Dear Sens. Thune, Stabenow, Capito, Baldwin, Moran, and Cardin:

Thank you for your leadership to protect and strengthen the 340B Drug Pricing Program and for your request for information (RFI). America’s Essential Hospitals is eager to work with you to ensure the 340B benefit continues to support underserved communities and improve access to care.

America’s Essential Hospitals is the leading champion for hospitals and health systems dedicated to high-quality care for all, including those who face financial and social barriers to care. Given their safety net mission and the challenges they face, essential hospitals rely heavily on federal support to fulfill their vital role. These hospitals operate on margins approximately 60 percent lower than other U.S. hospitals yet provide a disproportionate share of uncompensated care. With three-quarters of their patients uninsured or covered by Medicaid or Medicare, and only a fraction supported by commercial insurance, essential hospitals truly form the fabric of the nation’s health care safety net.¹

Further, our more than 300 member hospitals serve communities where millions of individuals live below the poverty line and lack health insurance. These hospitals not only care for marginalized and at-risk patients but also operate critical trauma centers, provide specialty care, and contribute significantly to training the next generation of the health care workforce. Despite making up only 5 percent of hospitals nationally, our hospitals operate a third of the

nation’s level I trauma centers, 40 percent of burn care beds, and more than a quarter of pediatric intensive care beds; and they train nearly three times more physicians than other U.S. teaching hospitals.2

We appreciate that you opened your RFI by underscoring congressional intent when creating the 340B program: “...to stretch scare Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” It is clear lawmakers intended 340B to directly support providers serving a safety net role, such as essential hospitals. So, it is unfortunate the 340B program is under direct attack by drug manufacturers, insurers, and pharmacy benefit managers. We urge lawmakers to protect the program by clarifying existing 340B policy to prohibit discrimination against 340B covered entities, including by protecting access to contract pharmacies.

Thirty-one years after 340B became law, the same issues that gave rise to the program—the poor financial position of providers serving a safety net role and unchecked drug price increases—persist. Considering these challenges, a strong 340B program is critical. For essential hospitals, which operate on narrow margins, 340B discounts help them to keep their doors open at nearly no cost to taxpayers.

Essential hospitals continue to be good stewards of 340B and support transparency in the program. By statute, hospitals must care for a significant volume of low-income patients to be eligible for the 340B program, and they must maintain this commitment to low-income patients to remain in the program. Through annual recertification, 340B hospitals must show they continue to meet 340B program requirements. Significant oversight already occurs in the 340B program: the Health Resources and Services Administration (HRSA), which administers 340B, has conducted more than 1,600 audits of covered entities since 2015. By contrast, just 36 manufacturer audits have taken place during the same period. The lack of parity and unequitable focus on safety net providers, rather than manufacturers, is striking—HRSA audits more covered entities in one year than the cumulative manufacture audits for the eight years since 2015. These audits have been robust, and hospitals have worked closely with auditors and have helped refine the program. In addition to being subject to HRSA audits, hospitals maintain stringent internal controls and procedures to ensure compliance with 340B requirements.

Essential hospitals are good stewards of the 340B program because their patients and communities depend on it. Hospitals demonstrate their commitment to transparency through their routine compliance with rigorous program audits, including significant data requests, and the steps they take to correct shortcomings that arise. Essential hospitals lead by example when it comes to transparency by providing detailed financial information on annual Medicare cost reports. Nonprofit hospitals are required to conduct community health needs assessments, have publicly available financial assistance policies, and include information about their community benefit in their tax filings. Hospitals lead the way in quality reporting by complying with complex requirements and are scored on their quality of care by private and public payers alike.

It is important to note 340B savings allow essential hospitals to meet their mission of caring for all and addressing social and financial barriers to health, work that is often unreimbursed. Consistent with their mission, essential hospitals adhere to Congress’ intent for 340B by using their 340B savings to offset the costs of programs and services that benefit those most in need.

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2 Ibid.
For example, essential hospitals have used 340B savings for these and other programs and services for disadvantaged patients:

- Provide mental health and substance abuse treatment.
- Reduce wait times for cancer drugs and improve medication adherence among cancer and HIV patients.
- Place pharmacists in outpatient pharmacies to help manage the care of vulnerable patients.
- Provide meaningful access to patients through clinic location, hours of operation, transportation availability, interpretation services, and patient education not otherwise available in many places.
- Support free clinics in their communities.
- Operate programs that help people in their community overcome the negative effects of food insecurity, homelessness, and other social determinants of health.

