



JOINT STATEMENT
U.S. Senate Bipartisan 340B Working Group
Request for Information – 340B Drug Pricing Program



July 24, 2023

The Honorable John Thune (R-S.D.)
United States Senate
511 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Debbie Stabenow (D-Mich.)
United States Senate
731 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Shelley Moore Capito (R-W.Va.)
United States Senate
172 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Tammy Baldwin (D-Wis.)
United States Senate
709 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Jerry Moran (R-Kan.)
United States Senate
521 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Ben Cardin (D-Md.)
United States Senate
509 Hart Senate Office Building
Washington, D.C. 20510

RE: REQUEST FOR INFORMATION ON 340B DRUG PRICING PROGRAM

Senators:

On behalf of the Community Access National Network and the ADAP Advocacy, we sincerely appreciate the opportunity to provide input regarding the 340B Drug Pricing Program (“340B program”) and our collective thoughts on ways to improve the 340B program. Our public comments are in response to the [Request for Information](#) (RFI) on policy solutions that would provide stability and appropriate transparency to ensure the 340B program can continue to achieve its original intent of supporting entities serving eligible patients.

The [Community Access National Network](#) is a coalition-based, national nonprofit organization with a mission to define, promote, and improve access to healthcare services and supports for people living with HIV/AIDS and/or viral hepatitis through advocacy, education, and networking. [ADAP Advocacy](#) is also a national nonprofit organization with a mission to promote and enhance the AIDS Drug Assistance Programs (ADAPs) and improve access to care for people living with HIV/AIDS.

In 1992, Congress struck a deal with pharmaceutical manufacturers to expand access to care and medication for more patients: If pharmaceutical manufacturers wanted to be included in Medicaid’s coverage, they’d have to offer their products to outpatient entities serving low-income patients at a discount. The idea was brilliantly simple; drug manufacturers could have a guaranteed income from participation in the Medicaid program, and “covered entities” could have guaranteed access to discounted medications. Congress set-up the 340B program as a payment system by way of rebates, affording healthcare providers a way to fund much-needed care to patients who could not otherwise afford it. Our collective thoughts in response to the RFI are designed to return the 340B program to the original intent of the law, namely improving access to care and treatment for low-income patients.



JOINT STATEMENT

U.S. Senate Bipartisan 340B Working Group Request for Information – 340B Drug Pricing Program



July 24, 2023

JOINT STATEMENT – PAGE TWO

U.S. Senate Bipartisan 340B Working Group | Request for Information – 340B Drug Pricing Program
July 24, 2023

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?

When the 340B program was established through the Veterans Health Care Act of 1992, the House Energy and Commerce Committee indicated that it was giving safety net providers “...access to price reductions...to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”¹ The Health Resources & Services Administration (HRSA) and Covered Entity stakeholders have continued to cite that essential purpose – to allow the safety net providers to do more with less funding – as the intent of the program.² Dr. Diane Nugent a nationally-recognized expert in pediatric hematology that includes blood disorders, bone marrow failure, bleeding and clotting disorders, and white cell and immune deficiencies; and the founder of the National Hemophiliac Treatment Center Network testified before the CANN National Commission on 340B and explained:

“At the inception [of the 340B program], these entities [Hemophilia Treatment Centers (caring for all patients with both bleeding and clotting disorders), Ryan White Clinics and FQHCs were specifically identified] were the prime targets to benefit from the three major goals of the initial PHS pricing program: first, that pharmaceutical products would be purchased at markedly reduced 340B pricing; secondly, the discounts would be passed on to the payors and finally that a small, reasonable, percentage would go to the entity itself, to sustain Covered Entities to care and expand diagnostic and clinical services.”³

The 340B program was created in a vastly different healthcare landscape than exists today; it was a means of restoring the discounts that manufacturers had voluntarily been providing safety net entities before the unintended consequences from the passage of the Medicaid rebate law.⁴ In the years since 1992, uninsured rates steadily decreased⁵ while the number of individuals insured through Medicaid nearly tripled.⁶ Today, nearly half of all Medicare acute care hospitals are 340B Covered Entities; even though, nonprofit hospitals are increasingly displaying the characteristics of for-profit hospitals.⁷

¹ H.R. 2890 - Medicaid and Department of Veterans Affairs Drug Rebate Amendments of 1992, H. Rept. No. 102-384 (Part 2), at 12 (1992).

² H.R. Rep. No. 102-384 (II), at 12 (1992). HRSA, OPA, 340B Program, at <https://www.hrsa.gov/opa/index.html>.

³ National Commission on 340B. 1 (2018, July 13) (Diane J. Nugent, MD).

⁴ La Couture, B. (2014, June 04). Primer: Understanding the 340B Drug Pricing Program. Washington, DC: American Action Forum: Research. Retrieved from: <https://www.americanactionforum.org/research/primer-understanding-the-340b-drug-pricing-program/#ixzz5RBdlVfYC>.

⁵ National Center for Health Statistics. (2018, February). National Health Interview Survey Long-term: Trends in Health Insurance Coverage. Atlanta, GA: United States Department of Health and Human Services: Centers for Disease Control and Prevention: National Center for Health Statistics. Retrieved from: https://www.cdc.gov/nchs/data/nhis/earlyrelease/trendshealthinsurance1968_2015.pdf.

⁶ Medicaid and CHIP Payment and Access Commission, The. (2017, December). MACStats: Medicaid and CHIP Data Book, Exhibit 10. Washington, DC: The Medicaid and CHIP Payment and Access Commission. Retrieved from: <https://www.macpac.gov/wp-content/uploads/2015/12/MACStats-Medicaid-CHIP-Data-Book-December-2017.pdf>.

⁷ Augustine, N.R., Madhavan, G., & Nass, S.J. (2018). Making Medicines Affordable: A National Imperative. Washington, DC: The National Academies of Sciences, Engineering, and Medicine: Health and Medicine Division: Board on Health Care Services: Committee on Ensuring Patient Access to Affordable Drug Therapies. Retrieved from: <https://www.nap.edu/read/24946>.



JOINT STATEMENT

U.S. Senate Bipartisan 340B Working Group Request for Information – 340B Drug Pricing Program



July 24, 2023

JOINT STATEMENT – PAGE THREE

U.S. Senate Bipartisan 340B Working Group | Request for Information – 340B Drug Pricing Program
July 24, 2023

Congress could not have predicted the changes in the healthcare landscape over the last quarter of a century. Congress expanded the program multiple times adding family planning clinics, rural hospitals, children’s hospitals, free-standing cancer centers, etc. As this occurred, some stakeholders increasingly disagreed regarding the original intent of the 340B program.

When originally drafted, Congress did not include extensive parameters to govern the entities. This means that the statute is silent on many critical program requirements that are necessary for it to function correctly today, ensuring that patients, and not hospital networks, are seeing the benefit of discounted medicines. But it is now more than 20+ years later, and difficult to argue about what occurred then as compared to now. The challenge and the opportunity are to focus on what Congress wants the program to be today, who it should serve, what healthcare providers should be qualified as “covered entities,” etc.

Some potential recommended solutions include:

- Require the same level of reporting for all Covered Entities on how their savings are used to benefit low-income, uninsured, and under-insured patients.
- Require all 340B Covered Entities to report on the patient mix, broken down by insurance status, for patients dispensed 340B medicines. Revisit the intent of the program, as suggested by the Energy and Commerce Report considering “how much the healthcare landscape has changed since the program’s inception, especially about hospitals.”

