MHA Michigan Health & Hospital Association | Leading Healthcare

April 1, 2024

RE: SUSTAIN 340B Act Discussion Draft and Supplemental RFI

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

On behalf of Michigan's more than 80 hospital covered entities, the Michigan Health & Hospital Association (MHA) appreciates the opportunity to respond to the Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future of (SUSTAIN) 340B Act. Fully effectuating the intent of the 340B Drug Discount Program (340B program) is important to its long-term success, but even more so to the patients who benefit from a robust and clarified program.

As noted in your 2023 request and in the SUSTAIN discussion draft, the 340B program is designed to stretch scarce federal resources; help safety net providers maintain, improve, and expand patient access; and ultimately support vulnerable communities and populations. Michigan 340B hospital covered entities take these responsibilities seriously, supporting clarification of certain elements of the program and codifying intent. However, we caution against alterations to the program that would impede a covered entity's ability to support their communities and flexibly apply program savings to needed community health needs, affordable prescription drug access and overall access to important healthcare services within geographic reach of patients who otherwise may lack the ability to maintain a relationship with a healthcare provider.

As noted in our 2023 RFI response (included as appendix document), Michigan hospital covered entities value the goals of the program and work tirelessly to ensure program dollars support multiple opportunities to increase access to healthcare, ultimately improving Michigan's overall health. The savings from the program are a lifeline for many Michiganders, allowing their community hospital to provide an array of services that they may not be able to offer without 340B program participation. Savings derived from hospital program participation assist an incredible range of services, including (but not limited to):

- Supporting important service lines like inpatient psychiatric services and obstetrics and gynecology.
- Allowing hospitals to design and implement robust financial assistance programs, which provide individuals in the community with extremely low- or no-cost care.
- Creating solutions to public health concerns like utilization of mobile health units.
- Funding comprehensive cancer care, specialized neonatal intensive care and comprehensive hemophilia treatment.
- Improving prescription drug affordability.

One of the most important aspects of the program, beyond the savings opportunities it presents to hospitals, is its flexibility. Hospitals reinvest their savings to address community-specific needs—embodying Congress's intent with the program— thereby allowing each participating hospital to reflect the health needs of their patients and communities. Without the program, and without opportunity to bolster the program's success, many Michiganders would see reduced access to low-cost, high-quality healthcare in their communities.

In response to the specific elements outlined in the discussion draft and accompanying explanatory statement and supplemental RFI, please find our recommendations below:

Section 3: Contract Pharmacy

The MHA supports contract pharmacy arrangement clarity, particularly regarding authority to enact limitations on valid contractual relationships. We support our members' ability to contract with pharmacies that meet their needs, meet their patients' needs and allow the 340B program to perform at its highest and best capacity. Arbitrary limits implemented by manufacturers result in a patchwork of restrictions; many manufacturers have their own individual restrictions on contract pharmacy arrangements making administration of the program difficult and unwieldy. The varied contract pharmacy restrictions result in increases in administrative costs, reducing savings that could be invested in communities and patients. Further, manufacturer-created restrictions threaten to alienate patients who may have transportation barriers or may travel for care but access prescriptions in their local community.

Michigan covered entity hospital members use contract pharmacy arrangements to meet patients where they are from a physical location standpoint, to augment their pharmacy capacity and to ensure access to medications is not compromised or smothered by arbitrary restrictions on beneficial contractual relationships. We do not support limiting contract pharmacy relationships or capping the number of contract pharmacy arrangements an individual covered entity may have. For many hospital-covered entities (urban, suburban and rural), contract pharmacy arrangements are a lifeline to properly ensuring patients can affordably access prescriptions. Limitations on how a covered entity contracts to deliver services to patients the program is designed to serve undermine the ability of the program to meet its intended purpose. **The MHA does not support restrictions on contract pharmacy arrangements. We do support reiteration that manufacturers do not have the authority to impose restrictions not contemplated by the federal law and support the role individual state's play in protecting against erosion of the program through filling in gaps not supplied by the current federal law.**

Section 4: Patient Definition

The MHA supports a broad definition of "patient," as is currently afforded in the plain language of the statute and reinforced recently in *Genesis Healthcare Inc. v. Xavier Becerra*. We support the opportunity to protect programs that positively impact affordability for all types of purchasers, as drug costs continue to be one of the largest contributors to hospital and health system financial expenses, as well as a top concern for individual patients who rely on life saving medications to manage any number of acute or chronic healthcare conditions.