Despite the vital role these providers play, 340B hospitals have a history of discrimination by drug manufactures, insurers, and even the Centers for Medicare & Medicaid Services (CMS). In fact, the U.S. Supreme Court unanimously rejected massive payment cuts CMS made over five years (calendar years 2018 to 2022) to hospitals participating in the 340B program and ruled the cuts to be unlawful.\(^3\) We urge lawmakers to protect and strengthen the 340B program to ensure stability and certainty for the health care safety net.

Our responses to specific items raised in the RFI follow.

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?**

To strengthen HRSA’s ability to oversee the 340B program effectively, ensure program integrity, and ultimately better serve the needs of patients and health care providers, we recommend:

- **Funding and resources:** Adequate funding and resources are critical for HRSA to effectively oversee the 340B program. Congress should allocate ample funding to HRSA, enabling it to carry out its responsibilities and implement program improvements. Annually, HRSA conducts more than 200 audits of 340B hospitals for program integrity but conducts only six audits of drug manufacturers. Greater oversight of drug manufacturers is necessary, especially given current illegal actions in the contract pharmacy space. HRSA should have the resources it needs to conduct audits of drug manufacturers and ensure audit parity.

- **Clarification of the existing statutory requirement to provide discounted drugs through contract pharmacies:** While we believe the statute already gives HRSA authority to enforce the provision of 340B discounted drugs without restriction on contract pharmacies, Congress should improve HRSA’s ability to enforce the statute by adopting the bipartisan Preserving Rules Ordered for the Entities Covered Through (PROTECT) 340B Act to make absolutely clear current actions by manufacturers violate the statute. The act also would give HRSA clear authority to penalize

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manufacturers not only for overcharging but for restricting the ability of covered entities to purchase a drug at all, as well as for subjecting entities to other unlawful conditions as a requirement for accessing discounts. HRSA should work with lawmakers to provide technical assistance in drafting legislation that clarifies existing policy, allowing for contract pharmacies to dispense 340B drugs. This will increase access to underserved communities and patients who face barriers.

- **Manufacturer transparency and reporting:** There are abundant transparency and reporting requirements aimed at covered entities but very little on the manufacturer side. Requiring drug manufacturers to provide more comprehensive and timely data on their 340B program participation and drug utilization would significantly assist HRSA in monitoring program compliance and identifying potential issues. Enhanced transparency in data would bolster HRSA’s ability to ensure compliance and uphold program integrity more effectively. Congress should give HRSA the authority, resources, and direction to enforce transparency and reporting requirements on drug manufacturers.

- **Stakeholder engagement:** HRSA should prioritize engaging with relevant stakeholders, including all types of covered entities, drug manufacturers, and advocacy groups. This collaborative approach can offer valuable insights into program challenges and opportunities for improvement, fostering a more effective and inclusive oversight process. It is essential for HRSA to maintain consistency in program operation and requirements, and policy changes should be clearly communicated to program participants well in advance of implementation.

- **Streamlined administrative processes:** Simplifying administrative procedures for both covered entities and HRSA is crucial in reducing administrative burdens and ensuring resources are utilized more efficiently.

- **Transparency and opportunity for feedback in HRSA guidance:** Within its existing authority, HRSA can and should continue its work to adhere to principles of transparency and provide opportunities for stakeholder feedback on its policymaking activities, from significant policy changes to changes in implementation that could cause operational costs and disruptions for covered entities. Policy changes should come with an explanation, provide transition periods when they are disruptive, and account for stakeholder reliance on prior guidance.

While HRSA has used the notice-and-comment process for many major policies, it has failed consistently to provide opportunities for meaningful stakeholder feedback before implementing guidelines. Uncertainty in how HRSA announces changes pertinent to compliance with the 340B program can cause confusion among essential hospitals and other covered entities, as well as among manufacturers. Policies issued without clear and advanced public notice lack stakeholder review, leading to unnecessary technical or operational challenges for compliance and/or misunderstandings about policy details due to the lack of opportunities for questions.

We encourage HRSA to universally use the notice-and-comment process for guidance to avoid confusion and differing interpretations among stakeholders about important program requirements. Making policy through a more formal process would ensure consistent interpretations among stakeholders and allow for more comprehensive guidance and clarity.