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

When the 340B program was created, Congress identified the types of safety net providers that it intended to benefit from access to lower-cost outpatient drugs. Some of those provider types, particularly Federally Qualified Health Centers and Ryan White HIV/AIDS clinics, lacked the infrastructure to provide pharmacy services and the resources to start a pharmacy program. Some entities entered into agreements with existing pharmacies to serve as their agents for dispensing the Covered Entities’ 340B drugs.⁸ These “contract pharmacies” are not described in the 340B statute but are a market creation in response to the program.

In 1996, HRSA broadly recognized these contract pharmacies as a permissible exercise of Covered Entities’ ability to contract for services with a third-party.⁹ However, the agency established some minimum ground rules for the use of contract pharmacies.

⁸ Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 FR 43549, 43550 (1996, August 23).

⁹ See *Ibid.* generally.



JOINT STATEMENT

U.S. Senate Bipartisan 340B Working Group Request for Information – 340B Drug Pricing Program



July 24, 2023

JOINT STATEMENT – PAGE FOUR

U.S. Senate Bipartisan 340B Working Group | Request for Information – 340B Drug Pricing Program
July 24, 2023

The greatest limitations imposed by HRSA were that a Covered Entity could only engage a single contract pharmacy and it could not engage a contract pharmacy at all if it operated an in-house pharmacy.¹⁰ If a Covered Entity wanted a multi-pharmacy network serving one Covered Entity or a multi-Covered Entity network using one pharmacy, it could apply to HRSA for an Alternative Methods Demonstration Project (AMDP). Sadly, the AMDP process was phased out after 2010.

In 2010, following a demonstration project that allowed approximately 30 Covered Entities to contract with more than one contract pharmacy, subject to stringent annual audit requirements, HRSA issued guidance allowing all 340B Covered Entities to contract with an unlimited number of pharmacies (retail, specialty or mail order).¹¹

Most importantly, this 2010 guidance did not continue the requirement for annual audits, although HRSA stated in the guidance that it does recommend independent audits. Because of this 2010 guidance, the number of 340B Covered Entities contracting with multiple pharmacies and the number of contract pharmacy arrangements per Covered Entity have grown dramatically.¹²

Operationally, a 340B Covered Entity can purchase and dispense 340B drugs through retail pharmacies. Such contract pharmacies hold the “virtual inventory” of a 340B Covered Entity. In 2010, HRSA permitted covered entities (including those that have an in-house pharmacy) to access 340B pricing through multiple outside contract pharmacies. Since the rule change, the number of contract pharmacies jumped sharply. About one-third of the more than 12,000 Covered Entities contract with contract pharmacies. Almost 70% of 340B participating hospitals have at least one contract pharmacy.

Because of the 2010 guidance, a single Covered Entity contracting with a chain pharmacy such as Walgreens or CVS could extend its 340B program to hundreds of locations. The private market met this demand by developing third-party administration systems that could monitor and track 340B inventory and identify Covered Entity patients quickly across multiple pharmacies. Purchases of 340B drugs increased accordingly, though the near-contemporaneous passage of the ACA and related expansion of the 340B program also contributed to that trend.

Contract pharmacy arrangements must meet certain essential compliance elements. Because a Covered Entity can only transfer or resell 340B drugs to its patients, the arrangements rely on a “bill to, ship to” mechanism through which the Covered Entity purchases and owns the drugs, but they are shipped to the pharmacy for handling and dispensing. Contract pharmacies may not bill fee-for-service Medicaid using 340B drugs unless there is an agreement among the pharmacy, Covered Entity, and state Medicaid agency that is submitted to HRSA establishing how manufacturers will be protected from duplicate discounts.

¹⁰ Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 FR 43555 (1996, August 23).

¹¹ Vandervelde, A. (2014, November). Growth of the 340B Program: Past Trends, Future Projections. Emeryville, CA: Berkeley Research Group. Retrieved from: https://www.thinkbrg.com/media/publication/524_Vandervelde_340B_GrowthDrivers_WhitePaper_20141202_FINAL.pdf.

¹² U.S. Government Accountability Office. (2018, June 28). DRUG DISCOUNT PROGRAM: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement. Washington, DC: United States Government Accountability Office: Products. Retrieved from: <https://www.gao.gov/products/GAO-18-480>.



JOINT STATEMENT

U.S. Senate Bipartisan 340B Working Group Request for Information – 340B Drug Pricing Program



July 24, 2023

JOINT STATEMENT – PAGE FIVE

U.S. Senate Bipartisan 340B Working Group | Request for Information – 340B Drug Pricing Program
July 24, 2023

There is no equivalent federal rule applicable to drugs billed to Medicaid Managed Care Organizations (MCOs). The 2010 contract pharmacy guidance predates the ACA, which established Medicaid rebates for MCO-covered drugs.

The contract pharmacy model spurred some unique developments. Covered Entities and pharmacies have developed virtual inventory or replenishment systems through which the pharmacy dispenses its inventory to Covered Entity patients, then backfills or replenishes what could have been dispensed with a Covered Entity's 340B drugs with 340B drugs purchased by the Covered Entity for the pharmacy. The replenishment model acts as a loan of non-340B drugs to be repaid with the Covered Entity's drugs.

The compensation model is also somewhat unique. Covered Entities own the 340B drugs dispensed to their patients (whether a physical 340B inventory or a retrospective virtual inventory is used). The contract pharmacies bill on behalf of the Covered Entities using the pharmacies' payer contracts. Contract pharmacies collect the reimbursement owed to the Covered Entity on behalf of the Covered Entity, whether from the patient, his or her payer, or a combination of the two. The third-party administrator (TPA) then forwards that reimbursement to the Covered Entity, less its fee and the fee charged by the pharmacy for providing contract pharmacy services. Different contract pharmacy fee structures exist in the market, including flat per-dispense fees, percent-age-of-reimbursement fees, predetermined reimbursement, and hybrids of the other methods. All contract pharmacy arrangements must comply with federal fraud-and-abuse laws.

Since 2010, many have sought reform of the contract pharmacy model by arguing, among other things, that: HRSA lacked the authority to create it; caused the program to grow larger than Congress intended; resulted in widespread diversion; caused manufacturers to suffer duplicate discounts, and incentivized the use of the 340B program in locations where wealthier (insured) patients reside.¹³ Some critics note that contract pharmacies often cannot identify whether a customer is a 340B eligible at the point of sale, resulting in a lack of transparency that lends itself to questions regarding duplicate discounts and diversion. However, until we have a software vendor that can address all point-of-sale decisions, identifying patients retrospectively ensures they still get it right regarding Medicaid coverage.

Why is this such an important issue?

First, there has been no comprehensive analysis regarding whether 340B contract pharmacies are truly benefitting patients. HRSA and OPA have failed patients by not initiating proper program oversight.

Second, a 2018 report from the GAO¹⁴ found weaknesses in HRSA's oversight of contract pharmacies that impede compliance. The GAO's analysis found:

¹³ Conti, R.M. & Bach, P.B. (2014, October). The 340B Drug Discount Program: Hospitals Generate Profits by Expanding to Reach More Affluent Communities. Health Affairs, 33(10), 1786-1792. <https://doi.org/10.1377/hlthaff.2014.0540>. See Also Stencel, K. (2014, November 17). Health Policy Brief: The 340B Drug Discount Program. Health Affairs. Retrieved from: <https://www.healthaffairs.org/doi/10.1377/hpb20141117.14335/full>.

¹⁴ U.S. Government Accountability Office (2018, June 21). Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement. Retrieved from: <https://www.gao.gov/products/GAO-18-480>.



