headline/2022-11-14-aha-survey-drug-companies-reduce-access-care-limiting-340b-community-pharmacies
[8] https://www.340bhealth.org/files/Contract_Pharmacy_Financial_Impact_Report_July_2023.pdf

language is necessary to ensure that drug companies cannot invent *any* possible loopholes that benefit their bottom line at the expense of Congress' intent. We therefore urge you to employ stronger language to protect 340B contract pharmacies.

Annual registration of contract pharmacies should be limited to only new contract pharmacies and should not require registration of contracts with each site of care. To reduce the unnecessary burden on 340B providers, annual registration should only be required for new contract pharmacy arrangements that have been established in the preceding year. Requiring hospitals to re-register existing contract pharmacies would be a waste of resources for both hospitals and the government. We also are concerned about the proposed requirement for hospitals to register each contract pharmacy arrangement with the parent, child, and other associated sites. Such a requirement is entirely unnecessary since it is the covered entity, inclusive of all its child sites, that is ultimately the legal entity contracting with the pharmacy. Submitting each and every contract would require significant staff time for hospitals and significant staff resources for the government to review each and every such contract. Further, requiring annual resubmission for every contract could create indefinite delays that could jeopardize the ability of hospitals to access drugs for their patients. For example, a hospital forced to re-register an existing contract pharmacy arrangement could experience delays in securing a specialty oncology drug that is in limited distribution for their patients. Patients should not have to wait for a lengthy Health Resources and Services Administration (HRSA) review process requiring review of all written contracts. Therefore, we believe that this is an unnecessary provision as existing requirements, which already require hospitals to register each contract pharmacy arrangement with HRSA and is publicly available through the HRSA Office of Pharmacy Affairs Information System (OPAIS), would suffice.

Contract pharmacies should not be subject to government or drug company audits. While it is customary for contract pharmacies to provide the necessary data to hospitals that would be required for a HRSA audit, the onus of program integrity rests with covered entities and drug companies, not individual pharmacies. Further, it is the covered entity that holds title to the 340B drug and is responsible for protecting against diversion and duplicate discounts, not the individual pharmacy. Requiring individual pharmacies to be subject to audit by the government or drug companies would be redundant and could disincentivize pharmacies from contracting with 340B hospitals. In fact, requiring contract pharmacies themselves to shoulder these burdens could very well turn out to be a poison pill that undermines congressional efforts to protect these arrangements. **We recommend that this provision be removed entirely.**

Congress should not require the submission of providers' written contracts with pharmacies. The AHA supports continued robust oversight of contract pharmacy relationships. But requiring the submission of a hospital's written contract with pharmacies raises a host of concerns, including the disclosure of sensitive business information and trade secrets, potential antitrust concerns, and unnecessary burden on providers and government officials. It is not clear that submission of thousands of pages of paperwork each year will accomplish Congress' goal of effective monitoring; instead, it will expose providers and pharmacies to undue business risk, causing hospitals and the government to spend precious dollars on compliance that could be spent on patient care.

Below are our responses to the specific RFI questions.

1. **If stakeholders are proposing additional limitations on the use of contract pharmacies, how should any restrictions reflect the difference between how urban and rural hospitals utilize contract pharmacy arrangements? If stakeholders are proposing geographic or other restrictions, please provide specific data-based suggestions and reasoning.**

Contract pharmacies are not only an integral component of the 340B program, but they also serve as important access points for patient care. In fact, studies have shown that patients visit their community pharmacies approximately 1-2 times as often as they visit their physician or other qualified health care professionals.[9] Moreover, contract pharmacies ensure that:

- Patients unable to travel to the main hospital to receive their prescribed medications can access it at their local pharmacy, and hospitals can better ensure that patients receive their medications and provide follow-up care as needed.
- Patients of hospitals that do operate their own in-house pharmacies can access drugs that the hospital is unable to keep in stock and/or are in limited distribution.
- Hospitals that do not operate their own in-house pharmacies can realize 340B savings to reinvest in improving access to care for patients.

These varied use cases underscore the need for maximum flexibility in contract pharmacy arrangements. Hospitals, depending on the needs and locations of their patients, are best equipped to decide which local, specialty, mail-order and other pharmacies they need to establish arrangements with. In some cases, hospitals are responsible for patient care across a wide catchment area that, in some cases, can span hundreds of miles and cross state lines.

Given the potential for expansive geographic reach, hospitals may need to establish contract pharmacy relationships that appear far away from the main hospital but are actually areas where their patients live and need access to their prescribed medications. In other cases, a hospital patient may need a particular drug in limited distribution that requires the hospital to contract with a specialty pharmacy outside the immediate geographic area of the hospital. These real-world examples highlight why Congress should not place any limits on the use of contract pharmacy, geographic or otherwise, as it would undermine the very purpose of these arrangements that Congress seeks to codify.

