AMERICA'S ESSENTIAL HOSPITALS

April 1, 2024

The Honorable John Thune
United States Senate
511 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Tammy Baldwin
United States Senate
141 Hart Senate Office Building
Washington, DC 20510

The Honorable Debbie Stabenow
United States Senate
731 Hart Senate Office Building
Washington, DC 20510

The Honorable Jerry Moran
United States Senate
521 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Shelley Moore Capito
United States Senate
172 Russell Senate Office Building
Washington, DC 20510

The Honorable Ben Cardin
United States Senate
509 Hart Senate Office Building
Washington, DC 20510

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

Thank you for your continued leadership to protect and strengthen the 340B Drug Pricing Program and your release of the SUSTAIN 340B Act with an explanatory statement and supplemental request for information (RFI). America's Essential Hospitals is eager to continue collaborating with you to ensure the 340B program 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 good health and health care. Given their safety net mission and the challenges they face, essential hospitals rely heavily on federal support to fulfill their vital role. Due to the disproportionate amount of uncompensated care they provide, essential hospitals incur an average operating loss six times that of other U.S. hospitals: –8.6 percent versus –1.4 percent, respectively.[1] 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 fibers of the nation's health care safety net.[2]

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

1 Taylor J, Ramiah K, Greig M, et al. *Essential Data 2022: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2020 Annual Member Characteristics Survey*. America's Essential Hospitals. https://essentialdata.info. Accessed March 12, 2024.
2 Ibid.

AMERICA'S ESSENTIAL HOSPITALS
401 Ninth St NW Ste 900
Washington DC 20004
t: 202 585 0100
f: 202 585 0101
e: contact@essentialhospitals.org

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, nearly 45 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.[3]

Essential hospitals offer comprehensive, coordinated care across large ambulatory networks to bring vital services to where patients live and work. These ambulatory networks are a central part of essential hospitals' efforts to combat structural and systemic inequities ingrained in the health care system at large by bringing culturally competent care to patients who otherwise lack access to care. These networks allow essential hospitals to bring care closer to where their underserved patients live, which is an important step in ensuring continuity of care for patients whose health is shaped by lack of transportation, unstable housing, and other social risk factors. Our members' ambulatory networks of hospital-based clinics include onsite features—radiology, laboratory, and pharmacy services, for example—not typically offered by freestanding physician offices. Our members' ambulatory networks also offer behavioral health services, interpreters, and patient advocates who can access support programs for patients with complex medical and social needs.

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.

340B savings allow our hospitals to meet their mission of caring for all and addressing social and financial barriers to health, work that often goes 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. Here are examples of how essential hospitals use their 340B savings:

- A West Virginia essential hospital relies on 340B savings to support a mobile mammography unit. The 340B program makes this vital screening available to patients who might otherwise lack access to it.
- Hospitals in Kansas report using 340B discounts to expand services, such as adding urgent care and ultrasound; fund social workers to coordinate mental health services across facilities, clinics, and the main hospital campus; provide full-time medical clinics in four communities with populations less than 1,000; and provide prescription assistance to help patients pay for lifesaving medications, such as insulin and inhalers.
- Michigan hospitals report that 340B savings enable them to support service lines, such as obstetrics or inpatient psychiatric care, which meet high community needs but require large financial commitments; create financial assistance programs for low-income patients; fund mobile health clinics; and provide low-cost access to prescription drugs.

The SUSTAIN 340B Act would take vital steps to protect the 340B program against current threats to the fundamental purpose and benefits of the program. It is appropriate that the first section of the SUSTAIN 340B Act would capture in statute Congress' intent when creating the 340B program: "…to help safety net providers maintain, improve, and expand patient access to

3 Ibid.

health care services by requiring drug manufacturers, as a condition of participation in Medicaid and Medicare Part B, to provide discounts and rebates to covered entities that serve a disproportionate share of low-income and underserved patients." It is clear lawmakers intended 340B to directly support providers serving a safety net role, such as essential hospitals.

We strongly support your inclusion of unambiguous language to prohibit manufacturers' unlawful restrictions on contract pharmacies and other actions that limit access to discounted drugs and to impose meaningful penalties for noncompliance. We also support SUSTAIN Act provisions that acknowledge the need to address discriminatory policies of other actors, such as insurers and pharmacy benefit managers, that siphon off the 340B program's intended benefit. While we identify considerations related to the specifics of the proposals in our detailed feedback below, we strongly support your efforts to identify solutions to these issues. Identifying and implementing solutions to these ongoing issues are critical to the 340B program's future.