JOINT STATEMENT

U.S. Senate Bipartisan 340B Working Group Request for Information – 340B Drug Pricing Program



July 24, 2023

JOINT STATEMENT – PAGE SIX

U.S. Senate Bipartisan 340B Working Group | Request for Information – 340B Drug Pricing Program
July 24, 2023

- 16 out of 28 hospitals (57%) did not provide discounted drug prices to low-income, uninsured patients who filled prescriptions at the hospital's 340B contract pharmacy; and

- Many 340B contract pharmacies earn between 12% and 20% of the revenue generated by brand-name 340B prescriptions. This means, for example, that large, publicly traded pharmacies are sharing in the 340B discounts generated for Covered Entities.

Third, the report underscored two important points:

- Weaknesses in the audit process; and
- Lack of specific guidance for the providers involved.

In the report, GAO offered seven recommendations:

- The Administrator of HRSA should require Covered Entities to register contract pharmacies for each site of the entity for which a contract exists.
- The Administrator of HRSA should issue guidance to Covered Entities on the prevention of duplicate discounts under Medicaid managed care, working with CMS as HRSA deems necessary to coordinate with guidance provided to state Medicaid programs. Social Security Section 1927(j)(1) states that 340B drugs billed to Managed Care Organizations (MCOs) are not eligible for rebates. Some states are ignoring that and blocking Covered Entities from using 340B drugs so that they can obtain the rebates. It cannot be ignored that without managed care reimbursement for 340B drugs, FQHCs are disproportionately financially impacted. Important here is establishing a national solution – not one left to the States to decide individually.
- The Administrator of HRSA should incorporate an assessment of Covered Entities' compliance with the prohibition on duplicate discounts, as it relates to Medicaid managed care claims, into its audit process after guidance has been issued and ensure that identified violations are rectified by the entities.
- The Administrator of HRSA should issue guidance on the length of time Covered Entities must look back following an audit to identify the full scope of noncompliance identified during the audit. This is a major enforcement weakness in the 340B statute. The audit only reviews a sample of drugs and does not have the information needed to order repayment. Further complicating this is the fact that current law does not permit HRSA to order repayment for any drugs other than those reviewed in the audit.
- The Administrator of HRSA should require all Covered Entities to specify their methodology for identifying the full scope of noncompliance identified during the audit as part of their corrective action plans and incorporate reviews of the methodology into their audit process to ensure that entities are adequately assessing the full scope of noncompliance.
- The Administrator of HRSA should require all Covered Entities to provide evidence that their corrective action plans have been fully implemented before closing audits, including documentation of the results of the entities' assessments of the full scope of noncompliance identified during each audit.



JOINT STATEMENT

U.S. Senate Bipartisan 340B Working Group Request for Information – 340B Drug Pricing Program



July 24, 2023

JOINT STATEMENT – PAGE SEVEN

U.S. Senate Bipartisan 340B Working Group | Request for Information – 340B Drug Pricing Program
July 24, 2023

- The Administrator of HRSA should provide more specific guidance to Covered Entities regarding contract pharmacy oversight, including the scope and frequency of such oversight.

While the U.S. Department of Health & Human Services (HHS) agreed with four of the recommendations, it took exception with three.

Among the recommendations with which HHS did not concur was the recommendation to require Covered Entities to register contract pharmacies for each site of the entity for which a contract exists. HHS stated that its current registration process is responsive to the GAO's concerns for all Covered Entity types other than hospitals and health centers. Rather than implementing the GAO recommendation, HHS stated that HRSA would make changes to its audit selection process; it will assume that all contract pharmacies registered with the parent site would also be used by all sites of the Covered Entity before selection entities for risk-based audits.

HHS also did not concur with the two recommendations requiring Covered Entities to specify their methodologies for identifying the full scope of noncompliance outlined during their audits as part of their corrective action plans and to provide evidence that these plans have been Covered Entities fully implemented before HRSA closing audits.

In its response, HHS noted that on April 1, 2018, HRSA implemented these requirements for entities subject to targeted audits (including re-audits), which represent 10% of all entities audited. HHS also expressed concern that these additional steps would significantly delay the audit process and repayments to manufacturers.

Today, another contract pharmacy challenge is the fact manufacturers do not have complete information on which Covered Entity sites have contracts with a pharmacy to dispense 340B drugs -- information that could help pharmaceutical manufacturers confirm that they were providing 340B discounts to pharmacies for the prescriptions written at contracted sites.

The majority of contract pharmacies (75%) were retail chain pharmacies, with independent pharmacies making up 20% of those in the program and 5% being other pharmacies (government-owned, physician office or other). This differs from the pharmacy landscape overall in the U.S., in which chain pharmacies comprise about half of the drugstores while another third is independent. Also, "the five biggest pharmacy chains—CVS, Walgreens, Walmart, Rite-Aid and Kroger—represented a combined 60% of 340B contract pharmacies, but only 35% of all pharmacies nationwide," according to the report.

What Do We Know About Contract Pharmacies?

First, in 2010 there were fewer than 1,300 contract pharmacies.



JOINT STATEMENT

U.S. Senate Bipartisan 340B Working Group Request for Information – 340B Drug Pricing Program



July 24, 2023

JOINT STATEMENT – PAGE EIGHT

U.S. Senate Bipartisan 340B Working Group | Request for Information – 340B Drug Pricing Program
July 24, 2023

Second, about 20,000 pharmacy locations now act as contract pharmacies for the hospitals and other healthcare providers that participate in the 340B program.¹⁵

Third, five retail pharmacy chains (CVS, Wal-Mart, Albertsons / Rite Aid, and Kroger) account for 60 percent of contract pharmacies. Walgreens remains the dominant 340B contract pharmacy participant – 31 percent of all contract pharmacies are Walgreens while the chain represents just 10 percent of all pharmacies.¹⁶ Thousands of independent pharmacies and small chains participate, as well.

Dr. Adam Fein, Ph.D., in testimony before the National 340B Commission,¹⁷ stated “Many Covered Entities have relatively small 340B contract pharmacy networks. However, some have built large networks. Our research has uncovered the following facts about these networks;¹⁸

- About 4,900 340B Covered Entities with contract pharmacies have small networks of fewer than ten pharmacies.
- About 1,000 providers have networks with 11 to 50 pharmacies, accounting for 45% of contract pharmacy arrangements.
- A small group of 156 healthcare providers (2.6% of Covered Entities with contract pharmacies) accounts for more than one-quarter of all contract pharmacy relationships. These providers have built networks with an average size of 89 pharmacies. Of the 156, 98 are disproportionate share hospitals (DSH).

Some potential recommended solutions include:

- Due to increasing concerns about the growth of contract pharmacies within the 340B program – particularly the fact that little information has been made public about whether and how they truly benefit the uninsured and underinsured patients – the Office of the Inspector General at HHS analyzed these relationships.
- This analysis, Contract Pharmacy Arrangements in the 340B Program,¹⁹ found that five out of the study’s 15 hospitals contract pharmacies offered uninsured patients the 340B discount prescription price. The other ten hospitals’ contract pharmacies required uninsured patients to pay the full, non-340B price, even though hospitals were purchasing the drugs at the deeply discounted 340B price. By contrast, 13 of the study’s community health centers reported offering the discounted 340B price to uninsured patients in at least one of their contract pharmacy arrangements.

¹⁵ National Commission on 340B. 4 (2018, June 13) (Adam J. Fein, PhD).

¹⁶ National Commission on 340B. 4 (2018, June 13) (Adam J. Fein, PhD).

¹⁷ National Commission on 340B. 4 (2018, June 13) (Adam J. Fein, PhD).

¹⁸ Fein, A.J. (2017, July 13). 10 Hospitals With 340B Contract Pharmacy Mega-Networks. Philadelphia, PA: Pembroke Consulting, Inc.: Drug Channels. Retrieved from: <https://www.drugchannels.net/2017/07/10-hospitals-with-340b-contract.html>.

¹⁹ Office of Inspector General, U.S. Department of Health and Human Services, OEI-03-13-004e1IG, February 4, 2014.



