Bipartisan 340B Senate Working Group
SUSTAIN 340B Act
Discussion Draft Explanatory Statement and Supplemental RFI

SECTION 1. Short Title

- Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future of 340B Act or the "SUSTAIN 340B Act".

SECTION 2. Sense of Congress

Background: While previously only expressed in report language**,** we are now providing clarity in statute about Congress's intent for the 340B program.

Summary:

- The section codifies that the intent of the 340B program is to help safety net providers maintain, improve, and expand patient access to 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.[1]

SECTION 3. Contract Pharmacy[2]

Background: Since the inception of the 340B program, covered entities have often used contract pharmacies to expand the locations and hours at which patients can access 340B drugs, particularly if they have no in-house pharmacies or cover a large service area. Furthermore, some medications are only available through specialty pharmacies that are not located near a covered entity and thus medications must be dispensed from pharmacies in alternative locations or through mail order.

Due to a lack of statutory clarity, there has been ambiguity over the use of contract pharmacy arrangements which has led to litigation. We seek to provide statutory clarity in this section to ensure patients have access to medications, while also enhancing program integrity and accountability around the use of contract pharmacies in the program. As we are also asking for comment on patient definition, we believe the specifics on contract pharmacy requirements are also dependent on how the patient definition is crafted and the interactions should be taken into consideration.

Some stakeholders have expressed concerns with the number of contract pharmacies used by some covered entities. The number of contract pharmacies used by individual covered entities ranges from 0 to 439 with the average covered entity who utilizes a contract pharmacy using 12.[3] We would appreciate stakeholder feedback on how to achieve the correct balance of patient access, accountability, and program integrity in the use of contract pharmacy arrangements. To

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[1] The text is a combination of language taken from FY23 and FY24 Senate Labor, Health and Human Service, and Education Appropriations Subcommittee bills.

[2] The text utilizes guidance released by the Human Resources and Services Administration (HRSA) in 2010 regarding 340B contract pharmacy services: https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf.

[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10665972/

that end, we would appreciate if stakeholders could provide more detail on the following areas:

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

- Many community health centers and hospitals in rural and underserved areas see patients from large service areas, many of whom have limited transportation options. Many of these health centers and hospitals do not have an in-house pharmacy and thus rely on contract pharmacy arrangements to provide patients access to medications. How would you structure any geographic restriction or other restriction on contract pharmacies to ensure patients in rural and underserved areas maintain access to drugs?

- A greater number of 340B medications are now specialty medications, which can often only be obtained through specialty pharmacies. These specialty pharmacies often only have a few locations throughout the country. How would you structure any limitation on contract pharmacy while also ensuring patients have access to these specialty medications?

- We have heard concerns from stakeholders about the number of contract pharmacies used by covered entities in the program. However, we also understand that not all of these pharmacies may be actively providing prescriptions to patients as part of the 340B program and are only included due to other contractual requirements, such as effectively requiring them to contract with an entire pharmacy chain, regardless of their need or preference. What policies would allow covered entities to contract with pharmacies to ensure patients have access, without additional requirements or limitations? What policies should be implemented to limit the role of PBMs' influence in the 340B program and ensure the benefits of the 340B program remain with the covered entities and eligible patients?

Summary:

- Contract pharmacies can be used by covered entities in accordance with HRSA's 2010 guidance. As part of contract pharmacy arrangements in the program, manufacturers participating in the program are required to:

    1) offer covered entities the 340B price for an outpatient drug regardless of whether the drug is dispensed at a contract pharmacy or an in-house pharmacy;

    2) deliver covered outpatient drugs purchased by a covered entity and their associated sites to pharmacy locations as requested by the covered entity; and

    3) not place conditions on the ability of a covered entity to purchase drugs at the 340B price, including a drug that is dispensed at a contract pharmacy location.

- Covered entities must annually register their contract pharmacy sites with the Department of HHS and registration requirements include covered entities providing such information as:
    1) submitting all contract pharmacy arrangements in a timely manner;
    2) registering each contract pharmacy arrangements with the parent, child, and associated sites prior to implementing the contract pharmacy agreement; and
    3) attest to their compliance with the requirements under this section.

- The Secretary shall promulgate rules to carry out the provisions of this section, including in regards to the written agreements between the covered entity and the contract pharmacy, standard contract provisions, guidance to covered entities regarding best practices for contract pharmacy oversight, and the retention of relevant records of their arrangement.

- The section also clarifies a manufacturer can be charged civil monetary penalties if intentionally refusing to offer a covered outpatient drug for purchase at the 340B price, refusal to deliver the drug, or place conditions on the ability of a covered entity to purchase a covered outpatient drug.

SECTION 4. Patient Definition

Background: Recent litigation has raised a question over HRSA's authority to enforce and administer their previously proposed definition of "patient" in the 340B program. Congress has previously not weighed in through statute on the definition of "patient". We believe this has resulted in uncertainty in the administration of the program. 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.