To the extent the use of frequently asked questions (FAQ) on the HRSA or Apexus website is more practical or appropriate, HRSA should begin dating FAQ on their website and providing alerts when an FAQ is posted or revised on its website or Apexus. This would enable stakeholders to easily track new compliance information.
2. What specific policies should be considered to establish consistency and certainty in contract pharmacy arrangements for covered entities?

Contract pharmacies play a crucial role in expanding the 340B program’s reach and impact. These arrangements allow essential hospitals to extend their services to underserved communities, remote areas, and patients who face transportation challenges or other social drivers of poor health. Without the ability to partner with contract pharmacies, many essential hospital patients would be forced to either return to the hospital for retail drugs or not refill their medications. Especially for patients who receive specialty care at a level I trauma center or academic medical center, a return trip could be prohibitively far and burdensome. Even for patients who receive care in their community, a return trip to that originating facility instead of their local pharmacy requires access to reliable transportation, child care, and time off work or away from family responsibilities. This is especially significant for patients with limited means or who are in poor health.

Further, an increasing number of specialty drugs are available only through specific specialty pharmacies with which hospitals must contract to access those drugs. Such pharmacies often have centralized locations for shipping, making geographic restrictions on their use arbitrary. Also, hospitals often need to work with more than one specialty pharmacy to access the range of drugs needed for their patients. It is important to note that the 340B savings achieved at a particular contract pharmacy, including specialty pharmacies, accrue to the covered entity, not the pharmacy. The entity delivering care can use those savings to directly support patient services and access.

Despite manufacturer compliance with contract pharmacy for decades, more than 20 pharmaceutical manufacturers are now illegally withholding or restricting access to 340B pricing at contract pharmacies. HRSA should refer all such manufacturers to the U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG), and the OIG should impose monetary penalties on drug companies flagrantly violating the law. Many of these companies have sued to avoid these penalties and continue their illegal practices, stripping billions of dollars from safety net providers simply to pad pharmaceutical companies’ already substantial margins.

To put it in perspective, the average essential hospital operates on 3.2 percent operating margin.4 Conversely, for pharmaceutical companies, the average operating margin is greater than 21 percent.5

Contract pharmacy litigation and restrictions are needlessly draining resources from HRSA, the Department of Justice (DOJ), and providers serving a safety net role—nonprofit entities that face significant financial challenges. While we do not believe there is a lack of legal clarity, Congress should nonetheless adopt legislation to make undeniably clear the intent of the statute to require provision of discounted drugs, including through contract pharmacies, and to clearly impose penalties on unilateral actions to withhold or create barriers to discounts drugs. By imposing restrictions on contract pharmacies, in blatant violation of current law, drug manufacturers are directly harming disadvantaged patients who depend on the 340B program

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for affordable access to necessary medications. This also contributes to drug shortages and affects the supply chain for all providers.

The drug companies’ restrictions on 340B pricing are particularly egregious, given the lack of a credible reason for their actions other than to increase profits at the expense of the patients and taxpayers.

A recent report\(^6\) highlights in striking fashion the increasing use of restrictions by drug companies to circumvent congressionally imposed inflation penalties and discounts on expensive specialty drugs. A significant portion of the savings under the 340B program arises from penalties imposed when drug companies raise their prices at rates exceeding inflation. When such price increases are both substantial and frequent, these penalties can drive down the 340B ceiling price to an insignificant level.

The report reveals that 12 of 21 manufacturers have more than half the discount on targeted drugs associated with drugs for which the inflationary penalties have raised the 340B discount well beyond the statutory requirement of 23.1 percent to 85 percent or higher. Essentially, these penalties are applied to drugmakers who repeatedly increase prices by more than the rate of inflation.

Further, for 13 manufacturers, discounts on high-priced specialty drugs account for more than half the discount on restricted drugs. This situation poses a challenge for the majority of 340B hospitals, as they lack specialty pharmacies and depend on contract pharmacies to access these drugs. All manufacturers, except one, derive at least half the discount either from drugs with a discount of 85 percent or more or specialty drugs.