Hospital drug costs per patient increased 19.7% between 2019 and 2022[1], with the median cost of a new drug exceeding $300,000 in 2023[2]. Drug affordability is not a new issue, but rarely are we presented with occasions to meaningfully impact the affordability of prescription drugs for all end consumers. Congress established the 340B program to help covered entities stretch limited resources in support of patients and communities. Program participants include hospitals that serve a disproportionate share of low-income and Medicaid patients, critical access hospitals, rural referral centers, sole community hospitals, cancer hospitals and children's hospitals. Each of these entities offers services to communities and patients who are experiencing complex and expensive care. The program recognizes the role 340B hospitals serve in their community and the costs associated with the range of care and services they deliver.

Rising drug costs, drug shortages and off-label drug use all present impediments to access; a broad "patient" definition for purposes of 340B is a space where, within the confines of one

[1]AHA, The Financial Stability of America's Hospitals and Health Systems is at Risk. https://www.aha.org/system/files/media/file/2023/04/Cost-of-Caring-2023-The-Financial-Stability-of-Americas-Hospitals-and-Health-Systems-Is-at-Risk.pdf

[2]Beasley, Deena. Prices for new US drugs rose 35% in 2023, more than the previous year. Prices for new US drugs rose 35% in 2023, more than the previous year | Reuters

program, Congress can continue to propel prescription drug affordability. The MHA agrees with the outcome of *Genesis v. Becerra*, and specifically the supposition that "the only statutory requirement for 340B eligibility of a person is that the person be a patient of a covered entity, as clearly stated in 42 U.S.C. § 256b(a)(5)(B)."

Hospitals and healthcare systems are familiar with and understand the importance of a patient relationship. Those relationships govern access to care in many instances, and a strong patient relationship results in better health outcomes. **The MHA supports a broad definition of "patient" for purposes of the 340B program and does not support restrictions that would negatively impact drug affordability, health outcomes and access for patients who seek care at covered entities.**

Section 5: Child Sites

Like contract pharmacy arrangements, the advent of outpatient site usage allows 340B covered entities to fully effectuate the intent of the program. Child sites perform needed outpatient services at an ever-increasing rate, delivering care to individuals in a setting that meets their needs. These sites may be specific, like an infusion clinic, more generalized outpatient settings, or a series of outpatient departments in one building. As patient care continues to evolve, it's important the 340B program recognize these evolutions and continue to integrate them into the program. **The MHA supports continued recognition of child sites in the 340B program and the benefit they offer to patients**. The MHA would not support new limitations on child sites and does not support the inaccurate narrative that child sites contribute to an erroneous growth of the program or the suggestion they are part and parcel to nefarious program execution. The success of the 340B program and the ability for it to produce real savings for both covered entities and patients depends on continued evolution, innovation and recognition of changes in healthcare practice. Child sites, like contract pharmacies, allow covered entities to more practically, efficiently and affordably serve their communities.

Section 6: Transparency

Michigan 340B hospitals share their community investments from the program in a variety of ways. One of the strengths of the 340B program is its flexibility. The program grants significant latitude to covered entities to reinvest their savings in community health needs. Michigan hospitals use community health needs assessments to identify appropriate areas for improvement and report much of their work through community benefit reporting and Medicare cost reports. In addition, covered entities are subject to IRS reporting to maintain their tax-exempt status and comply with both HRSA initiated and pharmaceutical manufacturer-initiated auditing of their programs. Further, all programs attest annually to their compliance, legally reiterating their commitment to being auditable and reporting on the work they do to support their communities.