Further, the use cases mentioned above are equally true for urban and rural 340B hospitals, which may be even further impacted by the drug manufacturer-imposed restrictions. For example, some urban and rural hospitals rely entirely on a network of contract pharmacies to ensure access to medications for their patients. While we firmly believe that any limitations on the use of contract pharmacies could jeopardize access to

[9] Valliant SN, Burbage SC, Pathak S, Urick BY. Pharmacists as accessible health care providers: quantifying the opportunity. J Manag Care Spec Pharm. 2022 Jan;28(1):85-90.

care, imposing different restrictions for rural and urban hospitals would be particularly imprudent.

2. **How would you structure any geographic restriction or other restriction on contract pharmacies to ensure patients in rural and underserved areas maintain access to drugs?**

Restrictions on the use of contract pharmacy would only undermine the utility of these arrangements to 340B hospitals and their patients. This is particularly true for rural hospitals that often do not operate their own in-house pharmacies and rely on contract pharmacies not only for their 340B savings to reinvest in patient care but also to ensure access to medications for their patients.

Contract pharmacies are serving large numbers of underserved patients. Specifically, 80% of rural counties had a 340B contract pharmacy. Additionally, as of the time of the study, contract pharmacies were located in 74% of counties with higher-than-average uninsured populations, 81% of counties with higher-than-average unemployment, and 82% of counties with high food insecurity. Further, these arrangements are also helping hospitals address pervasive public health issues and improve patient outcomes by providing care to needy populations. 340B contract pharmacies are located in 73% of counties that have very high prevalence of diabetes and 76% of counties that report significant numbers of newborns with low birthweights — a clinical indicator of poor maternal and child health issues. Congress should not interfere with the vital care that contract pharmacies help hospitals to provide.

3. **How would you structure any limitation on contract pharmacy while also ensuring patients have access to these specialty medications?**

Any limitation on contract pharmacies must account for the nuance and complexity of the U.S. health care market, including limited availability of specialty medications and historical reliance on cross-state transactions to efficiently maintain and distribute these medications. Specialty drug spending has grown considerably over the last several years, now accounting for over half of all drug spending or over $300 billion annually. For hospitals and their patients, specialty drugs are critical to treating many chronic and particularly complex conditions like certain cancers and autoimmune diseases. These specialty drugs may require special handling or other special care and are not always kept in inventory at hospitals that do operate their own pharmacies. Further, patients taking these drugs often require close monitoring by their doctor, underscoring the importance of hospitals ensuring their patients receive their specialty medications. In many cases, these drugs are only available through certain specialty pharmacies. For example, hospitals in 47 states have a contract with Walmart Specialty Pharmacy, which maintains just two locations in the country, because it ensures access to certain critical specialty medications. **Therefore, geographic or other limitations on the use of contracts with specialty pharmacies would undermine the ability of hospitals and their patients to access these vital drugs.**

In addition, many specialty pharmacies are owned by insurance companies that engage in particularly harmful behavior steering patients to the pharmacies that they own. This means that patients must either use the pharmacy that their insurer mandates or risk not having their prescription covered by their insurer, which in the case of specialty medications, could come at a significant cost. When this occurs, providers are essentially forced to establish contracts with these insurer-owned pharmacies to ensure that their patients can access these drugs and provide any needed follow-up care. In fact, approximately *three-quarters* of specialty contract pharmacy arrangements are with pharmacies owned by Aetna, UnitedHealthcare, Cigna and Humana. These ownership issues make restrictions on contract pharmacy relationships even more damaging: If insurers require hospitals to use particular pharmacies, but drug companies will not honor those relationships, then the losers will be hospitals, patients and communities. Further, 80% of new drug approvals by the Food and Drug Administration (FDA) were for specialty drugs, a further indicator that the reliance on contract pharmacy relationships with specialty pharmacies to provide access to those drugs will only increase.[10] Congress must account for these complexities of the specialty pharmacy market when enacting any 340B legislation, as these complexities make clear that there should be no restrictions on contract and specialty pharmacy arrangements.

4. **What policies would allow covered entities to contract with pharmacies to ensure patients have access, without additional requirements or limitations? What policies should be implemented to limit the role of PBMs' influence in the 340B program and ensure the benefits of the 340B program remain with the covered entities and eligible patients.**

We reemphasize the need for Congress to provide maximum flexibility for hospitals to contract with pharmacies based on the unique needs and locations of the patients and communities they serve. We understand that such flexibility requires efforts to ensure program integrity — a fact that hospitals take very seriously. Hospitals regularly work with their contract pharmacies and third-party administrators to conduct periodic self-audits to ensure that all contract pharmacies and their related claims are in compliance with program rules and regulations. In addition, the rigorous audits that HRSA conducts annually ensures contract pharmacy arrangements are in compliance with program rules and regulations. These existing policies are sufficient to balance the need to ensure that patients can access their medications through contract pharmacies while maintaining program integrity and compliance.