JOINT STATEMENT

U.S. Senate Bipartisan 340B Working Group Request for Information – 340B Drug Pricing Program



July 24, 2023

JOINT STATEMENT – PAGE NINE

U.S. Senate Bipartisan 340B Working Group | Request for Information – 340B Drug Pricing Program
July 24, 2023

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?

It is important to underscore the long-term value that federal HRSA grantees (Ryan White Clinics, FQHCs, hemophilia centers, etc.) have provided to patients and that they have been excellent stewards of the federal dollars given to them. They reinvest all revenue derived from the 340B program into activities that advance their HHS-approved mission of expanding access for an under-served population.²⁰

In testimony before the 340B National Commission, Sue Veer, President, and CEO of Carolina Health Centers, Inc. underscored the point that:

“The 340B statute does not specify how providers should use the savings they accrue under 340B. However, the authorizing statute for the health center program - Section 330 of the Public Health Service Act in Subsection 330(e)(5)(D) - requires that health centers must reinvest all 340B savings into activities that advance their goal of providing high-quality, affordable care to medically underserved populations. Those activities must also be consistent with the Scope of Project that HHS (specifically HRSA) has approved. There is a growing compendium of examples of how savings are being used by health centers to expand access to comprehensive primary care, improve clinical outcomes, and bend the cost curve in the right direction.”

Ironically, hospital 340B DSH hospitals are not required to report how 340B program “savings” or the revenues from 340B drug sales are used, or the extent to which the entities provide charity care using 340B program savings. As a result, all Covered Entities should be treated equally, that is, required to follow all the same reporting requirements to ensure against the “hospital” vs. “non-hospital” 340B program.

It is important that we consider all 340B program income the property of the Covered Entity. However, when shared with other entities (PBMS, TPAs, etc.) it should all be reported to HRSA including copies of any contracts. This ensures that the process is transparent, and government officials could access the information without having to request it. Moreover, these reporting requirements should apply to all Covered Entities to both levels the playing field and demonstrate true transparency.

Though the 340B statute does not contain any discussion or expectations regarding how 340B savings or revenues are to be used, some argue that Covered Entities should be required to publicly account for how they use the benefits of program participation in the name of transparency.²¹

²⁰ National Commission on 340B. 9-10 (2018, July 10) (Sue Veer).

²¹ Alliance for Integrity and Reform of 340B. (2017, October). 340B Facilities and Charity Care. Washington, DC: Alliance for Integrity and Reform of 340B. Retrieved from: http://340breform.org/wp-content/uploads/2017/10/AIR340B-Designed_340B_CharityCare_FINAL.pdf.



JOINT STATEMENT

U.S. Senate Bipartisan 340B Working Group Request for Information – 340B Drug Pricing Program



July 24, 2023

JOINT STATEMENT – PAGE TEN

U.S. Senate Bipartisan 340B Working Group | Request for Information – 340B Drug Pricing Program
July 24, 2023

Hospital groups counter that they treat more low-income patients than non-340B hospitals and provide more uncompensated care than their non-340B counterparts.²² Some have raised the notion that Covered Entities should be required to provide a certain level of “charity care” to remain eligible for the 340B program, but different stakeholders measure charity care in different ways.

Transparency is important to demonstrate how 340B “savings” are being used. Sadly, they are measured and reported differently from Covered Entity to Covered Entity.

Federal grantees (such as FQHCs, Ryan White AIDS clinics, and hemophilia treatment centers), have strict reporting requirements and must redirect revenue from programs such as 340B back to their grant services for the patients they serve.

In contrast, 340B hospitals are not required to track, let alone report, how the revenue generated from 340B program savings is used. Nor are they required to provide a minimum amount of charity care to qualify for the program. The lack of reporting requirements means that even across hospitals, 340B “savings,” net income, is measured differently. This inability to measure “savings” contributes to a lack of transparency regarding how money generated through the 340B program is being used to benefit patients or access to care. To address discrepancies in reporting requirements and better determine how 340B program savings are being used to help patients, Congress and the Administration should place the same reporting requirements on all Covered Entities participating in the program.

Hemophilia Treatment Centers (HTC), operating under the ‘HM’ 340B Covered Entity designation, are required to reinvest all revenues back into their Centers to expand services and treat more patients. Most important, because of the nature of the disease state, dollars are used for “multidisciplinary teams composed of physicians, nurses, physical therapists, social workers, health psychologists, pharmacists, genetic counselors, etc.”²³ Additionally, each year HTCs submit detailed financial reports, which specifically list program “savings,” and detail how the net program income is used to benefit patients through a rigorous review process by a team of financial, clinical, and legal experts.²⁴

Some potential recommended solutions include:

- Legislation should create data collection and reporting requirements applicable to all entities operating in the 340B program. HRSA/ OPA should be required to create a database that allows Congress and the Administration to fully understand how 340B program income is being used, and specifically, create and implement a database for hospitals that provide Congress a thorough understanding of how 340B program income is being used.
- The total amount spent to purchase 340B medicines and how much revenue they earn from the sales of those medicines, payer mix for the hospitals, and each 340B site, should be reported.

²² 340B Health. (n.d.b). 340B DSH Hospitals Treat More Low-Income Patients Than Non-340B Hospitals. Washington, DC: 340B Health: Research: Infographics. Retrieved from: https://www.340bhealth.org/images/uploads/340B_MoreLowIncomePatients.png.

²³ National Commission on 340B. 4 (2018, July 13) (Diane J. Nugent, MD).

²⁴ National Commission on 340B. 4 (2018, July 13) (Diane J. Nugent, MD).



JOINT STATEMENT

U.S. Senate Bipartisan 340B Working Group Request for Information – 340B Drug Pricing Program



July 24, 2023

JOINT STATEMENT – PAGE ELEVEN

U.S. Senate Bipartisan 340B Working Group | Request for Information – 340B Drug Pricing Program
July 24, 2023

- Transparency should become grounded in the 340B program allowing Congress and Covered Entities to understand whether and how the 340B program is generating revenue, for which specific types of Covered Entities are utilizing the program and how.
- All Covered Entities should be required to demonstrate (annually) to HRSA how 340B dollars are being reinvested in the Covered Entity operation, utilized for direct and indirect patient care, hiring medical professionals, helping reduce patient out of pocket costs, etc.
- Congress should impose charity care requirements upon all 340B DSH hospitals.
- Beginning in October of this year, manufacturer invoices for Hemophiliac factor purchased at 340B and non-340B will be submitted to Medi-Cal (the California Medicaid program) every quarter, in addition to, the pharmacy Dispense Report (factor only) which is also submitted to Medi-Cal every quarter. In addition to these successful tracking and reporting procedures for smaller programs like the HTCS or Ryan White clinics, we recommend that if hospitals are to be included in the 340B PHS programs that the following might be considered:
 - State Boards of Pharmacy draft regulations regarding pharmacy oversight of 340B.
 - Without regulations, hospital systems will not invest in pharmacy compliance costs;
 - Hospital systems staff 340B pharmacies sufficiently. In pharmacy, the number one priority will always be an accurate dispense of medication promptly;
 - Split billing software programs should be evaluated by HRSA/OPA or an appointed commission to determine the top three best in class with recommendations then made to all 340B participants (and this would be updated annually). This will help 340B participating entities to prevent diversion. Additionally, these best in class split billing software providers software should help pharmacies that receive a mix of 340B and non-340B prescriptions manage their inventory; and
 - Hospital systems offer 340B educational opportunities to their pharmacy staff.²⁵

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

The 340B Drug Pricing Program requires drug manufacturers to provide steep discounts on outpatient drugs to qualifying hospitals and safety net facilities, known as Covered Entities. Covered Entities can purchase at a discounted price “covered outpatient drugs” defined in Section 1927(k)(2) of the Social Security Act – which is the same set of drugs subject to statutorily required manufacturer rebates. But the law prohibits the same covered outpatient drug from being subject to both a 340B discount and a Medicaid rebate. This is key financial protection for manufacturers, given that both programs require steep discounts.