Acknowledging your desire to respond to concerns related to covered entity oversight and transparency, we urge you to avoid proposals that purport to address these concerns but would simply serve to restrict the size of 340B discounts by narrowing the program's scope. The 340B program is a proven and effective means to enable providers to serve patients and communities in need *at nearly no cost to taxpayers*. We urge you to continue your thoughtful work to understand the impact of proposals on covered entities' varied and complex systems of care and not unduly or unintentionally restrict the program to a point that undermines its purpose. Congress should avoid prescriptive rules and limitations related to the definition of a patient to whom covered entities can provide discounted drugs and additional eligibility requirements for child sites. Given the diversity and complexity of safety net health systems around the country, it is critical that program rules are sufficiently flexible to avoid excluding the very providers Congress intended to benefit through 340B savings. Ultimately, proposals to restrict the program's scope will come at a cost to patients and taxpayers.

Below, we provide additional feedback on the proposed provisions in the SUSTAIN 340B Act and the supplemental RFI. We appreciate this opportunity and invite continued dialogue between you and our members as this important work continues.

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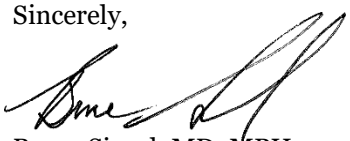
America's Essential Hospitals appreciates the opportunity to provide these comments. If you have questions, please contact Jason Pray, vice president of legislative affairs, at 202.412.2491 or jpray@essentialhospitals.org.

Sincerely,



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

America's Essential Hospitals–Additional Feedback on SUSTAIN 340B Act

America's Essential Hospitals presents the following considerations as Sens. Thune, Stabenow, Capito, Baldwin, Moran, and Cardin ("the senators") continue their efforts to support the future of the 340B program. We will continue to explore the policy considerations with our member hospitals and health systems and look forward to an ongoing dialogue.

A. Contract Pharmacies

BACKGROUND

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 at all. Especially for patients who receive specialty care at a trauma level I or academic medical center, a return trip could be lengthy 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 who have limited means or 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. 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 manufacturers' decades-long compliance with the requirement to provide 340B discounts for drugs dispensed by contract pharmacies, more than 20 drug manufacturers now are illegally withholding or restricting access to 340B pricing at contract pharmacies. These unlawful actions undermine the 340B benefit for patients and financially strained essential hospitals and violate the statutory obligation to provide these discounts to covered entities. By imposing restrictions on contract pharmacies, in blatant violation of current law, drug manufacturers are directly harming low-income and other disadvantaged patients who depend on the 340B program for affordable access to necessary medications. This also contributes to drug shortages and affects the supply chain for all providers. Contract pharmacy litigation and restrictions are needlessly draining the resources of the Health Resources and Services Administration (HRSA), the Department of Justice (DOJ), and providers serving a safety net role—nonprofit entities that face significant financial challenges.

Rep. Doris Matsui (D-Calif.) recently introduced legislation, the 340B PATIENTS Act of 2024, that would provide crucial contract pharmacy protections.[4]

4 340B PATIENTS Act of 2024, 118th Congress (2024).

FEEDBACK

While we do not believe there is a lack of legal clarity regarding manufacturers' obligations to provide 340B pricing at contract pharmacies, we were grateful to see that the SUSTAIN 340B discussion draft included provisions that would specifically prohibit certain manufacturer restrictions on 340B pricing, whether through contract pharmacies or more broadly. We support the breadth of the proposed measures to prohibit restrictions on contract pharmacy arrangements, including prohibitions on:

- Refusing to offer or deliver 340B drugs to covered entities (CEs) or their contract pharmacies.
- Restrictive distribution policies targeting covered entities, covered outpatient drugs, or contract pharmacies.
- Requiring submission of claims data directly to manufacturers.

Because the nature of manufacturer restrictions might evolve, providing targeted authority to HRSA to identify other prohibited restrictions would address unforeseen barriers.

We strongly urge the Working Group to avoid limitations on the use of contract pharmacies that do not ensure accountability and integrity but rather are intended to limit the scope of the program. This includes, for example, limiting discounts at contract pharmacies based on geographic location or limiting the number of contract pharmacies. We appreciate that the explanatory statement identifies some of the access challenges these types of limits would create. For example, the Working Group identifies transportation challenges associated with returning to hospital's in-house pharmacy. Such challenges can be particularly acute for a low-income patient in an urban setting, where public transportation is limited or prohibitive, or a patient of a state academic medical center who travels several hours for specialty care. The ability to receive medications through a nearby pharmacy makes care accessible for both.