Transparency is a tool that benefits 340B covered entities due to the multitude of reporting currently available to aggregate the value of the program. **However, the MHA has concerns about adding new reporting or transparency requirements that could be weaponized, taken out of context and used to further undermine a program that provides vital access to urban and rural communities across Michigan.** The MHA is comfortable with and supports existing reporting mechanisms and auditing requirements and supports covered entities in their voluntary reporting and information sharing efforts above and beyond what is required across numerous regulatory structures.

Section 7: Enhancing Program Integrity

As noted with regard to program transparency, **the MHA supports existing structures that maintain the integrity of the 340B program for covered entities and would support extending those structures to other program partners**. 340B covered entities participate in annual attestation, robust audits at multiple levels and ever-increasing compliance requirements.

However, pharmaceutical manufacturers are not held to the same standards. Covered entities are subject to more than 200 audits annually, with more than 1,700 audits of covered entities occurring since 2012. Pharmaceutical manufacturers see significantly fewer audits and are not subject to the same level of program scrutiny as their healthcare provider partners. Equitable administration of the program, appropriate oversight and remedial measures when program violations are revealed are integral to the program's long-term success.

Equitable program administration could mean increased price transparency and information exchange between covered entities and pharmaceutical manufacturers. Many covered entities participate currently in the 340B ESP program, which requires significant information sharing from hospitals without much, if any, information shared back. Approaching this program as a true partnership, as it was intended, and sharing appropriate information will ensure program participants can effectuate the goals of the program, while also reducing opportunities for adversarial interactions. Confidence in the program begins with building strong partnerships. Maintaining those partnerships requires free flowing information exchanges to drive all participants to the goal of increasing the benefit to communities served by covered entities.

Section 8: Preventing Duplicate Discounts

Hospital covered entities in Michigan greatly value program participation and diligently work to avoid duplication of discounts. Sharing appropriate information that allows covered entities to check their work quickly and efficiently would be beneficial to reducing risks of duplication. Addressing the risk on the front end streamlines the program and creates opportunity for more savings stability by avoiding the discovery of duplications later. However, it would be beneficial for all parties participating in the program to share appropriately blinded information to ensure uniform compliance, minimize errors and reduce instances where manufacturers are independently requiring claims data sharing or utilizing more than one data sharing platform. Clarity, guidance and uniformity with enforcement ability would serve all program participants and allow for the maximum savings benefit to get back to patients and communities.

The MHA supports opportunities to minimize discount duplication risk and appreciates the goal set forth in the SUSTAIN discussion draft of creating a third-party claims clearinghouse to assist in information sharing and the ability for covered entities to mitigate duplications. We caution, however, what implementation of a claims clearinghouse would look like and encourage this type of continued thoughtful dialogue with program partners as a claims sharing requirement is contemplated.

Section 9: Ensuring Equitable Treatment of Covered Entities and Participating Pharmacies

The MHA supports ensuring 340B program savings are not siphoned off, reduced, diminished or otherwise conditioned by non-covered entity parties. We value our partnerships with healthcare stakeholder partners, but in this particular instance, the ongoing machinations by non-covered entities to either condition or otherwise discriminate against a 340B covered entity continues to result in savings that are not accrued by the intended program participants. When those savings are not realized by the intended program participants, they aren't reinvested in the intended communities for the benefit of patients.

Much like the discussions around administrative burden, when non-program participants create and administer discriminatory practices, it negatively impacts the downstream beneficiaries of the program. Covered entities utilize their 340B savings to support specific service lines, financial assistance programs, drug affordability and community and public health programming, among other things. Each time an element of the program is conditioned, or a fundamental aspect of the program is limited outside the scope of the statute or intent of the program, patients and communities are ultimately losing out on the intended 340B savings and affordability benefits.

T**he MHA supports protecting against discriminatory or predatory practices that negatively impact 340B covered entities and appreciates the SUSTAIN Act discussion draft's goal to prevent those practices**.