Again, we urge lawmakers to clarify existing policy in legislation to codify contract pharmacy arrangements in statute. The legislation should include provisions to limit the ability of manufacturers to impose conditions on obtaining the 340B discount, which would apply to all sales, including both contract pharmacy and non-contract pharmacy. Additionally, companies must be prohibited from extracting concessions or creating conditions that impede access to 340B but that do not directly result in an overcharge. This provision would address current conditions, such as requiring a provider to use a different wholesaler than its usual one just for drugs subject to 340B or requiring that providers sign contracts guaranteeing 340B compliance to receive the 340B price on the manufacturer’s drugs.

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?**

340B benefits are intended for providers serving a safety net role to improve health care access and quality for the communities and patients they serve. Lawmakers must protect the upfront discount that goes directly to these providers and ensure third-party entities are not encroaching. Over time, payers and pharmacy benefit managers (PBMs) have sought to keep a portion of the benefit from the 340B program for themselves, for example, by reimbursing 340B providers less than non-340B providers for drugs or dispensing fees and keeping that

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difference for their own profits. Certainly, the 340B program was not designed to benefit such entities, including for-profit insurers and PBMs.

Important legislation pending in the U.S. House of Representatives, the PROTECT 340B Act (H.R. 2534), sponsored by Reps. Dusty Johnson (R-S.D.) and Abigail Spanberger (D-Va.), would prevent group health plans, health insurers, and PBMs from imposing requirements, exclusions, reimbursement terms, or other conditions on covered entities and pharmacies participating in the 340B program that differ from those applied to non-covered entities or pharmacies. It also would extend the requirements related to the 340B program to Medicare Part D prescription drug plans and Medicare Advantage plans. We urge lawmakers to take up and pass this important legislation, which seeks to protect covered entities and pharmacies participating in the 340B program from discriminatory actions, ensure fair treatment, and safeguard the program’s benefits for patients served by safety net providers.

Lawmakers also should consider these principles to ensure the benefits of the 340B program accrue to covered entities for the benefit of patients they serve:

- **Prohibit payers and insurers from undermining covered entities.** To safeguard the integrity of the 340B program and its benefits for covered entities and patients, specific policies should be implemented to prohibit PBMs and insurers from imposing restrictions or barriers that hinder covered entities’ participation or access to 340B savings. Attempts to undermine the program’s intended benefits must be curtailed to ensure cost savings are fully realized by the covered entities and ultimately benefit patients.

- **Prevent pharmacy chains from exploiting 340B savings.** To prevent pharmacy chains from taking advantage of the 340B program and profiting from the savings meant for covered entities, policies should be put in place to prohibit these chains from charging higher prices to fill 340B prescriptions. Also, covered entities should not be compelled to contract with a pharmacy-owned 340B claims administrator to engage with the pharmacy in serving patients. The savings from the program should directly benefit the covered entity, ensuring that large pharmacy chains do not leverage their market power to force covered entities to share their savings.

- **Ensure appropriate Medicare and Medicaid payments to 340B providers.** The 340B program is intended to enable covered entities to “stretch scarce federal resources.” Many essential hospitals have significant uninsured and underinsured patients, and their primary payers are Medicaid and Medicare. The ability to purchase 340B discounted drugs for Medicaid patients is crucial to many essential hospitals. Congress should take the steps discussed below to prevent states from usurping providers’ choice to use discounted drugs for Medicaid patients and should support efforts to improve duplicate discount compliance that preserve the ability of providers to access 340B discounted drugs. Congress also should preserve the ability of Medicaid managed care plans to reimburse providers for drugs and dispensing fees without regard to 340B status. Likewise, on the Medicare front, CMS should continue the lawfully restored policy of paying the statutorily defined rate for separately payable outpatient drugs under the Outpatient Prospective Payment System regardless of whether the drug was subject to a 340B discount. Congress also should urge CMS to adopt the policies in its proposed remedy for past illegal payments and repay hospitals as quickly as possible.

- **Ensure provider flexibility to address unique community needs.** Protecting the benefit for covered entities and their patients also means Congress and HHS should avoid policies that would unnecessarily, and contrary to program intent, restrict the
concept of permissible use of program savings to the benefit of patient access and care. Policies should be designed to give covered entities flexibility to tailor their services and resources to meet the unique health care needs of their communities. It is important that there are no restrictions placed on how covered entities, such as essential hospitals, use their 340B savings; every community is different. By allowing covered entities to adapt their strategies to changing patient population needs, the program's benefits can be maximized for the patients they serve.