Limiting contract pharmacies at hospitals that have in-house and hospital-owned pharmacies would also arbitrarily restrict access. Out of necessity, most hospitals have in-house pharmacies and often might have a retail pharmacy at the main campus and, potentially, at other hospital locations. But if the hospital does not have pharmacies throughout its service area, restricting the use of contract pharmacies will restrict access, just as it would for a community health center without an onsite pharmacy. It also does not make policy sense to force covered entities into the pharmacy business simply to enable access to 340B benefits when there are existing contract pharmacies that service the hospital's patients.

Similarly, limiting the number of contract pharmacies does not account for the significant variation in covered entities and their communities. Some areas would be pharmacy deserts if not for the willingness of covered entities and contract pharmacies to collaboratively provide access points for low-income patients who other entities are unable or unwilling to serve. Some covered entities have service areas covering several states, for example, because the entity is a regional academic medical center with expertise not otherwise available or because of a lack of providers in a neighboring rural area.

We appreciate the senators' acknowledgment that specialty pharmacies deserve specific and careful consideration. The number of specialty pharmacy contracts is not driven by covered entities. It is driven by manufacturers and/or insurers and their pharmacy benefit managers (PBMs) identifying where particular drugs must be accessed. Arbitrarily limiting the number of

specialty pharmacy relationships will directly impact patient access to drugs offered only by the specialty pharmacies with which covered entities cannot contract. The 340B program should not penalize entities making prescribing choices based on what is best for the patient.

Use of contract pharmacies should be driven by patient access, not by arbitrary limitations or by large chain pharmacies leveraging market power. We appreciate the senators considering whether there is federal authority to prevent chain pharmacies from requiring that a covered entity contract with all locations in a chain just to use a subset of preferred locations.

As the senators consider 340B contract and audit requirements, we encourage the Working Group to consider existing requirements related to contract pharmacy use. Covered entities and their contract pharmacies are already subject to requirements applicable to contracts, registration, and independent audits, and HRSA audits contract pharmacy use as part of covered entity audits. Many of the proposed requirements in the discussion draft applicable to contract pharmacy agreements would appear to codify existing rules. We think this is appropriate. However, we are concerned the draft bill's proposals that go beyond existing guidance, such as requiring HRSA to review contracts—especially before they take effect, would be cumbersome for HRSA to implement and could delay registration and access.

We urge the senators to look to the legislation introduced by Matsui, the 340B PATIENTS Act of 2024, as a model for providing crucial contract pharmacy protections without the limitations being considered.

B. Ensuring Equitable Treatment of Covered Entities and Participating Pharmacies

340B benefits are intended for safety net providers working 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 do not encroach on it. Over time, payers and 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 difference for their own profits. Certainly, the 340B program was not designed to benefit such entities, including for-profit insurers and PBMs.

The draft's protections against such policies closely resemble the language of pending bipartisan legislation in the House of Representatives, the "Preserving Rules Ordered for The Entities Covered Through 340B Act of 2023," or PROTECT 340B Act (H.R. 2534), which America's Essential Hospitals strongly supports. However, unlike the PROTECT Act, this draft would not apply to Medicare Part D plans, and neither proposal would extend to Medicaid managed care organizations. We urge the senators to adopt this broader scope. For providers with a significant share of Medicare and Medicaid managed care patients, extension of antidiscrimination protections to these payers is crucial to ensure covered entities receive the intended benefit.

Lawmakers should consider these principles to ensure 340B program benefits accrue to CEs to support care for their patients and communities.

- **Prohibit payers and insurers from undermining CEs.** To safeguard the integrity of the 340B program and its benefits for CEs and patients, specific policies should be implemented to prohibit PBMs or insurers from imposing restrictions or barriers that hinder CEs' participation in 340B and access to its savings. Attempts to undermine the program's intended benefits must be curtailed to ensure cost savings are fully realized by the CE 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 savings meant for CEs, policies should be put in place to prohibit these chains from charging higher prices to fill 340B prescriptions. Further, CEs should not be compelled to contract with a pharmacy-owned 340B claims administrator to engage with the pharmacy in serving patients. Program savings should benefit CEs directly, ensuring that large pharmacy chains do not leverage their market power to force CEs to share savings.
- **Ensure appropriate Medicare and Medicaid payments to 340B providers.** The 340B program is intended to enable CEs "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[5] Essential hospitals care for a large volume of 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 patient care and the financial stability of essential hospitals. Congress should take steps to prevent states from usurping providers' choice to use discounted drugs for Medicaid patients. In addition, Congress should preserve the ability of Medicaid managed care plans to reimburse providers for drugs and dispensing fees without regard to 340B status. Similarly, 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. These policies and principles will help ensure the intended benefits accrue primarily to CEs and the patients they serve.