We are seeking additional feedback from stakeholders on how to appropriately structure a definition of patient.

- The 340B statute does not include a definition of patient. In 1996, HRSA proposed a patient definition and then proposed a revised definition in 2015 which they then withdrew. Since the program has evolved since the original statute was written, how should these changes be reflected in how a patient is defined?

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

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

- Should the patient definition include a requirement to determine when the patient is first identified as a patient? Should there be an ability to retroactively recoup payments?

- When a patient is served by multiple covered entities, what elements should be considered when determining which covered entity claims a discount for a given patient?

- 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?

SECTION 5. Child Sites

Background: Stakeholders have expressed concerns about the lack of clarity in the establishment and use of child sites in the 340B program. There have been examples in recent years of child sites that have benefitted from participation in the 340B program but have not provided access to needed benefits in their communities. We believe it is important to the integrity of the program that child sites are wholly-owned by and financially and clinically integrated into the covered entity.

We are seeking additional feedback from stakeholders on how to appropriately ensure child sites are aligned with the intent of the 340B program:

- We propose using the Medicare provider-based guidelines outlined in 42 CFR 413.65 as a framework to appropriately determine eligibility for a child-site to participate in the program. Do the guidelines, as proposed, reflect how a wholly-owned child site should be clinically and financially integrated into the covered entity? Are there additional requirements that should be added to be sure the child site is clinically and financially integrated into the covered entity?

- What level of oversight of the child site is appropriate to ensure adequate control and integration with the covered entity?

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

- Are there other specific policies we should consider to clarify the eligibility criteria of child sites?

- Are there additional program integrity measures or reporting requirements that should be considered to ensure the appropriate eligibility of child sites?

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

Summary:

- A child site must be wholly-owned by and clinically and financially integrated with the covered entity and provide care consistent with the covered entities' policies.

- Covered entities operating such a child site must register it with the Secretary and apply the same financial assistance policies, aligned with other sites operated by the covered entity.

- In order to ensure the clinical services of a child site and covered entity are fully integrated, the child site's providers and medical staff must meet certain requirements in line with the parent site, such as be employees or contractors with the covered entity and other clinical services and medical records must be fully integrated.

- The financial operations of the child site must be fully integrated within the financial system of the covered entity, including by having y shared income and expenses between the covered entity and the child site.

- The covered entity must publicly acknowledge the child site as part of its operations and meet specific requirements to prove the child site is operated under the ownership of the covered entity.

- The reporting relationship between the covered entity and the child site must have the same frequency and level of accountability as the covered entity shares with its other departments.

- The Secretary must promulgate regulations to establish procedures in the event that a child site has previously been deemed qualified as a child site but now no longer meets the new requirements set forth in this legislation.

- Both the covered entity and child site are required to maintain records that are subject to audits to ensure compliance.

Section 6. Transparency

Background: Stakeholders have expressed concerns about a lack of transparent reporting from covered entities about their administration of the 340B program. We believe that requiring covered entities to report detailed information regarding their program savings, policies, patient and prescription information, and then enabling that information to be publicly available by the Secretary will help ensure all stakeholders have trust and confidence that the program is being used as intended.

Summary:

- Beginning one year after enactment, covered entities will be required to report specific information about their use of the 340B program for the preceding year as an addendum to their Medicare cost report.

- The report must include such information as the number of individuals who were dispensed or administered drugs at the 340B price (specific to type of health insurance coverage), the cost incurred at each site for charity care, patient demographics, State/local contracts (for non-governmental hospitals), a list of contract pharmacies, the discount realized under 340B and a description of the covered entity's use of savings.

- If a covered entity does not submit a Medicare cost report, the covered entity must provide to the Secretary a report that includes charity care levels and a qualitative description of the charity care provided by the covered entity in a manner the Secretary requires.

- Covered entities must retain records as the Secretary deems necessary and permit the Secretary to audit the savings uses of the covered entity.

- The Secretary must publish the information reported by covered entities on a public website at HHS in a searchable format that shows each category of reported information, while ensuring that any proprietary information be redacted before posting such information.

- GAO must submit a report to Congress on the information collected under this section.

SECTION 7. Enhancing Program Integrity
Background: Stakeholders expressed concerns about the need for HRSA to provide updated audit guidelines to ensure compliance of all stakeholders in the program. We propose language that would require the Secretary to issue additional guidance regarding audits in the program and provide appropriate consequences if a covered entity does not meet compliance requirements.

Summary:
- This section authorizes the Secretary to perform audits on covered entities, child sites, contract pharmacies, and manufacturers to ensure compliance under the statute.

- The Secretary must conduct audits in accordance with generally accepted government auditing standards and cannot close an audit until a corrective action plan has been fully implemented.

- Covered entities are required to only contract with vendors that agree to submit data to the Secretary and independent outside auditors and respond to requests from auditors in a timely manner.