By adopting these policies and principles, the 340B program can be optimized to ensure the intended benefits accrue primarily to covered entities and the patients they serve.

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

Essential hospitals are committed to compliance with the prohibition on duplicate discounts under the 340B statute, which provides that there cannot be both an upfront 340B discount on a drug provided to a Medicaid beneficiary and a back-end rebate on that drug paid to the state Medicaid agency. Essential hospitals treat a disproportionate share of Medicaid patients, and the ability to access 340B discounts for drugs provided to those patients is crucial. Concerns about duplicate discounts can lead states to prevent 340B providers from using discounted drugs for Medicaid patients, depriving the providers of the benefit of the discount. Thus, essential hospitals and similar providers have a significant interest in avoiding duplicate discounts, even beyond the statutory requirements.

Covered entities have long complied with HRSA’s requirement to prevent duplicate discounts in Medicaid fee-for-service programs by use of the Medicaid Exclusion File (MEF). Covered entities that chose to use 340B drugs for their Medicaid patients must provide HRSA with their Medicaid provider number for billing, so that states can avoid requesting rebates on drugs billed under those provider numbers.

As state Medicaid programs increasingly have moved to managed care, the flow of information between the provider and the Medicaid agency now is interrupted by the managed care plan. Thus, in Medicaid managed care, covered entities, such as essential hospitals, are just one link in a chain of participants that play a concerted role to ensure duplicate discounts do not occur.

Federal lawmakers should work hand-in-hand with state Medicaid agencies to scale programs that are successful to the national level yet still give these state-based agencies flexibility and autonomy in administering their programs. Existing CMS regulations provide states flexibility to work with their plans to ensure 340B drugs are excluded from drug utilization data provided to the state for purposes of rebate collection. Similarly, HRSA encourages covered entities to work with states to develop strategies to prevent duplicate discounts for drugs reimbursed through managed care.

In considering options for avoiding duplicate 340B discounts and Medicaid rebates, these principles are important:

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7 42 CFR 438.6(s).
• The solution is not for states to force covered entities to “carve-out” Medicaid patients—that is, prohibit covered entities from using 340B discounted drugs for Medicaid patients. Indeed, Congress should prohibit states from dictating “carve-outs.”

• Any federal or state policy should include an option for covered entities to identify 340B drugs retrospectively and not just through claims identifiers or modifiers (see discussion of Oregon approach below).

• Policies should enable covered entities to use contract pharmacies to dispense drugs to Medicaid patients, whether covered under fee for service or managed care. Oregon, for example, has developed a process that avoids duplicate discounts on drugs dispensed through contract pharmacies, and CMS has highlighted Oregon’s approach as a best practice.

• Flexibility is a hallmark of the Medicaid program and should be part of any federal proposal. The relationship between states and their contracted Medicaid managed care entities, and between providers and managed care entities, vary greatly among and within states. Any federal model should provide sufficient flexibility to account for the differences.

• Congress, CMS, HRSA, and states must provide sufficient time for covered entities and other stakeholders to transition to any approach. For essential hospitals struggling with little to no margin, resources, as well as time, should be considered.

One approach that has received some attention is the clearing house model. Under such a model, a contractor collects rebate data from states and 340B claims data from Medicaid managed care plans and/or directly from covered entities and contract pharmacies. Then, the contractor excludes 340B claims from the rebate data to avoid duplicate discounts. Oregon Medicaid has implemented a clearinghouse approach that CMS identified as a best practice in avoiding duplicate discounts. In addition, the PROTECT 340B ACT would direct HHS to engage a contractor to serve this clearinghouse function.

These principles are important in any clearinghouse model:

• Operated by a neutral, government contractor, free of conflicts of interest.

• Option for covered entities to identify 340B drugs retrospectively through, for example, submission of a file directly to the clearinghouse. Oregon Medicaid currently uses such a process. It would be insufficient to permit only the use of identifiers on claims.

• Permit 340B drugs dispensed through contract pharmacies to be identified retrospectively through submission of a file to the clearinghouse. For example, Oregon requires covered entities to provide the state with a list of each 340B drug dispensed to a Medicaid managed care beneficiary at a contract pharmacy so the state could exclude those drugs from its rebate requests.

• Give covered entities the option to report to Medicaid managed care organizations (MCOs) or to report directly to the clearinghouse.