We share your concern about pharmacy benefit managers and insurance companies siphoning 340B savings away from patients and providers to line their own pockets. This is a pervasive problem that stems from the vertical integration among insurers, pharmacy benefit managers and pharmacies. As we note above, insurers are increasingly buying specialty pharmacy chains steering patients to those pharmacies. Insurance companies can therefore exercise control of their beneficiaries to use the pharmacies they own to receive their drugs. In the event that the beneficiary is a 340B-eligible patient, the PBM/insurer can assume control of the prescription and retain the 340B benefit along with any dispensing

[10] https://blog.navitus.com/specialty-pipeline-2022-0

fees. **Such patient steering practices should be prohibited by Congress because they undermine Congress' intent for the program to provide savings to hospitals and other covered entities to support the provision of community benefits — not to increase the wealth of for-profit insurance companies.**

II. Patient Definition

To date, the definition of patient under the 340B program has been governed by HRSA guidance promulgated in 1996. This guidance provides a clear three-part test that individuals must meet to be considered a 340B-eligible patient. This test largely relies on ensuring that the patient has an established health care relationship with the 340B covered entity and that the relationship is documented in the patient's health care records. The simplicity of this test and the flexibility it affords providers underscores the wisdom and continued viability of this definition. Take, for example, the advent of telehealth, an important and now ubiquitous method for care delivery. When HRSA implemented its patient definition in 1996, telehealth did not exist. But the flexible definition has allowed the 340B program to evolve with the times. A codified or restrictive patient definition that would limit the nature of the service performed and creating an ambiguous "meaningful relationship" standard could create additional uncertainties and jeopardize the use of telehealth (or future service methods) for 340B eligible patients.

The existing patient definition also makes oversight of the program easier. Hospitals and health systems across the country have put in place for many years the necessary compliance programs and systems to adhere to the 1996 patient definition guidance. These systems, based on the patient definition 340B hospitals have used for nearly three decades, are already a core component of HRSA's auditing process to protect against diversion of drugs to ineligible patients. **Therefore, the AHA believes that existing HRSA guidance is sufficient in defining a 340B patient and does not see the need to legislate this issue.**

As Congress weighs whether additional limitations are needed, it is important to consider what purpose this would serve. HRSA, in 2015, attempted to regulate a narrower 340B patient definition, which was subsequently withdrawn. At the time, the agency received over 1,200 comments providing innumerable examples of how a narrower patient definition would be unworkable given the range of patient-provider relationships and modes of care delivery that exist.[11] For example, one hospital noted they routinely receive referral patients from external providers who require specialized care; a more restrictive patient definition that excludes such referral patients would be devastating to the hospital's 340B program and their ability to furnish high-cost medicine to these patients.

A narrower patient definition would be antithetical to the very "Sense of Congress" that the discussion draft would codify in Section 2. This section importantly states that the purpose of 340B is to "maintain, improve, and expand patient access to health care services." A narrower patient definition would achieve the *exact opposite* goal; it would potentially exclude patients who could benefit from access to medications through the 340B program. Ultimately, limits on 340B patient would reduce hospitals' access to 340B savings

[11] https://www.regulations.gov/docket/HRSA-2015-0002/comments

that can be used for patient care. The *only* entities that stand to benefit from imposing additional limits on the current patient definition are drug companies.

For all these reasons, the current definition strikes the right balance and therefore we do not believe this issue needs to be legislated. Therefore, HRSA's 1996 patient definition guidance should continue to govern this issue.

Below are our responses to certain key RFI questions.

1. **Since the program has evolved since the original statute was written, how should these changes be reflected in how a patient is defined?**

We agree that the program and the broader health care landscape has evolved since the program was established in 1992. Of particular consequence is the increased use of technology-enabled services to deliver outpatient care to patients — a mechanism that was especially important during the COVID-19 pandemic where in-person care was difficult and potentially dangerous. In addition, the types of outpatient services offered have evolved from simple doctor visits to a whole array of services including minimally invasive surgeries and chemotherapy infusions. Further, modes of care delivery can be different for providers located in urban, suburban and rural settings. For example, some rural hospitals operate mobile treatment clinics or home-based outpatient therapy to care for patients. It is precisely these factors that underscore the need to employ a patient definition that is maximally flexible. In addition, it is virtually certain that the health care landscape will continue to evolve over the next 30 years with the emergence of artificial intelligence and other technologies that have the potential to transform patient care. This requires a patient definition that is durable in the face of such changes. Employing a narrow and inflexible statutory patient definition now could require frequent modification in the future or could be rendered entirely obsolete within years. This reality is yet another reason why flexibility in defining a 340B patient is not only prudent, but necessary. **Therefore, the AHA supports the continued use of the 1996 patient definition guidance without additional need for Congress to legislate this issue.**