Section 10: User Fee Program

The MHA is opposed to a user fee program. The more than 80 covered entity hospitals in Michigan represent both urban and rural areas and serve an incredible array of patients, communities and needs. They are all unique in their own ways, delivering care at the highest and best level, but one of the items that identifies them all collectively is the need to protect against erosions to their financial viability. The central purpose of the 340B program identifies that those who are eligible to participate are those who are serving high need, underserved, under resourced or otherwise vulnerable patient populations and communities. Program proponents and describers oft repeat the Congressional intent to stretch scarce resources further, recognizing the entities participating are not those with unending financial resources. In fact, they are the opposite and 340B savings are frequently the difference between a community with access to care and a community without. Michigan 340B hospitals are suffering increased administrative costs and burdens, as well as discriminatory practices, all at a time where healthcare costs are increasing dramatically. **We are opposed to a user fee program that would divert any 340B savings away from covered entities and the communities they serve.**

Sections 11, 12, 13 and 14: Reports, Appropriations, Definitions and Enactment Date

T**he MHA is supportive of minimizing exposure to duplication of discounts** and has recommended in the past state Medicaid opportunities to effectuate reduction through a searchable BIN/PCN database. We look forward to understanding best practices from state Medicaid agencies across the country when it comes to ensuring duplication risk is mitigated as much as possible.

The MHA supports allocating funds specifically for administration of the 340B program, and much prefers direct appropriations over a user fee program.

Dependent on the full scope of changes contemplated in a final draft, **the MHA would be supportive of an enactment date that recognizes the need to operationalize changes to program administration.**

The MHA thanks you for your support of the 340B Drug Pricing Program and for your consistent engagement with a variety of stakeholders as you explore ways to improve and strengthen the long-term viability of 340B.

Sincerely,

Laura Appel
Executive Vice President, Government Relations & Public Policy
Michigan Health & Hospital Association

APPENDIX A: MHA 2023 340B RFI RESPONSE

July 28, 2023

RE: Bipartisan Request for Information on the 340B Drug Discount Program

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

On behalf of Michigan's 86 hospital covered entities, the Michigan Health & Hospital Association (MHA) appreciates the opportunity to share information and recommendations to fully effectuate the intent of the 340B Drug Discount Program (340B program).

As noted in your request, the 340B program was designed to stretch scarce federal resources and support vulnerable communities and populations. Michigan hospital covered entities value the goals of the program and work tirelessly to ensure program dollars support multiple opportunities to increase access to healthcare, ultimately improving Michigan's overall health. The savings from the program are a lifeline for many Michiganders, allowing their community hospital to provide an array of services that they may not be able to offer without 340B program participation. Savings derived from hospital program participation assist an incredible range of services, including (but not limited to):

- Supporting important service lines like inpatient psychiatric services and obstetrics and gynecology.
- Allowing for hospitals to design and implement robust financial assistance programs which provide individuals in the community with extremely low- or no-cost care.
- Creating solutions to public health concerns like utilization of mobile health units
- Funding comprehensive cancer care, specialized neonatal intensive care, and comprehensive hemophilia treatment.

One of the most important aspects of the program, beyond the savings opportunities it presents to hospitals, is its flexibility. Hospitals reinvest their savings to address community-specific needs—embodying Congress's intent with the program— thereby allowing each participating hospital to reflect the health needs of their patients and communities. Without the program, and without opportunity to bolster the program's success, many Michiganders would see reduced access to low-cost, high-quality healthcare in their communities.

In response to your specific questions, below are several solutions and opportunities to strengthen the program:

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?*

   Program oversight, management and enforcement are integral to ensuring overall success of the 340B program. Several issues impact hospital covered entities and their ability to efficiently run a 340B program, including the need for clear and concise guidance on program administration. Contract pharmacy relationships in particular present difficulty, and the inability for HRSA to issue and enforce guidelines on those arrangements has resulted in pharmaceutical manufacturers choosing the limitations unilaterally. Without uniform application of a policy, program administration becomes extremely burdensome, inefficient, and ultimately fails to serve the patients and communities who should benefit from the program's savings. HRSA should be granted appropriate authority to develop clear guidance, implement the guidance and enforce the parameters of program administration, ensuring all parties participating in the program have the requisite knowledge to maximize compliance and support vulnerable populations.