8 On the flip side, some states require 340B providers to use 340B for Medicaid patients and then reimburse at cost for the drugs, known as mandatory Medicaid “carve-in” policies. As with carve-outs, in both situations, the covered entity is deprived of the benefit of the 340B discount. Congress should ensure the choice is left to the covered entity.


• Preserve the structure of the 340B program as an upfront discount to providers in purchasing covered outpatient drugs—this is critical for cash flow in hospitals with thin margins.
• Ensure data security in accordance with HIPAA standards so that claims information or personal identifiable information are not compromised.
• Data collection should be limited to Medicaid claims, as Medicaid duplicate discounts are the only duplicate discount compliance issue identified in the 340B statute. (The third-party entities working with manufacturers to impose claims reporting requirements to use contract pharmacies sometimes claim the purpose of the data collection is program integrity to avoid duplicate discounts, yet their data requests include claims from all payers.)

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?

Essential hospitals take program integrity and accountability seriously. The 340B program is crucial to our members’ ability to keep their doors open and serve their missions; protecting the program’s integrity, in turn, protects its benefit to essential hospitals and their patients. Covered entities—particularly hospitals, as the largest and most complex of the covered entities—already spend significant time and resources on 340B compliance, and HRSA has expanded compliance efforts over time, fueled by increased appropriated funding. 340B covered entities must annually recertify their eligibility to remain in the 340B program. Beyond this annual recertification process, HRSA undertakes significant compliance efforts related to covered entities and their participation in 340B. These include audits and related corrective action plans upon any findings, a self-disclosure process to identify noncompliance, quarterly disproportionate share hospital (DSH) percentage integrity checks, nongovernmental hospital contract reviews, and contract pharmacy integrity checks.

Pharmaceutical Manufacturer Reporting
While covered entities have significant transparency and compliance requirements, drug companies have relatively few. Further, manufacturers sometimes refuse to change their behavior, even when HRSA alerts them to instances of noncompliance. We saw this in May 2021, when HRSA sent letters to six drug companies that restricted access to 340B pricing at contract pharmacies and demanded these manufacturers “immediately begin offering...covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements.” Expanding HRSA oversight of manufacturer actions, including overcharges and barriers to discounted drugs, and increasing the number and depth of manufacturer audits are crucial to a sense of accountability and parity across all program stakeholders. Congress also should consider these reporting requirements for drug manufacturers:

• Total value of 340B discounts provided in aggregate for the previous year (the difference between the price charged to non-340B hospitals and the price charged).
• Value of 340B discounts as a percentage of a drug manufacturer’s total U.S. revenue (for the same drugs or overall) for the previous year.
• Total value of aggregate 340B discounts during the previous year as a percentage of the manufacturer’s Medicaid sales/revenue for the same period. Notably, manufacturers commit to providing 340B discounts in their participating provider agreements, allowing their drugs to be covered by Medicaid. In exchange for providing 340B
discounts, manufacturers access federal reimbursement for their drugs—a tremendous value. Congress and HRSA should be able to compare that value to the discounts.

- Total drug manufacturer Medicaid sales/revenue for the previous year.
- Report each brand-name drug for which the price has increased more quickly than the rate of inflation and the percentage of the increase.
- A descriptive account of their participation in Patient Assistance Programs (PAPs) and the cost of these programs as a percentage of revenue. This will provide Congress with insights into how manufacturers would use the 340B discount amount if not provided to covered entities.
- Report on how manufacturers utilize net revenue from covered outpatient drugs, including spending on marketing, research, and PAPs, for both total, Medicaid, and Medicare sales/revenue.

**HRSA Audits**

HRSA’s audits are one of its main tools for enforcing compliance with program rules. These proposals would improve the audit process and meaningfulness of outcomes:

- All program stakeholders should be subject to audits to ensure proper compliance with the 340B program. This includes random audits of manufacturers, as well as covered entities. Congress should require HRSA to allocate no less than a third of its audit resources for manufacturer audits.
- HRSA should conduct both risk-based/random and targeted audits of manufacturers, similar to the covered entity structure. Clear methodologies should ensure all manufacturers are potentially subject to audits. Risk factors for targeted audits should be clarified, including higher-risk indicators, such as changes in distribution to specialty distributors, repeated use of limited distribution plans, drugs subject to inflationary penalties, or other practices that could indicate overcharging or restricting availability at 340B pricing.
- HRSA should make public the guidelines provided to auditors for both covered entities and manufacturers. In some cases, auditors impose standards not clearly apparent in published HRSA guidance.
- HRSA should distinguish between technical audit findings related to, for example, out-of-date information on the 340B Office of Pharmacy Affairs Information System and substantive findings that threaten program integrity or suggest a need for clarification of program rules. Otherwise, published information related to numbers of audit findings does not reflect the true state of program compliance.