2. **What factors should inform whether the covered entity has a meaningful relationship with a patient? Should the type of patient encounter or specific level of services provided be considered in determining whether a relationship exists between a covered entity and a patient? If so, how would these improve or provide additional program integrity?**

Given the range of care delivery mechanisms we outline above, it is nearly impossible to define a standard for "meaningful relationship" that would sufficiently capture this variation. The word "meaningful" is inherently a vague term. What one patient may consider a meaningful relationship with the provider may not hold true for another patient. For example, a patient may consider it meaningful when they have repeated visits with a particular provider, while another patient may consider it meaningful with only a single visit. Therefore, to legislate a definition of "meaningful relationship" is not only challenging from an enforcement perspective, but an unnecessary complication of a patient definition standard that already works — and has worked for 30 years. It is for this same reason that Congress

should not be prescriptive in establishing specific types of encounters or services that would qualify a 340B patient. **Therefore, the AHA strongly objects to any "meaningful relationship" or other such standards that would limit the current 340B patient definition.**

3. **Should the length of time a relationship exists between a covered entity and a patient be a factor in how a patient is defined? If so, what is an appropriate time frame? Should there be a time limit on how recently an individual must have qualified as a patient in order to continue to be eligible for 340B?**

The issue of timeframe is another imperfect standard that would not adequately capture the range of relationships that could exist between a patient and a provider. There are several examples where public health emergencies and other crises have forced patients to avoid or delay care. Employing a restrictive timeframe could render such patients 340B ineligible — a particularly punitive standard that would disadvantage both providers and patients who were simply the victims of extraordinary circumstances. As the Court opined in its ruling in the *Genesis* case, most all ordinary and plain definitions of the term "patient" do not prescribe a timeframe for the care being provided — they simply state that the person is under or awaiting medical care.[12]

This issue is not a new one. In 1996, when HRSA proposed its patient definition guidance, one commenter raised this very issue stating that the 340B patient definition should "require that a covered entity patient be currently receiving care, and an additional section should be added to address the frequency of medical care."[13] In response to this comment, HHS correctly pointed out that "it would be inappropriate for the Department to proceed further and dictate to health care providers guidelines regarding the appropriateness of certain prescriptions. We understand that States typically regulate the refilling of prescriptions."[14] It is just as inappropriate today, as it was back in 1996, for HHS or Congress to set a strict timeframe for when someone is a patient of an entity. **The AHA therefore opposes any restrictions on timeframe or frequency of visits in the definition of a 340B patient.**

4. **What tools should be provided to HRSA to ensure it can implement a patient definition that accommodates diversity in covered entity types while promoting consistency, clarity, and integrity in the program?**

We do not believe HRSA requires additional authority to implement its 1996 patient definition standard. Promulgating these kinds of definitions is within HRSA's role and responsibility. The Court in *Genesis* did not reject the 1996 patient definition guidance as unlawful and, in fact, rejected the Plaintiffs argument that HRSA could not promulgate guidance to define a 340B patient. The only requirement that the Court emphasized is that any patient definition guidance should adhere to the plain text of the 340B statute, which the 1996 patient definition guidance surely meets. HRSA has already established audit protocols to protect against the diversion of drugs to ineligible patients, which it enforces as part of the 200 audits it conducts annually of 340B covered entities. We believe this audit

[12] Genesis Health Care Inc. v. Becerra, No. 04:19-CV-01531 RBG (D.S.C.) Nov.3, 2023).
[13] https://www.govinfo.gov/content/pkg/FR-1996-10-24/pdf/96-27344.pdf
[14] *Ibid.*

authority that is already present in the 340B statute is sufficient to protect against the statutory prohibition against diversion of drugs. **The AHA also urges HRSA to finalize the 340B Administrative Dispute Resolution (ADR) process that was mandated under the Affordable Care Act and is yet to be established by the agency after nearly *14 years* of uncertainty.** Congress has provided HRSA with a key oversight tool through this 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. The AHA believes that HRSA should be given a chance to implement this before patient definitions are added, particularly if the goal of those definitions is to address the diversion of 340B drugs.