C. Patient Definition

BACKGROUND

The 340B program maintains eligibility requirements for CEs to receive discounted pricing on covered outpatient drugs. The term "patient" is referenced in a requirement that a CE "shall not resell or otherwise transfer the drug to a person who is not a patient of the entity."[6] This requirement was intended to ensure eligible providers are not mere distributors of discounted covered outpatient drugs to a third party. It was reasonable for Congress not to further define the term patient, given that essential hospitals and other providers must implement their understanding of a patient-provider relationship every day for a variety of purposes, including for a vast array of legal and regulatory requirements and simply to provide coordinated care in a complex health system.

When HRSA set forth its 1996 patient guidance,[7] the agency adopted a set of principles regarding covered entity responsibility for an individual's care and maintenance of the record of care. The agency made explicit its desire to maintain flexibility to capture the arrangements that might exist for the varied categories of covered entities and the structures that best serve their communities. The guidance then presented a discrete example of an activity that would not

5 H.R. REP. 102-384(II), p. 12.
6 42 U.S.C. § 256b (1952).
7 61 Fed. Reg. 55157 (Oct. 24, 1996).

meet the requirements of a provider-patient relationship: only dispensing a drug for self-administration or administration in the home setting. The approach of adopting straightforward and flexible principles to capture existing concepts of patient relationships has proved reasonable and implementable. But over time, HRSA has attempted to narrow the definition, whether through more formal proposals or through audits and informal guidance, and we fear that further efforts to define "patient" could result in inflexible rules that do not reflect the complexity and diversity of essential hospitals.

Experience with HRSA's proposed and withdrawn "mega-guidance" demonstrates the challenges that arise from attempts to create a 340B-specific concept of a patient relationship. Among other issues, the 2015 proposal would have delinked patient status from the actual patient, defining patient on a prescription-by-prescription/order-by-order basis, and narrowing the types of services and professional relationships with the covered entity sufficient to use discounted drugs. An individual could be a patient for one prescription but not another; a patient for an initial prescription but not a renewal; or a patient when prescribed an order but not when sitting in the hospital and receiving the drug from a licensed practitioner.

The resulting complex, multipart legal concept would have been utterly unrecognizable to any practicing health care professional, let alone patients themselves. Many of HRSA's proposals in the 2015 guidance would have prohibited the use of 340B drugs for individuals who would be considered patients of the hospital in any other context. Senseless distinctions between patients for whom hospitals can and cannot use 340B discounts also require associated administrative and compliance mechanisms to educate providers and track and audit patients, based on such distinctions. The definition would have complicated rather than improved program integrity, exponentially increasing complexity and the potential for confusion and creating extensive and complicated legal requirements that would have been exceedingly difficult for even the most well-intentioned providers to meet.

FEEDBACK

The draft bill proposes to include a section on patient definition but does not propose legislative language. The explanatory document, however, states that "in an effort to provide more clarity, accountability, and integrity to the program, we believe it is important for Congress to provide a clear definition of 'patient' in the 340B statute."

The rules defining the patients to whom a covered entity may provide 340B discounted drugs are at the very core of the program. Changes to the definition have the potential to significantly disrupt patient access to essential services and undermine efforts to coordinate care across providers, a goal of so many other federal health care programs. We urge the Working Group to resist proposals to define the term "patient" that simply seek to restrict the program's scope.

The explanatory document suggests Congress might seek to define whether the covered entity has a "meaningful relationship" with a patient. We caution that attempts to craft a 340B-specific concept of that relationship could lead to the same results as the 2015 mega-guidance, and we urge the senators to revisit the significant commentary that led to HRSA withdrawing that guidance. For example, the supplemental RFI asks, "should the type of patient encounter or specific level of services provided be considered in determining whether a relationship exists…?" Patients receiving care in a hospital location focused on one or a few specialties of greatest need in the community are not any less "patients" than individuals treated in another location providing a mix of primary and specialty care, again based on community need. Nor is Congress or HRSA in the best position to evaluate those needs.

Defining the length of a patient relationship is similarly complicated, though, perhaps, superficially appealing. How often a patient needs to be seen by a physician is disease- and patient-specific. For example, for some patients, initial diagnosis of a chronic disease and prescription of a medication at an academic medical center could result in long-term stability and management in less intensive or more convenient settings. But for others, frequent visits to manage uncontrolled illness could be required. Again, hospitals and their professionals are in the appropriate position to make such decisions.