Further, drug manufacturers are permitted to conduct audits of 340B hospitals in certain instances in coordination with HRSA, but covered entities are given no comparable opportunity to audit drug manufacturers. There are many instances when drug companies have violated program rules and requirements, such as overcharging, denying 340B pricing for certain drugs, and arbitrarily placing drugs in limited distribution. Congress should provide covered entities with the same ability to audit drug manufacturers, subject to parallel limitations on burden.

**GAO Report**

Congress could direct the Government Accountability Office (GAO) to issue a report addressing these aspects of the 340B program:
• Comparing 340B discounts to other costs borne by manufacturers, such as research and development, marketing, etc.
• Identifying the top 10 340B covered drugs with the largest price differentials between the average sales price in the United States and the sales price in international markets for the most recent fiscal year prior to passage.
• Identifying the top 10 drugs with the largest percentage increase in average sales price for the U.S. market compared with the prior 12 months, along with an explanation for the significant price rise.
• Comparing 340B discounts to Medicaid reimbursement to manufacturers for the previous 12 months, which manufacturers can access only if they agree to provide discounts to 340B covered entities.

The GAO should be directed to protect manufacturer confidentiality while preparing and presenting the report’s information.

Implementing ADR for the 340B Program
HRSA has issued a proposed rule to revise its administrative dispute resolution (ADR) process. The implementation of a functional ADR process could prove crucial to covered entities’ ability to challenge manufacturer noncompliance, as well as HRSA’s interpretation of program rules. Congress should urge HRSA to finalize the ADR rule, subject to concerns raised by the 340B Coalition of covered entities.

Expanding the Program to Inpatient Drugs
One of the complex compliance issues for hospitals is that 340B discounts are limited to outpatient covered drugs, so hospitals with mixed-use settings must implement systems to ensure discounted drugs are used only in outpatient settings (including the emergency department) and for discharge prescriptions. Congress could expand the program to inpatient drugs, removing a costly compliance issue and providing transparent and direct benefits to disadvantaged patients and populations. In addition to reducing compliance costs and complexities, such an approach will enhance the program’s positive impact on patient care, especially for those facing critical health care needs.

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?

Essential hospitals have a long and rich history of providing a plethora of information and data to HHS and its agencies. For example, hospitals were the first providers to report on quality measures and value-based arrangements. We value our partnership with lawmakers and the administration in ensuring access to care for all. Hospitals report uncompensated care, charity care, and other benefits to their patients and communities. Medicare-certified providers, such as essential hospitals, are required to submit an annual cost report to a Medicare Administrative Contractor. The cost report contains provider information, such as facility characteristics, utilization data, cost and charges by cost center (in total and for Medicare), Medicare settlement data, and financial statement data. Further, essential hospitals provide significant financial information through the annual Return of Organization Exempt from Income Tax (Form 990), which is a comprehensive overview of a nonprofit entity’s financial data, performance, activities, and governance. Both documents are publicly available and completely transparent.
Specific to the 340B program, HRSA requires annual recertification and audit compliance. Should Congress decide to direct HRSA to include additional measures to report savings, there must be an accurate, consistent definition of savings, and such measures must consider various factors to capture the larger and broader picture of the 340B program. Moreover, there must be similar transparency requirements for manufacturers. HRSA has asked essential hospitals to partner with drug companies in administering and implementing the 340B program; we also can and should be partners in transparency. We urge lawmakers to increase oversight of drug companies to ensure they do not continue to undermine the law and their obligations to provide 340B discounts.

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America’s Essential Hospitals appreciates the opportunity to provide these comments. If you have questions, contact Jason Pray, vice president of legislative affairs, at 202-412-2491 or jpray@essentialhospitals.org.

Sincerely,

Bruce Siegel, MD, MPH
President and CEO
America’s Essential Hospital