²⁵ National Commission on 340B. 4 (2018, July 13) (Diane J. Nugent, MD).



JOINT STATEMENT

U.S. Senate Bipartisan 340B Working Group Request for Information – 340B Drug Pricing Program



July 24, 2023

JOINT STATEMENT – PAGE TWELVE

U.S. Senate Bipartisan 340B Working Group | Request for Information – 340B Drug Pricing Program
July 24, 2023

Despite this very clear statutory prohibition, duplicate discounts continue to occur because current policies and systems are ineffective in preventing them. Further compounding the issue, the expanded use of contract pharmacies and the Affordable Care Act’s extension of Medicaid rebates to Medicaid Managed Care Organizations (MCO) increased the risk of duplicate discounts.

Solving this problem will require collaborative efforts from both CMS and HRSA to put forth guidance and policies to provide greater clarity to states, MCOs, pharmacies, Covered Entities, and other stakeholders in addressing gaps and further preventing duplicate discounts—something both Agencies have thus far not effectively done.²⁶

The growth of Contract Pharmacies, Medicaid Managed Care Organizations

Since 2010, the rapid growth of contract pharmacies participating in the 340B program has increased the complexity of the program and hampered the ability for effective management and oversight.

Many Covered Entities now have extensive contract pharmacy networks and outsource much of their 340B program implementation and operation to third-party administrators (TPAs), greatly limiting the Covered Entities’ visibility into their program utilization and compliance.

Changes made to the MDRP about MCOs in 2010 have also added to the complexity of 340B and preventing duplicate discounting. Before March 2010, the MDRP only gave states the right to obtain a rebate on drugs covered by fee-for-service Medicaid. The ACA expanded the MDRP to establish rebates for drugs covered by an MCO. In 2016, CMS issued an MCO rule requiring states and MCOs to have arrangements in place ensuring that 340B drug utilization is excluded from MCO rebate requests.²⁷ However, despite this requirement, the OIG recently found that states vary greatly in their methods of identifying duplicate discounts.²⁸

Lack of Policies to Address Duplicate Discounts in Medicaid Managed Care Organizations

HRSA has interpreted the 340B statute, which states that a Covered Entity shall not bill Medicaid for a drug subject to a rebate, to mean that compliance with the duplicate discount prohibition is solely the responsibility of the CE.²⁹ In HRSA’s view, compliance for Covered Entities means providing accurate information to the 340B Medicaid Exclusion File (MEF) and consistently applying the decision to carve in or carve out drugs purchased through 340B. HRSA created the MEF to prevent duplicate discounts in fee-for-service Medicaid, requiring Covered Entities to inform HRSA at registration whether they intend to use 340B drugs when billing Medicaid (also known as “carve in,” meaning the state should not seek a Medicaid rebate).

²⁶ United States Government Accountability Office. (2018b, June). DRUG DISCOUNT PROGRAM: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement (GAO-18-480). Washington, DC: United States Government Accountability Office: Assets. Retrieved from: <https://www.gao.gov/assets/700/692697.pdf>.

²⁷ Code of Federal Regulations (annual edition), 42 C.F.R. § 438.3(s)(3) (2016).

²⁸ IBID.

²⁹ Health Resources and Services Administration. (2017, September). Duplicate Discount Prohibition. Rockville, MD: United States Department of Health and Human Resources: Health Resources and Services Administration: 340B Drug Pricing Program. Retrieved from: <https://www.hrsa.gov/opa/program-requirements/medicaid-exclusion/index.html>.



JOINT STATEMENT

U.S. Senate Bipartisan 340B Working Group Request for Information – 340B Drug Pricing Program



July 24, 2023

JOINT STATEMENT – PAGE THIRTEEN

U.S. Senate Bipartisan 340B Working Group | Request for Information – 340B Drug Pricing Program
July 24, 2023

This information is reflected on the 340B Medicaid Exclusion File to notify states and manufacturers that drugs purchased under that Medicaid provider number or NPI are not eligible for a Medicaid rebate. Covered Entities that choose to “carve out,” do not submit NPIs to HRSA, meaning the state will secure drugs for Medicaid patients outside the 340B program and is free to seek a rebate. If a Covered Entity decides to carve-out, entirely or for a Medicaid provider number or NPI, the Covered Entity does not submit its Medicaid billing number or NPI to HRSA, and that Medicaid provider number or NPI will not be listed on the 340B Medicaid Exclusion File.

The MEF is only intended for use for fee- for-service Medicaid claims, and HRSA has not issued any duplicate discount prevention method for Medicaid MCO claims. HRSA released duplicate discount guidance in 2014 that specifically excluded MCO utilization, only stating that it is working with CMS to develop policies related to this issue.³⁰ This is particularly problematic as spending on prescription medicines through MCOs is now more than half of all Medicaid claims, and likely growing, and contract pharmacies, which have limited oversight, comprise many pharmacies in the 340B program. The lack of clarity or guidance from either Agency in addressing such a large gap of the 340B program creates greater vulnerabilities.

HRSA’s guidance requires Covered Entities to take an “all or nothing” approach to Medicaid patients and 340B products, essentially requiring Covered Entities to bill the Medicaid program under a provider identification number (NPI). The NPI must be listed on the MEF and must be used for all drugs billed by NPI.

While identifying 340B claims and exempting them from state rebate billing processes sounds like a simple proposition, the reality of operationalizing these processes is complex. For example, HRSA currently does not address how a CE that carves out should report exceptions to use 340B drugs – a scenario which can and does happen.

States recognize that contract pharmacies may have difficulty or be unable to identify whether a patient is 340B eligible, and the guidance from HRSA/OPA and CMS has been dismal. 340B drug claims can be identified at the point-of-sale using billing modifiers (such as codes established by the National Council for Prescription Drug Programs (NCPDP) for retail claims, or state-specific modifiers for medical claims). However, because eligible claims are often identified retrospectively by contract pharmacies and Covered Entities, point-of-sale requirements can be not as effective. Provider-level filters, such as National Provider Identifiers, can be too broad when the provider submits claims involving both 340B and non-340B drugs (as is typically the case with contract pharmacies).

³⁰ Health Resources and Services Administration. (2014, December 12). CLARIFICATION ON USE OF THE MEDICAID EXCLUSION FILE (2014-1). Rockville, MD: United States Department of Health and Human Services: Health Resources and Services Administration: Program Requirements: Policy Releases. Retrieved from: <https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/clarificationmedicaidexclusion.pdf>.



JOINT STATEMENT

U.S. Senate Bipartisan 340B Working Group Request for Information – 340B Drug Pricing Program



July 24, 2023

JOINT STATEMENT – PAGE FOURTEEN

U.S. Senate Bipartisan 340B Working Group | Request for Information – 340B Drug Pricing Program
July 24, 2023

Modification to the “all or nothing” approach, however, would require thoughtful consultation with states to ensure it does not have unintended consequences or create new challenges.

Some potential recommended solutions include:

Because of the lack of regulations from HRSA and OPA, different entities have different standards for identifying 340B eligible prescriptions. This means Covered Entities and 340B vendors will classify prescriptions via a nonpublic process that is also not subject to any current federal regulations.