We also urge the senators to avoid indirectly legislating patient definition as part of other substantive policy changes. Specifically, the proposed definition of child site eligibility would include provisions that go beyond demonstrating that a child site is part of the eligible hospital to address issues of responsibility for specific care—i.e., the contractual relationship between the covered entity and the professionals at the site and the relationship between the service provided and the 340B prescription.[8] First, any such proposals should be considered as part of the discussion of patient definition. Second, we would have significant concerns with patient definition proposals that turn on the elements identified in those draft provisions. The proposed requirement that "the covered entity have clinical responsibility for health care services that are directly related to the use of the covered outpatient drug purchased under this section that is dispensed" suggests a return to a prescription-by-prescription definition of a patient that, as in the 2015 mega-guidance, would have conflicted with customary understandings of a patient relationship. (Also, neither Congress nor HRSA should evaluate whether a particular professional has clinical responsibility for health care services directly related to the use of a particular drug.)

In addition, the proposed requirement "that the provider who prescribes a covered outpatient drug purchased under this section is an employee or bona fide contractor of the covered entity and a member of the entity's medical staff" was similarly part of the 2015 mega-guidance definition, prompting concerns about potentially excluding common relationships between hospitals and professionals (e.g., it is common to have a separate medical group that staffs the hospital with no direct contractual relationship between any individual professional and the covered entity). Such a requirement could also result in excluding the use of 340B discounted drugs for prescriptions written by referring practitioners or, even, by a practitioner who sees a patient both in the hospital and in their private office.

The definition of patient must align with the way the covered entity provides care or it will penalize entities that make decisions based on appropriate patient care and community need rather than on maximizing benefit under the 340B program. The supplemental RFI asks, "Since the program has evolved since the original statute was written, how should these changes be reflected in how a patient is defined?" That evolution was driven in significant part by underlying changes in health care and care delivery that are only likely to continue. A flexible definition of patient that can align with such changes will continue to be crucial.

Finally, the supplemental RFI asks "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?" Based on the recent federal court decision in *Genesis Health Care Inc. v. Becerra,* HRSA has authority to implement its interpretations of the term "patient" to administer the dispute resolution process that addresses

8 42 U.S.C. § 256b (1952).

issues of diversion, as long as the interpretation is consistent with the plain language of the 340B statute and congressional intent.[9]

D. Child Sites

BACKGROUND

In the 340B context, child sites are offsite departments or services that are part of the eligible hospital. Large hospital systems provide integrated care through different care settings, including multiple ambulatory locations providing diverse types of services. At any ambulatory location, a hospital might have various service lines, such as primary care, specialty care, and pediatric care. Or, it might focus on specific specialties of greatest need. Even though these locations are geographically distinct from the main hospital, they maintain integrated financial, clinical, and electronic health records, because these ambulatory locations are considered part of the main provider. In fact, to qualify for 340B discounts, these locations must be part of the main provider, such that they operate under the same license, and are clinically and financially integrated with the main provider.

The ability to expand access to otherwise underserved patients through networks of community clinics enables essential hospitals to advance their mission of providing high-quality, equitable care for all, including those who face social and financial barriers to care. These patients' ability to access health care is shaped by social determinants of health, including transportation barriers, homelessness, and other factors that hinder their ability to travel to distant hospitals or physician offices. Off-campus community clinics of essential hospitals thus provide convenient access to high-quality, culturally and linguistically competent care. They are often the only source of primary and specialty care in their communities for medically and socially complex patients.

FEEDBACK

The discussion draft proposes to define "child site" as "a site that is wholly-owned and operated by a covered entity."[10] We appreciate that the discussion draft appears to move away from HRSA's current, hyper-technical concept of child site being every service or department located off-campus, even if in the same building, to a more straightforward understanding of a "site." In the spirit of further limiting unnecessary administrative burden, particularly burden that could impact care, we encourage the Working Group to address the issue of delayed eligibility of child sites. Under current HRSA implementation, child sites must appear on a filed Medicare cost report before they can be registered as part of the covered entity. Given the time gap between starting to provide services and filing a cost report, combined with quarterly eligibility determinations, the result can be more than a year of delay in accessing discounted drugs for patients being seen at the hospital site. With regard to the "wholly-owned" requirement, while we do not believe joint ventures in provider-based settings are common, these structures are possible under Medicare provider-based rules and we would not want useful clinical investments for a community to be arbitrarily excluded from access to 340B discounts. We urge the Working Group to share and consider feedback on this issue.