III. Child Sites

One of the most significant outgrowths of the increased use of technology and advances in clinical medicine is the shift from inpatient hospital care to outpatient hospital care. This shift has been accelerated by government regulations promoting the move of certain services (especially low-cost and less complex services) that had been traditionally performed in the inpatient setting to the outpatient setting. In fact, nearly 60% of total hospital visits in 2019 — prior to the COVID-19 pandemic which artificially changed many dynamics—were for outpatient care, an increase of nearly 10 percentage points from 2010. This trend is expected to continue, with some forecasting up to 19% growth in hospital outpatient visits over the next five years.[15] These broader system-wide trends that have created an environment for increased demand for outpatient care and the critical need for so-called "child sites." Consistent with the goals of the 340B program, these outpatient facilities allow 340B hospitals to expand access to their services. The scope of services offered at child sites varies based on the needs of the community. In some cases, child sites offer a broad range of care; in other cases, they offer a single service like an infusion clinic where patients can access chemotherapy necessary for cancer treatment.

We recognize that the use of child sites has been a concern for drug companies that allege misuse and unfettered growth. But those arguments are not grounded in facts. *First*, as we note above, broader system-wide trends have hastened the need and demand for outpatient care, and the growth of child sites is simply an effort to meet that patient demand and expand access to outpatient care. *Second*, the exact number of 340B child sites has often been mischaracterized and miscalculated. HRSA mandates that covered entities register *each and every* site of care, even if they are located at the same physical address. Therefore, a 10-story building where each floor is a different outpatient department may need to be registered as 10 different child sites, though they share the same physical address and are essentially a single outpatient facility. As a result, the actual growth of child sites is far less than what drug companies assert. *Finally*, despite some growth in the 340B program and child sites, the discounts drug companies provide to 340B hospitals remains a small share of their revenues — approximately 3.1% of drug companies' global revenues.[16]

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[15] https://www.businesswire.com/news/home/20210604005089/en/Sg2-Impact-of-Change-Forecast-Predicts-Enormous-Disruption-in-Health-Care-Provider-Landscape-by-2029
[16] https://www.aha.org/guidesreports/2024-03-12-340b-drug-pricing-program

As such, discounts for child sites are an even smaller percentage of drug companies' already tremendous revenues. There is no factual or policy justification to create additional restrictions on the use of child sites. Those restrictions would reduce access to care and diminish the value of the 340B program to patients.

Below we highlight our specific concerns with this section of the discussion draft and our responses to key RFI questions.

Requiring 340B child sites to be wholly-owned does not sufficiently account for the range of relationships that can exist in the operation of a child site. While some child sites may be wholly-owned, other "child sites" are operated as joint ventures, as recognized under the Medicare provider-based guidelines in 42 CFR 413.65(f). This is especially true for some rural hospitals that operate a child site at a facility that is jointly owned by another hospital or health system and staffed by physicians that are either contracted or employed by the 340B hospital. Restricting the ability of such joint ventures to be eligible for the 340B program undermines Congress' intent of the program and will sharply reduce access to care, especially in rural communities.

340B hospitals should not be subject to ambiguous registration requirements that are burdensome and unnecessary. The current language simply states that each covered entity must "register each child site with the Secretary" but includes no additional language about how that registration process would be operationalized. It would be duplicative, burdensome and unnecessary to require hospitals to submit documentation and an attestation to the Centers for Medicare & Medicaid Services (CMS) for provider-based status and be required to submit similar documentation to HRSA for registration as a 340B child site.

Child site provisions should not be used to limit 340B patient definition. The draft bill appears to suggest that providers at the child site be clinically responsible for the care that is directly related to the 340B drug received by the patient. This appears to narrow patient definition like what HRSA attempted in its 2015 "mega guidance" that was subsequently withdrawn. It is unclear whether this would limit the ability of providers to administer infusions at child sites if no other service is being performed. Similarly, another provision in this section pertaining only to disproportionate share hospitals would appear to limit the ability of referral prescriptions to be 340B eligible, as it is unclear whether a referral provider would be considered a "bona fide contractor" of the covered entity. The term "bona fide contractor" is ill-defined and could disallow certain provider-hospital relationships that would satisfy current requirements. Further, hospital-physician relationships vary significantly from state to state (see corporate practice of medicine laws in New Jersey, California, Texas, and Tennessee), language like "bona fide contractor" would serve to overcomplicate and confuse myriad existing provider relationships. In addition, many 340B hospitals, particularly those located in vulnerable rural and urban communities, face substantial challenges attracting physicians willing to enter into an employment or independent contractor relationship. Ultimately, these limits would significantly diminish 340B hospitals' savings and impact patient access to vital services.

The term "clinically meaningful range of services" is an arbitrary and ambiguous

standard. It is unclear what this term means in the context of services provided at child sites. If interpreted narrowly, it could exclude from the 340B program child sites that provide only a single service — for example, infusions or medication management therapy. Also, it is unclear who would determine what is a "clinically meaningful range of services" and how such a requirement would be enforced. Such ambiguous language could result in further challenges and uncertainty for providers. Most problematic, it would most likely diminish the scope of the program and the benefits afforded to patients.