We are recommending that HRSA/OPA and the HHS OIG work with the top five 340B software vendors (Sentry Data Systems, Rx Strategies, PharMedQuest, McKesson, and Cardinal Health) to create a national database to prevent the fear of and lack of compliance with HRSA/OPA 340B oversight. Such a database would ensure that the OIG at HHS has complete access to all 340B claims being Covered Entities.

This will create a common set of requirements to address the lack of different regulations, different standards for identifying 340B eligible prescriptions. It will also reassure Congress, HHS, and the pharmaceutical manufacturers that 340B determination is being undertaken in a uniform and agreed upon set of standards (Adam Fine JMCP Article).

- Affirm that Covered Entities have a right to use 340B drugs when billing Medicaid MCOs.
- Prohibit reimbursement discrimination against 340B drugs billed to MCOs.
- Require the use of a 340B-specific claims modifier (at the point-of-sale or otherwise) when submitting Medicaid claims involving 340B drugs (as the HELP Act would).
- Establish a nationwide clearinghouse or retrospective claims identification process to identify and remove 340B claims from Medicaid managed care drug rebate claims that:
 - Could be funded with a user fee on Covered Entities that would be administered without the involvement of manufacturers; and
 - Could be a private sector solution.

5. What specific policies should be considered to implement common sense, targeted program integrity measures that will improve the accountability of the 340B program and give health care stakeholders greater confidence in its oversight?

HRSA’s Office of Pharmacy Affairs (OPA) administers the 340B program but has limited authority to regulate it. The 340B statute only provides HRSA with rulemaking authority in three areas:

- 340B ceiling price calculation;
- Manufacturer overcharge civil monetary penalties; and
- Alternative dispute resolution.



JOINT STATEMENT

U.S. Senate Bipartisan 340B Working Group Request for Information – 340B Drug Pricing Program



July 24, 2023

JOINT STATEMENT – PAGE FIFTEEN

U.S. Senate Bipartisan 340B Working Group | Request for Information – 340B Drug Pricing Program
July 24, 2023

In other key areas, it has issued guidance, including, for example, defining a 340B patient, allowing hospitals to expand their access to 340B drugs through offsite outpatient facilities and creating rules that allow unlimited numbers of contract pharmacy arrangements for all covered entities. These are areas critical to the functioning of the program, yet this guidance has been specifically called out by the HHS, OIG, and GAO³¹ as either being too vague (patient definition)³² or leading to increased incidence of diversion and duplicate discounts (contract pharmacy).³³

To take critical steps to improve 340B program integrity, HRSA should use the authority it already has to issue new interpretive guidance to tighten up the definition of who constitutes a 340B patient and place adequate limits on the contract pharmacy program.

Congress could also choose to revise the 340B program, while concurrently granting HRSA the regulatory authority to create additional rules to better govern the program. It is important to recognize that HRSA has not done well with its proposed guidance. As a result, if this cannot be fixed, then Congress, HHS, and the White House will need to explore a market-based solution. Additionally, defining who are 340B patients is long-overdue. In an October 24, 1996, Federal Register notice on the OPA website, HRSA defined eligible 340B patients using three criteria:³⁴

- First, the individual must have an established relationship with the Covered Entity in which the Covered Entity maintains records of the individual's care;
- Second, the individual must receive care from a professional employed by the Covered Entity, or under a contract or other arrangement (such as a referral consultation) in which the Covered Entity maintains responsibility for the care of the individual; and finally,
- Third, the individual must receive medical services from the Covered Entity or a contractor of the Covered Entity that comply with the scope of services granted to that Covered Entity.³⁵ Ironically, this only applied to grantees, not hospitals. The goal of these criteria was to ensure that the person was receiving care from the Covered Entity, not merely access medication at a 340B price with this, and for years after, the controversy surrounding the definition of the patient escalated.³⁶

³¹ United States Government Accountability Office. (2011, September). DRUG PRICING: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement (GAO-11-836). Washington, DC: United States Government Accountability Office: Products. Retrieved from: <https://www.gao.gov/assets/330/323702.pdf>.

³² Examining HRSA's Oversight of the 340B Drug Pricing Program, Testimony of: Erin Bliss Assistant Inspector General for Evaluation and Inspections Office of Inspector General U.S. Department of Health and Human Services, July 18, 2017, Testimony Before the United States House of Representatives Committee on Energy and Commerce: Subcommittee on Oversight and Investigations.

³³ Office of Inspector General. (2014, February 04). Memorandum Report: Contract Pharmacy Arrangements in the 340B Program (OEI-05-13-00431). Washington, DC: United States Department of Health and Human Services: Office of Inspector General: Reports. Retrieved from: <https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf>.

³⁴ Medicare Payment Advisory Commission, The, (2015, May). Report to the Congress: Overview of the 340B Drug Pricing Program, pp. 11-12. Washington, DC: The Medicare Payment Advisory Commission: Reports. Retrieved from: <http://medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0>.

³⁵ Ibid at MedPac, pg. 8.

³⁶ Ibid at MedPac, pg.13. See Also Gellad, W.F. & James, A.E. (2018, February 08). Discounted Drugs for Needy Patients and Hospitals — Understanding the 340B Debate. The New England Journal of Medicine, 2018(378), 501-503. Z DOI: 10.1056/NEJMp1716139; Fein, A.J. (2016, March). Challenges for Managed Care from 340B Contract Pharmacies. Journal of Managed Care & Specialty Pharmacy, 22(3), 197-203. DOI: 10.18553/jmcp.2016.22.3.197; Office of Inspector General. (2015, March 24). Examining the 340B Drug Pricing Program. Washington, DC: United States Department of Health and Human Services: Office of Inspector General. Retrieved from: <https://oig.hhs.gov/testimony/docs/2015/maxwell-032415.pdf>.



JOINT STATEMENT

U.S. Senate Bipartisan 340B Working Group Request for Information – 340B Drug Pricing Program



July 24, 2023

JOINT STATEMENT – PAGE SIXTEEN

U.S. Senate Bipartisan 340B Working Group | Request for Information – 340B Drug Pricing Program
July 24, 2023

On August 27, 2015, HRSA released³⁷ changes to the “patient” definition as part of its proposed omnibus guidance, cheerfully known as the mega-guidance. The goal of the mega-guidance was to clarify many issues that 340B proponents and opponents have struggled with since the inception of the program.³⁸

Federal agencies – such as GAO – have issued several reports on the 340B program and testified before Congress. Perhaps the most biting report, “Manufacturer Discounts in the 340B Program Offer Benefits, But Federal Oversight Needs Improvement,” underscored the fact that HRSA’s oversight of the program was inadequate.³⁹ That report noted that the current patient definition allows patients to become eligible if they receive services from providers through “other arrangements” which were not defined.

The most significant recommended a change in the mega-guidance was a new, six-pronged definition of a “340B patient”– “which aimed to address the ambiguity in the current patient definition.” Under this proposed definition, an individual needed to meet these criteria:⁴⁰

- a) The individual receives a healthcare service at a Covered Entity site, which is registered for the 340B program and is listed on the public 340B database;
- b) The individual receives a health care service from a health care provider employed by the Covered Entity, or who is an independent contractor of the Covered Entity, such that the Covered Entity may bill for services on behalf of that provider;
- c) An individual receives a drug that is ordered or prescribed by the Covered Entity because of the service described in (2). An individual will not be considered a patient of the Covered Entity if the only health care received by the individual from the Covered Entity is the infusion of a drug or the dispensing of a drug;
- d) The individual receives a health care service that is consistent with the Covered Entities scope of grant, project, or contract. [Note: this does not apply to hospital Covered Entities];
- e) The individual is classified as an outpatient when the drug is ordered or prescribed. The patient’s classification status is determined by how the services are billed to the insurer (e.g., Medicare, Medicaid, private insurance). An individual who is self-pay, uninsured, or whose cost of care is covered by the Covered Entity will be considered a patient if the Covered Entity has clearly defined policies and procedures that it follows to classify such individuals consistently; and
- f) The individual has a relationship with the Covered Entity such that the Covered Entity has a provider- to-patient relationship, that the responsibility for care is with the Covered Entity, and that each element of this patient definition in this section is met for each 340B drug.