Several of the SUSTAIN 340B Act eligibility requirements for child sites appear to mirror the Medicare provider-based framework. Medicare requirements are, at this point, a well-understood way to define the scope of a hospital and have the benefit of significant implementation guidance from the Centers for Medicare & Medicaid Services (CMS). That said,

9 Genesis Health Care Inc v. Secretary Xavier Becerra, 143 (Nov. 3, 2023).
10 SUSTAIN 340B Act, 118th Congress, (2024).

there are examples of facilities the senators might want to support through the 340B program that do not meet the current requirements, and we would be interested in understanding the group's potential direction. For example, some essential hospitals operate clinics in homeless shelters. These hospitals do not own the shelter facility, and the site would not meet provider-based requirements. Nonetheless, use of discounted drugs for these patients receiving care from 340B hospital providers would serve the purposes of the program.

However, the Working Group should avoid child site eligibility requirements that go beyond identifying integrated parts of the hospital and exclude certain sites treated as part of a hospital for any other purpose. Specifically, the discussion draft adds a requirement that "the child site provides a clinically meaningful range of services, as determined by the services that providers employed or contracted by the child site are qualified to deliver." It is arbitrary to eliminate access to discounts in parts of a hospital that—for reasons having to do with patient care, community need, and access—are focused on particular specialties. Often, 340B discounts make it financially possible for essential hospitals to open or maintain those very facilities in specialty areas of shortage and for populations not served by other providers. It might be tempting to identify certain specialty facilities for exclusion, such as infusion centers, but those services are lifesaving, and we have found that patients seeking oncology care from our member hospitals tend to be both poorer and sicker and do not otherwise have access to the care they need. Limiting the scope of eligibility will only serve to limit access.

Similarly, as discussed in the patient definition section, we urge the Working Group to eliminate requirements that relate to responsibility for the care being provided at child sites rather than whether the scope of the hospital rightly includes such sites.

Congress should not limit eligibility based on a child site's location or an arbitrary number of sites. Essential hospitals should determine the location and mix of services, based on clinical and access considerations and not on fear of being penalized by losing 340B discounts. The explanatory document asks, "What exemptions or special considerations should be provided to child sites located in rural, frontier, or areas of high medical need?" While we do not believe the statute should incorporate child site limitations in the first place, we urge the Working Group to examine the impact of policies not just for rural providers or identifiers, such as Medically Underserved Area (MUA) or Health Professional Shortage Area (HPSA), but based on the patients served.

The discussion draft would require a child site to participate in Medicaid and Medicare. The child site is part of the hospital, and generally, hospitals do participate in Medicaid and Medicare. But any requirements should consider facilities (such as children's hospitals) and locations (such as maternal health clinics or uninsured clinics) that might not serve Medicare or, even, Medicaid populations but should certainly have access to 340B discounts and are important points of care for patients.

Finally, in the explanatory statement, you share concerns about certain child sites benefiting from the 340B program but not investing the benefits in their communities. We urge the Working Group not to deny discounts to critical access points at covered entities serving the purposes of the program to address certain alleged bad actors. The issue of use of savings is addressed in response to the transparency section below.

E. Transparency

BACKGROUND

As described in our response to the 2023 RFI, essential hospitals have a long and rich history of providing a plethora of information and data to the Department of Health and Human Services (HHS) and its agencies—from detailed Medicaid cost reports to the annual Return of Organization Exempt from Income Tax (Form 990) and comparable public reporting for governmental providers, as well as the many quality and value-based reporting programs across payers. We value our partnership with lawmakers and the administration in ensuring access to care for all. Specific to the 340B program, hospitals must invest significant resources for compliance and oversight, including inventory management; 340B-specific policies and procedures; independent, HRSA, and manufacturer audit compliance; and annual recertification.

Essential Hospitals consider the following principles in evaluating any proposed reporting requirements:

- Data reported by hospitals should be limited to content relevant to HRSA's ability to provide proper oversight and ensure program integrity.
- If covered entities are required to report specific data, this reporting should not lead to additional administrative burden and costs and should come from data sources already being reported by covered entities.
- To provide sufficient context and ensure accountability and parity across all program stakeholders, drug manufacturers should report data comparable to covered entities.

FEEDBACK

The discussion draft includes a requirement for an annual report of a significant range of information, including estimated 340B discounts and a description of the use of savings; operational costs to the entity of operating the 340B program; charity care costs as a share of total costs by site data related to patients and discounted drugs provided; contract pharmacy locations; entity policies to promote access and adherence to prescribed medication; third party administrators; and nongovernmental hospital contracts with governmental entities. If the Working Group continues its work on new reporting, we urge the following considerations.