- Covered entities must extend their patient financial assistance policies to patients served at their child sites and contract pharmacies. The covered entity must ensure the financial assistance option is made transparent to patients and publicly reported.

- The Secretary is required to issue guidance for 340B program auditors and must ensure that the audit results in consequences if a covered entity fails to meet all requirements.

- Within one year of enactment, the Secretary shall promulgate regulations regarding audit and reporting procedures for this section.

SECTION 8. Preventing Duplicate Discounts
Background: The 340B statute prohibits duplicate discounts. However, as has been highlighted by GAO[4] and the OIG[5], duplicate discounts continue to occur in the program due to a lack of a system to appropriately identify 340B claims. In an effort to address this problem, we propose the creation of a national third-party clearinghouse.

Summary:
- The section directs the Secretary to enter into a contract with an independent, third-party entity to carry out the duties of a national clearinghouse to prevent duplicate discounts between the 340B program and Medicaid.

- The national clearinghouse must perform the duties laid out in this section, including requesting and receiving claims level rebate file data from State Medicaid agencies and covered entities and maintaining the data in a confidential manner.

- Covered entities must participate in the data exchange with the third-party clearinghouse, including available data from contract pharmacies.

- All information exchanged between the third-party clearinghouse and the covered entities is subject to HIPAA privacy laws.

- Covered entities will also be required to repay manufacturers of identified duplicate discounts for 340B drugs.

- One year after enactment, CMS and HRSA must issue a report to Congress detailing coordinated efforts to address duplicate discounts.

- The Secretary shall promulgate regulations as determined necessary to address duplicate discounts.

SECTION 9. Ensuring Equitable Treatment of Covered Entities and Participating Pharmacies[6]
Background: Stakeholders have raised concerns about the role health plans and pharmacy benefit managers have played in recent years in managing access to drugs in the 340B program. In order to ensure that the 340B savings goes primarily to the covered entity, we include language to ensure plans and PBMs cannot place differential terms on covered entities or their contract pharmacies and ensure the benefit accrues to the covered entity and not other parties.

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[4] GAO-20-212. https://www.gao.gov/assets/gao-20-212.pdf
[5] State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates. OIG Report (OEI-05-14-00430). 06-06-2016
[6] The text utilizes language included in the Preserving Rules Ordered for The Entities Covered Through (PROTECT) 340B Act of 2023.

Summary:

- The section prohibits a group health plan, a health insurance issuer offering group or individual insurance coverage, or a pharmacy benefit manager from discriminating against covered entities, contract pharmacies, or other participants in the 340B program.

- The actions specifically prohibited include lower reimbursement rates for covered entities and contract pharmacies participating in 340B, refusal to contract with a covered entity or contract pharmacy, or interfering with an individual's choice to receive a 340B drug.

- Health plans and pharmacy benefit managers are also prohibited from imposing terms and conditions on covered entities and contract pharmacies that differ from other terms and conditions applied to similarly situated entities, such as chargebacks, clawbacks, or other fees.

- The Secretary is authorized to impose civil monetary penalties on any pharmacy benefit manager that violates these requirements.

SECTION 10. User Fee Program[7]

Background: As has been proposed by prior Republican and Democratic administrations, a user fee program would enable HRSA to be equipped with the appropriate resources to properly oversee and administer the 340B program**.**

Summary:

- The HHS Secretary is directed to begin a user fee program that will require covered entities participating in the program to pay a fee.

- The user fee amounts will amount to no greater than [.01]% of the savings the covered entity receives under the 340B program, calculated as the difference between the wholesale acquisition cost (WAC) and the 340B price of the drugs purchased under the 340B program. Those funds paid by the covered entities will be used for program administration, including enhancing program integrity and oversight activities included in this Act and the establishment, use and maintenance of the data clearinghouse as described in this Act.

- The text clarifies the user fee funds are meant to supplement not replace amounts provided through congressional appropriations.

- The Secretary shall promulgate regulations to implement the user fee program and the HHS Office of Inspector General is required to submit an annual report to Congress for the first five years of the program.

[7] The establishment of a user fee program for 340B has been included in previous budget proposals from both the Obama and Trump administrations.

SECTION 11. Studies and Reports
Summary:

- MACPAC must submit a report to Congress on the efforts of State Medicaid agencies to prevent duplicate discounts under the 340B program.

- To establish reasonable dispensing fees associated with contract pharmacies, HHS must conduct a study on dispensing fees and submit the study to Congress two years after the date of enactment.

SECTION 12. Additional Resources for Oversight
Summary:

- The section authorizes an additional $3,000,000 for the purposes of conducting the audits, investigations, oversight and enforcement activities associated with the 340B program.

SECTION 13. Definitions
Summary:

- This section defines key terms throughout the text including contract pharmacy and child site.

SECTION 14. Effective Date

- This Act will take effect on the date of enactment.