³⁷ Morse, C.M. (2015, September 03). Drastic Changes in “Patient” Definition as HHS Releases the Long-Awaited Proposed 340B Omnibus Guidance [Ober|Kaler]. Washington, DC: Baker, Donelson, Bearman, Caldwell & Berkowitz, PC: The Daschel Group: The Howard Baker Forum: Baker Donelson: Publications. Retrieved from: <https://www.bakerdonelson.com/drastic-changes-in-patient-definition-as-hhs-releases-the-long-awaited-proposed-340b-omnibus-guidance>.

³⁸ Johnson, S.R. (2015, August 27). 340B ‘mega-guidance’ may narrow drug discounts. Chicago, IL: Crain Communications, Inc.: Modern Healthcare: Government: Law and Regulation. Retrieved from: <https://www.modernhealthcare.com/article/20150827/NEWS/150829882>.

³⁹ United States Government Accountability Office. (2011, September). DRUG PRICING: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement (GAO-11-836). Washington, DC: United States Government Accountability Office: Products. Retrieved from: <https://www.gao.gov/assets/330/323702.pdf>.

⁴⁰ 340B Drug Pricing Program Omnibus Guidance, 80 FR 52300 (2015, August 28).



JOINT STATEMENT

U.S. Senate Bipartisan 340B Working Group Request for Information – 340B Drug Pricing Program



July 24, 2023

JOINT STATEMENT – PAGE SEVENTEEN

U.S. Senate Bipartisan 340B Working Group | Request for Information – 340B Drug Pricing Program
July 24, 2023

The mega-guidance was eventually withdrawn by HHS in 2017. However, withdrawal does not mean gone forever. In the spring of 2018, HHS Secretary Alex Azar announced that, as part of its broader drug pricing initiative, HHS was seeking comment from 340B stakeholders regarding the patient definition and a variety of other matters.⁴¹ However, it is unclear if the Administration is planning to release a new patient definition.

Despite the rancor on all sides regarding who is or should be a 340B patient, we believe that there is an opportunity to tighten the definition, without strangling the program.

We believe there is a middle ground that should be considered. Healthcare coverage has dramatically evolved since the inception of the 340B program. We have seen recent decreases in the number of uninsured: the growth of high deductible health plans; and most recently, the ability for Americans to once again purchase health plans that are not as comprehensive as what the Obama Administration sought after the initial passage of the Affordable Care Act. Like health-care coverage for Americans, it is essential that the 340B program evolve to recognize a new reality – increasing numbers of patients who cannot afford the medications they need, despite employer-provided coverage. Moreover, employers also see coverage costs grow dramatically.

We recommend the existing HRSA patient definition be left in place but make the following modifications: For those patients being discharged from the hospital, the prescriptions given to them as they leave will continue to be considered outpatient prescriptions. This is important to reduce avoidable readmissions by ensuring patients who are discharged have the medications needed to get them healthier. Most importantly, if they cannot afford the medications, the hospital will use its 340B revenue to cover those expenses.

Although some hospital lawyers may insist that this would be considered an illegal “inducement” or inurement for hospitals to provide free or markedly reduced-cost medications to patients. Additionally, a possible alternative would be to use 340B savings to help patients would be to create a community-based risk pool in which a portion of net income or “savings” would be placed and managed by a third party to address patients in need. This program could be managed by entities such as a nonprofit PBM, a community-based charity care program, or a patient-based organization, with proper credentials that are approved by biopharmaceutical corporations and HRSA.

Second, patients referred for infusion therapy must be ongoing patients of the referring Covered Entity. This means that when an FQHC, for example, refers a patient to a hospital-based infusion center or other 340B qualified infusion entity, the link between the patient and the Covered Entity cannot be broken. That patient must retain his or her patient status with the referring Covered Entity.

⁴¹ Luthi, S. (2018, May 14). HHS looks to alter 340B patient definition, regulatory authority for drug pricing initiative. Chicago, IL: Crain Communications, Inc.: Modern Healthcare: Government: Law and Regulation. Retrieved from: <https://www.modernhealthcare.com/article/20180514/NEWS/180519957>.



JOINT STATEMENT

U.S. Senate Bipartisan 340B Working Group Request for Information – 340B Drug Pricing Program



July 24, 2023

JOINT STATEMENT – PAGE EIGHTEEN

U.S. Senate Bipartisan 340B Working Group | Request for Information – 340B Drug Pricing Program
July 24, 2023

Further, we recommend the elimination of two Covered Entities both benefiting from 340B for the same patient. In other words, when a patient is referred to another Covered Entity for infusion therapy, the referring Covered Entity shall ship the medication with the patient or replenish it using its 340B program. As a result, the second Covered Entity will be paid for their services, but not benefit from the 340B program.

The exception for all of this would be when a patient is referred from an FQHC or other Covered Entity to a 340B eligible hospital, and it is discovered that the patient has an illness that the FQHC had not discovered. For any new outpatient medical treatment provided by the hospital, any medication required for that specific illness would be written by a hospital-based medical provider, and the 340B savings would remain with the hospital. However, if the patient is referred to his or her FQHC or another grantee for disease management, that entity assumes primary responsibility.

Furthermore, if medications are provided, the prescribing entity would realize those savings. The savings go to the entity prescribing and delivering the service if the patients' medical record is housed there. End-user protections for qualified patients should be considered in any final definition, so as to ensure patient choice of provider is sufficiently supported. A definition with a time-limited "lock-out" period might offer this type of protection while supporting federal and state laws and regulations prohibiting "doctor shopping".

Third, it is critical in rural America that we create 340B flexibility, recognizing that access to infusion therapy and other 340B-covered services may not be as readily available as it is in other service areas. To address this issue, we encourage Covered Entities in rural areas to explore partnering with Home Health Agencies, Visiting Nurses, and other professionals to provide the infusion service without the need for hospital partners. However, should medication be recommended for the patient, only the 340B Covered Entity that holds the patient's medical record could prescribe.

Fourth, it is important that all federally funded 340B programs embrace transparency and a standard for the use of 340B program income. For those participating in the 340B program, we believe that complete 340B program transparency should require all Covered Entities to report all profit of savings and document that all net income is re-invested in patient care services Covered Entities.

This would include but not be limited to hiring medical care staff that exclusively treat low-income, uninsured, and otherwise vulnerable patients, assisting patients with copays and deductibles with the discretion left to each Covered Entity to establish their program, and report it annually to HRSA / OPA.

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



JOINT STATEMENT

U.S. Senate Bipartisan 340B Working Group Request for Information – 340B Drug Pricing Program



July 24, 2023

JOINT STATEMENT – PAGE NINETEEN

U.S. Senate Bipartisan 340B Working Group | Request for Information – 340B Drug Pricing Program
July 24, 2023

One of the most critical components of accountability stems from transparency. The primary means of transparency for the 340B Program is provided by audits, as allowed by the program’s statutory language. However, the statutory language is vague as to any role of private stakeholder audit or potential auditing agencies other than HRSA for non-Grantee Covered Entities. Lack of transparency and accountability have recently earned an otherwise quiet program very splashy headlines due to:

- Syphoning 340B revenues from needy communities and steering those revenues to richer communities;⁴²
- Buying up competitive medical practices;
- Not being physically located in a geography of need, making access to care logistically harmful for patients;⁴³
- Paying salaries of non-medical adjunct staff, like a football coach;⁴⁴ and
- Failure to align with the charitable principles behind the program and locking needy patients out of accessing any care.⁴⁵

While Grantee entities are required to report annually to HRSA all program revenues and re-investments into qualifying programs, this is achieved by means of the Grant contract, rather than any regulatory or statutory requirement. Other covered entities, specifically disproportionate share hospitals, qualify by way of local or state municipal service contracts. However, there is no uniform standard for these contracts and hospitals are allowed to seek pre-dated contracts when found out of compliance of this requirement to avoid audit findings.⁴⁶ A GAO report considered this practice to “undermine the integrity of HRSA’s audits.” This area of local and state contracting poses an opportunity to shift some of the labor burden from HRSA to state and local governments by establishing minimum standards for qualifying contracts.