Should Congress decide to require an annual report of estimated discounts as a measure of program benefit, the calculation for hospitals subject to the group purchasing organization (GPO) provision should be the difference between the 340B acquisition cost and the GPO price, not the wholesale acquisition cost (WAC). Non-340B hospitals can secure discounts through GPOs, so a measure of 340B savings should be the incremental difference. In addition, we appreciate that the discussion draft would include reporting of the costs to the covered entity of operating the program (these costs can be significant in the hospital context, including for inventory management, internal and independent audits, legal services, and other compliance costs) and suggest this amount be deducted from the measure of program benefit, as it directly offsets new resources to participating entities.

Essential hospitals have long advocated that Congress should not restrict the concept of permissible use of program savings to the benefit of patient access and care, whether directly or by proposing rigid reporting requirements that effectively dictate such uses. Policies should be designed to provide CEs with the flexibility to tailor their services and resources to meet the unique health care needs of their communities. It is important that there not be restrictions on how CEs, such as essential hospitals, use their 340B savings; every community is different. By allowing CEs to adapt their strategies to changing patient population needs, they can maximize the program's benefits for the patients they serve. The approach in the discussion draft appears to align with this principle, allowing for qualitative description of the use of savings for a broad

range of "health care services or health-related benefits" and acknowledging that entities might invest both in benefits for specific patients, as well as for their broader "communities served." For example, essential hospitals have used 340B savings to:

- 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 locations, hours of operation, transportation availability, interpretation services, and patient education that is 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.

The discussion draft would require reporting of charity care as a share of total costs. We appreciate the acknowledgment that charity care alone does not capture the roles that our members play in their community. For example, the discussion draft would capture patient mix, a critical indicator of the role of the entity for the underserved. At the same time, we urge the Working Group not to request charity care by child site; charity care is not reported by child site on the cost report, and hospitals do not necessarily track charity care this way, given that child sites must be financially integrated with the rest of the hospital.

In general, we encourage the Working Group to consider specific feedback from hospitals on the alignment of requested measures with existing clinical and financial reporting systems to avoid additional administrative burden. In addition to the charity care by child site example, while information on patient coverage and eligibility for sliding scale fee programs might provide relevant context, the Working Group should work with hospitals to use existing data sources to report this data.

Finally, hospitals should not be asked to report data for this purpose that has already been reported to the federal government for other reasons. For example, information otherwise available from the cost report or other 340B-specific data is collected by HRSA and available in the Office of Pharmacy Affairs Information System and need not be duplicated.

Parity in Manufacturer Transparency

Moreover, there must be similar transparency requirements for manufacturers. HRSA has asked essential hospitals to partner with pharmaceutical manufacturers in administering and implementing the 340B program; we can and should also 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. Requiring drug companies 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. HRSA should be given the authority, resources, and direction by Congress to enforce transparency and reporting requirements on drug manufacturers.

While CEs have significant transparency and compliance requirements, pharmaceutical manufacturers have few. Further, HRSA alerts to manufacturers about noncompliance can have little or no effect. This was the case in May 2021, when HRSA sent letters to six drug companies that had restricted 340B access at contract pharmacies, demanding that the manufacturers reverse course; they did not. Expanding HRSA oversight of manufacturers, such as increasing the number and depth of manufacturer audits, is crucial to a sense of accountability and parity across all stakeholders in the program. In addition, Congress should consider implementing 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 to CEs).
- 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.
- Descriptive account of manufacturer's participation in Patient Assistance Programs (PAP) 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 CE.
- Report on how manufacturers use net revenue from covered outpatient drugs, including spending on marketing, research, and PAP, for both total, Medicaid, and Medicare sales/revenue.

F. Duplicate Discounts

BACKGROUND

Essential Hospitals are committed to complying with the prohibition on duplicate discounts under the 340B statute, which dictates 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.

CEs 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). CEs that choose 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 have increasingly moved to managed care, the flow of information between the provider and the Medicaid agency is now interrupted by the managed care plan. Thus, in Medicaid managed care, CEs, such as essential hospitals, are just one link in a chain of participants who all play a concerted role in ensuring duplicate discounts do not occur.

FEEDBACK

Federal lawmakers should work hand-in-hand with state Medicaid agencies to scale successful programs to the national level while giving these state-based agencies flexibility and autonomy to administer 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.[11] Similarly, HRSA encourages CEs to work with states to develop strategies to prevent duplicate discounts for drugs reimbursed through managed care.