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

   As noted above, clear and concise guidance would serve all who participate in the 340B program. Allowing covered entities to contract with pharmacy partners increases access points and allows covered entities to serve patients where they live. While the MHA does not support putting an arbitrary limit on the number of contract pharmacy relationships a covered entity can have, the association does support clarity in contract pharmacy regulation. Currently, the practical impact of decisions like *Sanofi-Aventis U.S. v. HHS et al.* is that pharmaceutical manufacturers have implemented their own regulatory restrictions, despite the silence in current law regarding number of protected contract pharmacy relationships. Again, without clear guidance and authority to enforce guidance, HRSA lacks the ability to meaningfully prevent drug manufacturers from unilaterally dictating the role contract pharmacy arrangements play in the program. Instead, covered entities face a constant barrage of emerging instructions, administrative hurdles and paperwork to comply with each manufacturer's requirements. Formal recognition of the importance of contract pharmacies, as well as protection of relationships between contract pharmacies and covered entities, would go a long way towards ensuring savings from the program are reinvested in patients and communities instead of program dollars being diverted to manage unwieldy administrative hurdles created by manufacturers that detract from the purpose of the program.

   Michigan 340B covered entities in deserve the ability to make protected decisions about program partnerships that maximize patient access to affordable healthcare, including contracting with pharmacy partners that align with covered entities' program goals and the goals of the 340B program globally.

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?*

   Congress established the 340B program to help covered entities further stretch limited resources in support of marginalized patients and communities. Program participants include hospitals that serve a disproportionate share of low-income and Medicaid patients, critical access hospitals, rural referral centers, sole community hospitals, cancer hospitals and children's hospitals. Each of these entities offers services to communities and patients who are experiencing complex and expensive care. The program recognizes the role 340B hospitals serve in their community and the costs associated with the range of care and services they deliver, as Congress intended.

   As noted in the opening, one of the strengths of the 340B program is its flexibility. The program grants significant latitude to covered entities to reinvest their savings in community health needs. Michigan hospitals use community health needs assessments to identify appropriate areas for improvement and report much of their work through community benefit reporting and Medicare cost reports. The MHA does not support limiting or specifically regulating the types of services savings can be used to support, However, we would be open to further discussions around the best ways for covered entities to share how their savings are positively impacting the health of their patients and communities. Michigan 340B hospitals can share countless stories of the program's impact, however, the complexity of program administration increases almost daily. Continuing to streamline program compliance to reduce unnecessary burden would ensure savings can be reinvested in patients, communities, and services that support patients with the greatest needs.

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

Hospital covered entities in Michigan greatly value program participation and diligently work to avoid duplication of discounts. There are several items that could serve to increase transparency while assisting covered entities in their work to prevent duplication of discounts.

In the Medicaid space, hospitals have shared that a statewide, searchable BIN/PCN database would serve covered entities well. BIN/PCN numbers are specific provider and routing numbers used in the healthcare industry to file insurance claims. Medicaid health plans have unique BIN/PCN/Group numbers, which are shared with the state. Having those unique numbers available for covered entities to quickly reference would ensure that duplication of Medicaid rebates and discounts do not occur within the program. The MHA understands these numbers can and do change annually, which is why the association supports a statewide, searchable database managed by the state Department of Health and Human Services, which has access to this information currently. Information sharing, and information accessibility in this instance, would serve to positively impact the program through reduction in duplicate discount risk while not concurrently creating new administrative requirements on the program, relying instead on existing state resources and infrastructure.

Further opportunities to share appropriate information that allows covered entity members to check their work quickly and efficiently would be beneficial to reducing risks of duplication. Addressing the risk on the front end streamlines the program and creates opportunity for more savings stability by avoiding the discovery of duplications later. However, it would be beneficial for all parties participating in the program to share appropriately blinded information to ensure uniform compliance, minimize errors, and reduce instances where manufacturers are independently requiring claims data sharing or utilizing more than one data sharing platform. Clarity, guidance and uniformity with enforcement ability would serve all program participants and allow for the maximum savings benefit to get back to patients and communities.