1. **Do the guidelines, as proposed, reflect how a wholly-owned child site should be clinical and financially integrated into the covered entity? Are there additional requirements that should be added to be sure the child site is clinically and financially integrated into the covered entity?**

The AHA does not support *any* requirement that would restrict child sites to be wholly-owned. As we note above, such a restriction ignores the many ownership types that exist. The AHA does not understand why the corporate form or relationship should dictate access to the 340B program. Joint ventures provide the same valuable access to care that wholly-owned outpatient facilities do, but the current draft draws an arbitrary line. We also do not support additional restrictions or limits that would be unnecessary and overly burdensome for hospitals to comply with.

2. **What policies should be considered to inform whether child sites located in different areas are responsible for using their 340B savings to help the underserved in the surrounding community, in the same manner as is expected of the parent entity?**

Child sites of care are merely extensions of the main hospital and are clinically and financially integrated into the parent hospital. They allow hospitals to extend their reach further into their communities, creating greater access to care. Accordingly, it is important for 340B savings to reside with the parent hospitals. Child sites and the main hospital are required to operate under a single financial system, the 340B savings achieved at the child site should accrue to the parent hospital registered in the 340B program. The parent hospital should then decide how to use its the 340B savings to meet the unique needs of all patients served by the hospital and its child sites. To better achieve the goals of the program, as set forth in Section 2 of the discussion draft, hospitals should be given the flexibility to determine how best to allocate their 340B savings to "maintain, improve, and expand patient access to health care services."

3. **What exemptions or special considerations should be provided to child sites located in rural, frontier, or areas of high medical need?**

The orphan drug exclusion, which prohibits free-standing cancer hospitals, rural referral centers, sole community hospitals and critical access hospitals from accessing 340B pricing for those drugs, creates unintended challenges for hospitals and their child sites in rural, frontier, or areas of high medical need. These sites are increasingly providing complex care to patients who require the use of orphan drugs. Indeed, many of the patients who stand to benefit from receiving orphan drugs are located in rural and frontier areas and are unable to

access orphan drugs elsewhere. It is challenging for these rural hospitals and their staff to ensure that drugs purchased through the 340B program have an orphan drug designation. Further complicating the issue is the fact that many of these orphan drugs are extremely high-cost medications; consequently, 340B discounted price is particularly important to assist providers in furnishing these drugs to their patients. **The AHA urges Congress to provide sites of care located in rural, frontier, or areas of high need an exception to the orphan drug exclusion.**

IV. Transparency

340B hospitals and the AHA are committed to ensuring transparency in the program and recognize the important role it plays in promoting program integrity. Any transparency measures should be meaningful, accurate and mitigate unnecessary burden. Otherwise, we risk transparency being misused by program opponents who wish to cut the program and reduce its benefits to providers, as well as the patients and communities they serve.

As we consider what, if any, additional transparency measures are needed, we should first consider the measures that already exist. Under the current framework, 340B hospitals already report a variety of information to demonstrate their commitment to providing care to underserved populations. Under the tax code, 340B hospitals report uncompensated care, charity care and other benefits provided to the communities they serve through both their annual Medicare cost reports and the IRS 990 form required for tax-exempt organizations. Of note, the most recently available IRS 990 data show that 340B hospitals provided nearly $68 billion in community benefits in 2020 alone. Further, the increase in community benefits has outpaced the increase in 340B discounts that hospitals have received, illustrating the outsized nature of hospitals' commitment to expanding access to care for the patients they serve. In addition to these data that are publicly available, HRSA requires separate reporting during its annual 340B hospital certification process including registration of child sites and contract pharmacies. Finally, the AHA has established its 340B Good Stewardship Principles, which ask 340B hospitals to voluntarily commit to publicly disclosing their 340B savings, sharing how those savings are used to benefit the communities they serve. Over 1,300 340B hospitals have signed this pledge and many more hospitals continue to voluntarily share their use of 340B savings publicly, underscoring the collective commitment of 340B hospitals to transparency.

Below we outline our major concerns with the discussion draft language on transparency.

The 340B program should not be used as a backdoor to increase reporting requirements under the tax code. And even if it should, charity care alone is not an accurate representation of the range of all the benefits the 340B program affords to patients. It is important to recognize that no single measure can fully define the benefit that 340B savings provide to patients, so using charity care as that measure would undermine the ability of hospitals to determine how best to "maintain, improve, and expand access to care" given the needs of the populations they serve. For example, examining just "charity care" fails to capture 340B savings used to furnish behavioral health treatment, medication management therapy, or opioid treatment — services that are just as important to patients

as providing financial assistance.