We would urge language, either by statute or rulemaking, that establishes minimum standards for qualifying contracts to include some combination of provisions which ensure some or all the following are enforceable:

- Documents must be actual contracts, with legally binding language and compliance penalties.
- Definition of qualifying patient (i.e., FPL ceiling similarly situated to determination or declaration of income as Medicaid or the Ryan White HIV/AIDS Program).

⁴² Thomas, Katie, and Jessica Silver-Greenberg (2022, September 24). Profits Over Patients: How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits. The New York Times. Retrieved from <https://www.nytimes.com/2022/09/24/health/bon-secours-mercy-health-profit-poor-neighborhood.html>.

⁴³ Alliance for 340B Integrity and Reform (2023, July 12). Two-Thirds of 340B DSH Hospitals Are Not Located in Medically Underserved Areas. Retrieved from <https://340breform.org/wp-content/uploads/2023/07/AIR340B-Press-Release-MUA-2023-FINAL.pdf>.

⁴⁴ Korman, Chris (2021, December 6). Miami is reportedly using medical profits to hire a new football coach, which made the internet properly irate. ForTheWin. Retrieved from <https://ftw.usatoday.com/lists/miami-is-reportedly-using-medical-profits-to-hire-a-new-football-coach-which-made-the-internet-properly-irate>.

⁴⁵ Kliff, Sarah, and Jessica Silver-Greenberg (2023, June 1). This Nonprofit Health System Cuts Off Patients With Medical Debt. The New York Times. <https://www.nytimes.com/2023/06/01/business/allina-health-hospital-debt.html>.

⁴⁶ United States Government Accountability Office (2019, December). 340B DRUG DISCOUNT PROGRAM: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements. (GAO-20-108). Washington, DC: United States Government Accountability Office: Products. Retrieved from <https://www.gao.gov/assets/gao-20-108.pdf>.



JOINT STATEMENT

U.S. Senate Bipartisan 340B Working Group Request for Information – 340B Drug Pricing Program



July 24, 2023

JOINT STATEMENT – PAGE TWENTY

U.S. Senate Bipartisan 340B Working Group | Request for Information – 340B Drug Pricing Program

July 24, 2023

- Minimum communication and program standards regarding financial assistance or charity care (including protections from program eligibility actions which may follow a patient in other aspects of their lives, such as a credit or asset check).
- Patient protections from predatory collections activities.
- Minimum qualifying rates of financial assistance or charity care, as a segregated metric from offsets from federally funded public health and payor programs (this might also be achieved by requiring a ratio of financial assistance or charity care relative to bad debt as reported on Schedule H).
- Metrics defining demonstration of allowable re-investment into communities in which revenues are generated (with geographical adjustments or scoring for rural areas).
- Non-listed other recommendations for strengthening hospital qualifying contracts should be considered.

Acknowledging HRSA's limited capacity to audit covered entities requires creative thinking as to other government entities or private stakeholders and their role and potential responsibilities in ensuring transparency. An underutilized consideration includes amendment to the federal tax code and leveraging the fiscal expertise and capacity of the Internal Revenue Service. Establishing a dedicated tax form, accounting rules for segregated banking accounts for non-Grantee, similarly situated to those trust accounts required for lawyers or landlord entities, wherein dollars or a dedicated program are held separate and apart from general accounting. A segregated account ensures a streamlined ability to audit revenues and use of program dollars.

Segregated accounting is particularly important as how 340B Program revenues might be contributing to hospital consolidation and pharmacy "deserts" remains unclear, though the issues are causing dramatic impacts for patients and threatening meaningful access to care. A dedicated, federal tax form for non-Grantee entities to describe necessary details of their programs would prove greatly beneficial to encouraging transparency, both for interested government agencies and for the general public in which these covered entities are supposedly serving.

Similarly, empowering the Federal Trade Commission to pursue anti-trust action against consolidation efforts, where 340B Program revenues are either funding anti-competitive consolidation or a considerable factor in pursuing investments which amount to consolidation is another essential tool for ensuring the integrity of the program. An additional, indirect benefit of preventing anti-competitive consolidation includes market encouragement of retaining healthcare staffing levels and protecting private providers from aggressive tactics utilized by private equity firms and large hospital systems.



JOINT STATEMENT

U.S. Senate Bipartisan 340B Working Group Request for Information – 340B Drug Pricing Program



July 24, 2023

JOINT STATEMENT – PAGE TWENTY-ONE

U.S. Senate Bipartisan 340B Working Group | Request for Information – 340B Drug Pricing Program
July 24, 2023

Legislators might also consider the role of private stakeholders to diffuse potential increases in government expenditure by directing HRSA to establish a private audit process, with a mind toward ensuring patient privacy remains protected, in which manufacturer stakeholders could initiate a private audit process of contract pharmacies, allowing for the for-profit stakeholders to navigate standards of transparency with HRSA's role returning to "referee" – ensuring auditing is not punitive, targeted, or disruptive, in nature and appropriately safeguarding the interests of those entities involved.

Lastly, private payors, particularly Pharmacy Benefit Managers (PBMs), should never be allowed to profit from the 340B Program. These payors carved a niche market by arguing their ability to decrease patient and sponsor costs by way of negotiating purchasing. Instead, the 340B Program presents such a significant revenue stream for PBMs that one of the largest PBMs lowered its anticipated *profits* by \$200 million in 2023 alone.⁴⁷ Many PBMs operate either a mail-order pharmacy program or a contract pharmacy, establishing a self-dealing situation to the detriment of patients and covered provider entities alike. Legislators should consider introducing statutory language or otherwise authorizing the Federal Trade Commission to restrict the ability of PBMs, especially those which have a vested interest associated with a contract pharmacy, to engage with the 340B for the sake of profit-making.

The Community Access National Network and ADAP Advocacy Association wish to congratulate lawmakers for engaging on the issues facing the 340B Program. We particularly wish to thank the legislative policy staff for prioritizing input from well-informed patients and patient advocacy organizations. Too many provider organizations claim to represent patients and speak on their behalf, but their interests aren't necessarily aligned with the interests of patients; in fact, many have no patients on their governing bodies, while also lacking adequate diversity. The 340B Program will continue to be plagued by problems if solutions are centered on the interests of non-patient stakeholders. This vital program has yet to live up to its potential or its intent. Re-orienting the program to be more patient-driven, aligning with most Grantees already performing to heightened standards, will only serve to strengthen the program.

Respectfully submitted by,

Jen Laws
President & CEO
Community Access National Network

Brandon M. Macsata
CEO
ADAP Advocacy Association

bmm:JL

⁴⁷ Tepper, Nona (2023, June 9). Drugmakers restricting 340B pharmacy sales threaten PBMs profits. Modern Healthcare. Retrieved from <https://www.modernhealthcare.com/payment/drugmakers-340b-sales-pbms-pharmacy-benefit-managers-caremark-express-scripts-optumrx>.