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

- The solution is not for states to force CEs to "carve out" Medicaid patients, meaning prohibit CEs from using 340B discounted drugs for Medicaid patients. Indeed, Congress should prohibit states from imposing "carve-outs."
- Any federal or state policy should include an option for CEs to identify 340B drugs retrospectively and not just through claims identifiers or modifiers. (See discussion of Oregon approach below.)
- Policies should enable CEs to use contract pharmacies to dispense drugs to Medicaid patients, whether covered under fee-for-service or managed care.
- Flexibility is a hallmark of the Medicaid program and should be a part of any federal proposal. The relationships 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 CEs and other stakeholders to transition to any approach. For essential hospitals struggling with little to no margin, not only time but resources 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, on the one hand, and 340B claims data from Medicaid managed care plans and/or directly from CEs and contract pharmacies, on the other, and then excludes 340B claims from the rebate data to avoid duplicate discounts. The PROTECT 340B ACT of 2023 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 CEs to identify 340B drugs retrospectively—for example, through submission of a file directly to the clearinghouse. Oregon Medicaid currently uses this process. It would not be sufficient to permit only the use of identifiers on claims.
- Permit 340B drugs dispensed through contract pharmacies to be identified retrospectively through submission of the file to the clearinghouse. For example,

11 42 CFR 438.6(s) (1952).

Oregon requires CEs to provide the state with a list of each 340B drug dispensed to a Medicaid managed care beneficiary at a contract pharmacy so that the state could exclude those drugs from its rebate requests.

- Give CEs the option to report to Medicaid managed care organizations or to report directly to the clearinghouse.
- 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 personally 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 that the purpose of the data collection is program integrity to avoid duplicate discounts, yet their data requests include claims from all payers.)

The discussion draft includes a clearinghouse model that deviates from the examples and principles above in several ways. First, the clearinghouse should not extend beyond Medicaid. It would be overly burdensome and unnecessary, for compliance purposes, to collect additional claims information. To the extent that the Working Group anticipates broader claims collection is needed to determine the proposed user fee, there would be other ways to apply a user fee (e.g., the proposed reporting of total discounts); and in any event, we believe Congress should appropriate adequate support to HRSA rather than rely on such a fee.

The draft also includes a provision that excludes hospitals from the "option of submitting claims level data on an aggregated retrospective basis that does not require the application of modifiers on individual claims or point-of-sale identification." We are not certain of the exact intent of this provision, but it is crucial that any clearinghouse permit hospitals to identify drugs retrospectively, as well.

We urge the senators to look to the PROTECT 340B Act for structuring a clearinghouse that could work as intended to support compliance.

Patient Assistance Programs

The discussion draft incorporates into the end of the duplicate discount section a new provision governing covered entity patient financial assistance policies. We urge the Senate to avoid using the 340B program to create new requirements outside of and beyond current IRS requirements. The current IRS requirements do not set a threshold federal poverty level for financial assistance.

We also raise concerns about the complexity of requiring the extension of such policies to separate entities, such as contract pharmacies. Even with the proposed waiver of federal fraud and abuse laws, entities would be left to contend with state fraud and abuse laws, operational challenges, and the resulting significant new administrative burden. Provision of discounted drugs is one, but not the only, way covered entities use their savings to benefit patients—including the patients receiving prescriptions from contract pharmacies.

G. Enhancing Program Integrity

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 thus protects its benefit to essential hospitals and their patients.

Much of the discussion draft would duplicate existing audit authority. For example, HRSA already may audit covered entities, including their child sites and contract pharmacies. We would request additional information on what examples the senators had in mind when adding certain language, such as "claiming a discount…on a drug that is not a covered outpatient drug" or "statutory violations related to improperly claiming eligibility for the program."

Other proposals, such as requiring the Health and Human Services Secretary to make protocols for audits publicly available, would assist in hospitals' proactive compliance.

We have concerns about delegating authority to HRSA to issue auditor guidance on an eligibility provision—i.e., the contracts between nonprofit hospitals and governmental entities. Eligibility requirements need to be clear in statute.

Hospital eligibility is also more complex in the context of the GPO prohibition. Congress could consider moving the requirement out of the eligibility section and into a separate prohibition; either way, what amount to software glitches or technical issues related to the GPO prohibition should not result in hospitals being fully excluded from the program.

Absent from the draft are proposals related to audits of manufacturers. We propose these steps to 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 CEs. Congress should require HRSA to allocate no less than one-third of its audit resources for manufacturer audits.
- HRSA should conduct both risk-based random and targeted audits of manufacturers, like the covered entity structure. Clear methodologies should ensure that 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 discounts.
- HRSA should make public the guidelines provided to auditors for both CEs and manufacturers. In some cases, auditors impose standards that are not clear, based on published HRSA guidance.

Further, drug manufacturers are permitted to conduct audits of 340B hospitals in certain instances in coordination with HRSA, but CEs 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 CEs with the same ability to audit drug manufacturers, subject to parallel limitations on burden.