It is important to employ common definitions that do not obfuscate or overstate the true savings achieved by 340B hospitals. The 340B program allows hospitals to purchase covered outpatient drugs at a price that is discounted relative to the price they would have paid had they not participated in the program. For most covered outpatient drugs, the price paid outside of the 340B program is a group purchasing organization (GPO) price or other similar price. It is not the wholesale acquisition cost (WAC). Estimating savings by comparing the 340B acquisition price to the WAC price would misstate and confuse how much 340B hospitals are saving from the program.

Transparency requirements should not be duplicative or overly burdensome. As we outline above, hospitals *already* provide to the government numerous data points through their Medicare cost report, Form 990 and other documents. Further, as child sites are fully integrated both clinically and financially, the systems that govern the operations of the hospital and its child sites are not equipped to track certain data like charity care, financial demographics or payer mix in a way that is specific to each site of care. In addition, requirements to extend this data collection to all contract pharmacy arrangements would be unworkable given that payer information is not always available at the point of purchase. To comply with such requirements would (1) require a pointless overhaul of current systems and processes, (2) come at a prohibitive cost, and (3) divert significant staff resources away from patient care to develop and maintain the systems and processes necessary to collect and report such information.

It also is concerning that these and other data would become part of the public domain and could be used by program critics to inaccurately suggest that hospitals are not serving vulnerable patient populations, when one of the requirements to participate in the 340B program is providing care to a significant number of vulnerable patients.

Transparency requirements should be balanced to ensure that 340B hospitals and drug companies *both* are maintaining program integrity. The language in this discussion draft targets only hospitals and does not place any transparency requirements on drug companies. While many 340B hospitals have voluntarily shared information about their 340B savings and how those savings are used, drug companies have repeatedly refused to report any information about how they set their prices, by how much, 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 and how stakeholders can mitigate arbitrary and egregious price increases for drugs that are critical and lifesaving for patients. **If Congress is going to increase transparency requirements for hospitals, it must do the same for drug companies. We urge Congress prevent drug companies from obfuscating their pricing practices, thereby undermining Congress' intent in establishing the 340B program.**

V. Enhancing Program Integrity

340B hospitals take seriously their role in ensuring program integrity and invest significant resources to maintain compliance with program rules and regulations. For this reason, the AHA included rigorous internal oversight as a key component of its AHA Good Stewardship Principles. 340B hospitals, at their own expense, conduct regular self-audits to identify and correct any issues with these systems and protocols and to maintain program integrity.

HRSA also exercises its existing regulatory authority to promote program integrity by conducting 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 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 be compliant with all program rules and regulations. **Given that these authorities already exist, we believe HRSA's current auditing measures are sufficient to ensure program integrity.**

Below, we highlight our key concerns with Congress' interest to expand HRSA's audit authority and create additional oversight.

Expanding the scope of audits could limit hospitals use of 340B. The discussion draft language appears to extend HRSA's auditing authority to include contract pharmacies. As we note in a prior section, subjecting independent pharmacies to government audits would likely require hospitals and their contract pharmacy to change existing contract terms — a challenging requirement on its own. More concerning, it also could create an environment where independent pharmacies choose not to contract with a 340B hospital. In such a scenario, it would limit a hospital's ability to use 340B and patients' access to care and medicines at the convenience of their local, specialty, or mail-order pharmacy would be jeopardized. Existing oversight of 340B hospitals is enough. Congress does not need to expand auditing of contract pharmacies, which is yet another poison pill that will dramatically reduce those arrangements.

The discussion draft also appears to expand the scope of issues that are subject to audit to include the use of contract pharmacies, improperly claiming 340B eligibility and claiming a discount for a drug that is not considered a covered outpatient drug. While the exact implications of this expansion are unclear, it is likely to have serious ramifications for hospital participation in the program without any clear added benefit to ensuring program integrity. For example, auditing 340B hospitals for claiming discounts on drugs that are not covered outpatient drugs could have unintended consequences for rural hospitals subject to the orphan drug exclusion, where it is already challenging to identify which drugs have been designated with orphan status.

Additional sanctions would be unjustly punitive for 340B hospitals. The current audit standard to remove a covered entity from the program requires that the audit violations be both "knowing and intentional" and "systematic and egregious." The discussion draft language appears to remove that standard, which is concerning because a single violation could theoretically result in grounds for expulsion from the program. Further, providing 340B

hospitals and other covered entities six months to implement a corrective action plan (CAP) does not consider situations where annual contracts may need to be amended to implement the CAP. Hospitals, if they are working *in good faith* with HRSA and drug companies, should not be terminated from the program or otherwise punished.