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 healthcare stakeholders greater confidence in its oversight?*

340B covered entities participate in annual attestation, robust audits at multiple levels and ever-increasing compliance requirements. However, pharmaceutical manufacturer are not held to the same standards. Annually, covered entities are subject to more than 200 audits, with more than 1,700 audits of covered entities occurring since 2012. Pharmaceutical manufacturers see significantly fewer audits and are not subject to the same level of program scrutiny as their healthcare provider partners. Equitable administration of the program, appropriate oversight and remedial measures when program violations are revealed are integral to the program's long-term success.

Equitable program administration could mean increased price transparency and information exchange between covered entities and pharmaceutical manufacturers. Currently, many covered entities participate in the 340B ESP program, which requires significant information sharing from hospitals without much, if any, information shared back. Approaching this program as a true partnership, as it was intended, and sharing appropriate information will serve to ensure program participants can effectuate the goals of the program while also reducing opportunities for adversarial interactions. Confidence in the program begins with building strong partnerships. Maintaining those partnerships requires free flowing information exchanges to drive all participants to the goal of increasing the benefit to communities served by covered entities.

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

Existing reporting structures could be used at a more appropriate and higher level. Adding new reporting requirements or administrative layers to the program will only divert savings away from

patients and communities and towards administrative operations. Currently, Michigan hospitals use reporting structures that include producing specific covered entity impact profiles detailing their 340B program and the work supported by it, Medicare cost reporting, community benefit reports and IRS 990 forms. There are many ways 340B hospitals share information on how they use program savings to support members of their communities and the MHA supports using these existing structures as opposed to creating new reporting requirements.

However, as noted in the response to the previous question, the same reporting and information sharing does not occur for pharmaceutical manufacturers. Hospitals are highly regulated, including in the 340B program. They report on numerous safety, quality, and efficacy fronts, are subject to audits and inspections across a multitude of services and are held to incredibly high standards to ensure the best possible outcomes for patients. Program transparency could be increased on the manufacturer side, creating accountability, and meeting the goals of the program which ultimately benefit patients across the country.

Michigan is home to more than 80 covered entities, many of whom rely on 340B participation to continue serving their communities. Considering this, ensuring the 340B program's continued success a top priority of the MHA and we would like to use this opportunity to offer additional notes:

1. The COVID-19 pandemic impacted hospitals in an unprecedented manner. The remaining effects of the Public Health Emergency include declines and gaps in services, resulting in decreased disproportionate share hospital (DSH) percentages in some cases. Therefore, we recommend Congress extend the 340B DSH eligibility waiver for affected covered entities in need of more time to recover from the impact of the pandemic.
2. 340B is a non-taxpayer funded opportunity to support marginalized communities and patients. The savings derived from the program are the result of a partnership between pharmaceutical manufacturers and covered entities, like hospitals and community health centers. Reductions in program efficiency, administrative burdens and unlawful practices create new financial barriers to increasing access to care. The MHA implores lawmakers to take advantage of any opportunity to strengthen the program, as the benefit it offers to patients and communities served by 340B covered entities is without parallel. The funding needed to fill the gap is staggering if the scope of the program were to be limited.
3. The MHA supports the Centers for Medicare & Medicaid Services (CMS) proposed remedy to provide a lump-sum payment to 340B hospitals to account for the unlawful reductions in Medicare Part B reimbursements from 2018-2022. However, the MHA has deep concerns about the way the repayment remedy is structured. The budget neutral approach requires CMS to offset the cost of repaying 340B hospitals and the proposal to cut Medicare reimbursements for non-drug services would impose new financial strain on hospitals and health systems for upwards of 16 years. The MHA encourages a remedy that does not include reductions in hospital payments and instead implores Congress to pass legislation that directs HHS to devise a remedy that is non-budget neutral.

MHA thanks you for your steadfast support of the 340B Drug Pricing Program and for your willingness to gather information to pursue targeted solutions to enhance the program's success.

Sincerely,

Laura Appel
Executive Vice President, Government Relations & Public Policy
Michigan Health & Hospital Association