Program integrity requirements should be equal for 340B hospitals and drug companies. The discussion draft language is *solely* focused on expanding program integrity measures and the scope of audits for hospitals and other covered entities. It places no additional requirements for drug companies, which are equally responsible to ensuring program integrity. There are many instances when drug companies have violated program rules and requirements such as overcharging hospitals, denying 340B pricing for certain drugs and arbitrarily placing drugs in limited distribution for which hospitals have little to no recourse. Ironically, while drug companies are permitted to conduct audits of 340B hospitals in certain instances in coordination with HRSA, hospitals and other covered entities are unable to audit drug companies. What's more concerning is that HRSA conducts on average *less than six audits* annually for drug manufacturers, as compared to over 200 for covered entities. Since FY 2015, HRSA has conducted only 31 audits of drug companies, 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 companies should be equalized. If Congress wishes to enhance program integrity, it should do so in a manner that holds *both* drug companies and 340B covered entities to the same level of accountability.**

VI. Preventing Duplicate Discounts

340B hospitals recognize the importance of preventing duplicate discounts and have attempted to mitigate against this issue. It is important to consider that there are many components to ensuring duplicate discounts do not occur and it requires the cooperation and partnership with State Medicaid agencies, especially as it relates to Medicaid managed care claims. To that end, the AHA has been generally supportive of efforts to establish a third-party national claims clearinghouse as proposed by Reps. Spanberger, D-Va., and Johnson, S.D., in H.R. 2534, the PROTECT 340B Act. We appreciate the draft discussion's effort to establish a third-party clearinghouse that is free of any conflicts of interest to be sure that the process is fair. However, we do have some concerns with this section of the discussion draft, which we outline below.

It is unclear why this section amends the Social Security Act instead of the Public Health Service Act. The 340B program and prohibitions against 340B duplicate discounts are established under the Public Health Service Act (PHSA). Yet, the draft bill addresses this issue in the Social Security Act (SSA), which raises the question of whether HRSA or CMS would oversee the clearinghouse and its data collection. It also is unclear what the data would be used for if the prohibition against duplicate discounts is governed by statute under the PHSA, not the SSA, and whether it is the intention of Congress to use this data beyond the scope of simply preventing duplicate discounts.

Mitigating duplicate discounts should not require the collection of claims data from all payers, and data should not be shared with drug companies. Since the issue of

duplicate discounts in the context of the 340B program is limited to ensuring that a drug is not subject to both a 340B discount and a Medicaid rebate, 340B hospitals should not be required to provide all-payer claims. Not only would such a requirement be overly burdensome, but it is not necessary to address the issue of preventing duplicate discounts. Further, 340B hospitals should not be required to provide all payer claims data only for that data to be shared with drug companies as they undoubtedly will use that data to their financial advantage.

340B legislation should not seek to amend the Tax Code through the backdoor by setting a new financial assistance requirement. It appears that the discussion draft goes beyond current financial assistance requirements under 501(r)(4)(A) of the IRS tax code by setting a numerical floor at 200% of the federal poverty level. Not only does this set a dangerous precedent to legislate this issue outside of the IRS tax code, but also it creates challenges for hospitals that currently have flexibility to design their financial assistance policies based on the needs and financial demographics of their patients. In addition, it is unclear whether this 200% figure accounts for geographic variability, including whether this requirement will impact hospitals in certain states harder than others. Further, the fact that hospitals would be required to extend such financial assistance policies at the point of sale at all sites of care, including at contract pharmacies, adds unnecessary complexity and burden to hospitals. Though the draft bill appears to waive any anti-kickback or Stark law concerns, the very concept of requiring hospitals to extend their financial assistance policies to third-party entities like independent pharmacies sets another dangerous precedent. Collectively, it appears that the purpose of this section is to legislate how 340B hospitals and covered entities are to use their 340B savings, which directly contravenes the purpose of the 340B program: to allow *covered entities,* not the government, to decide how to use its savings to maintain, improve and expand access to care that address the unique needs of the covered entity's patients and communities.

VII. Ensuring Equitable Treatment of Covered Entities and Participating Pharmacies

The AHA has longstanding concerns about the role that insurers and PBMs play 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 to protect their rebate revenue from drug manufacturers. PBMs have required 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 that threaten hospitals' ability to provide more comprehensive services to their patients as the law intends to ensure patient access to drugs through PBM pharmacy networks. Some of the tactics of concern entail 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.

Therefore, the AHA is fully supportive of the draft bill's efforts to prohibit PBMs and insurers from engaging in discriminatory pricing and patient steering tactics, which directly undermine the purpose of the 340B program.

VIII. User Fee Program

The proposed user fee program would effectively charge 340B hospitals and covered entities a fee to participate in the program. The concept of taking money away from covered entities to participate in a program that is intended to provide financial resources to covered entities is difficult to justify. Doing so would take money away from critical patient services that are intended to further Congress' intent for the program to allow providers to "maintain, improve, and expand access to care" as stated in Section 2 of the discussion draft. **Therefore, the AHA opposes a user fee program.**