

340B Commission's
FINAL REPORT ON THE



DRUG DISCOUNT PROGRAM

The Issues Spurring Discussion,
Stakeholder Stances
and Possible Resolutions



February 2019

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Why This Report?

THE 340B DRUG PRICING PROGRAM was created at a time when nonprofit health-care providers were spending to ensure that patients had access to medicine to treat acute and chronic healthcare problems. Their goal then and today – help ensure that the patient’s acute care problem did not become chronic.

At the inception of the 340B program, the number of the uninsured were greater, many state Medicaid programs limited who was eligible, and access to free or subsidized medication programs was not as robust as it is today.

Today, 26 years later, the 340B program has grown in the number of people being served and the kinds of what providers allowed to participate in the program. It is important to underscore the value of the program in helping patients access medications at the most affordable cash price. Participation in the Program results in significant savings estimated to be

20% to 50% on the cost of pharmaceuticals Covered Entities.

But like every federal program, as it ages in place, questions arise. Should the status quo just be maintained? Should Congress take a new and fresh look at the definition of the patient as well as whether the number and types of providers have grown too much? Is the program transparent, and how should this area be enhanced/modified? Why are hospitals participating in the 340B program treated differently than other covered entities in how they can spend 340B program revenue? And, the list goes on.

The Community Access National Network (CANN)¹ is a 501 (c)(3) national nonprofit organization has been involved in 340B policy issues for many years. Because of its commitment to the program, it recognized an important opportunity to gather a diverse group of healthcare professionals to take a careful and

¹The Community Access National Network (CANN) is a 501(c)(3) national nonprofit organization (formerly incorporated under the “Ryan White CARE Act Title II Community AIDS National Network”) focusing on public policy issues relating to HIV/AIDS and Viral Hepatitis. CANN’s mission is 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. CANN’s coalition-based work is done on behalf of the patient advocacy groups, pharmaceutical partners, and government agencies.

thoughtful look at the program with the hope of providing Congress, the White House, and other elected officials and regulators with an open assessment of the program today and tomorrow. As a result, the National 340B Commission was launched co-chaired by Bill Arnold the President of CANN, and Jeffrey Lewis, a CANN board member.

What follows is our report and recommendations. It tackles some of the tough

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choices Covered Entities Congress, the White House, Regulators, and State Legislators must ultimately address. The 340B program, like many federal programs, needs elected officials to address the short and long-term challenges. The longer they are ignored, the greater the opportunity for confusion. Specifically, as outlined below, we hope that Congress, the White House, Regulators, and State Legislators will address:

- The challenge of duplicate billing under the Medicaid program. At a time when Governors and State Legislators are seeking greater clarity in the Medicaid program, they must decide whether and why covered entities should be allowed to choose between 340B priced medications or those that are eligible for rebates.
- Hospitals participating in the 340B program are treated differently than other covered entities. Specifically, they are operating opaquely not transparently like other covered entities. They are not required to report how they re-invest (if they do) their 340B program revenue and how.
- Hemophiliac Treatment Centers operate as the most transparent and efficient 340B covered entity. In California, they have created a program that protects the state from the fear of duplicate billing and loss of state rebate

revenue. Their efforts should be addressed nationally and recognized as a national model for every state and federal agency operating in the 340B space.

- Technology vendors like Sentry Data Systems, Rx Strategies, and Pharm Med Quest should be hired to assist the Department of Health and Human Services Covered Entities create a national system where every medication can at the retail counter be immediately determined if it was a 340B medication or not. While the retroactive analysis is helpful, in this age of technology we should be able to avoid it.
- Who the 340B program should be helping continues as an important and controversial question, proponents argue that the status quo should not be changed. But even reasonable minds would want to know whether this program should be using 340B program revenue also to be helping people in high deductible health plans? What about people who are fully insured but in need of expensive specialty medications that require a percentage co-pay? Should covered entities be required or given the flexibility to use 340B revenue to assist them? The longer the needs of the middle class are ignored, the greater the disparities and the fostering of more programs that care for the poor while ignoring the legitimate needs of working families whose needs are just as great.

As you review the Commission's report and have questions, comments or concerns, please feel free to contact us.

Sincerely,



William Arnold
Commission Co-Chairman



Jeffrey Lewis
Commission Co-Chairman

The Issues Spurring Discussion, Stakeholder Stances and Possible Resolutions

The 340B Drug Pricing Program (from now on “340B program”) began as a small, but a highly effective component of our nation’s healthcare safety net. In the 26 years since it was created, many at-risk clinics and the complex patients they served have benefitted from this program. However, the 340B program in 2018 is a very different program than what was created in 1992.

Members of Congress, economists, the Department of Health and Human Services (HHS), the Office of the Inspector General (OIG), the Government Accountability Office (GAO), patient advocacy groups, consumer watchdogs and the pharmaceutical industry have all argued that considering the program’s evolution, it needs to be reevaluated and possibly overhauled.² Congress appears interested in taking action but faces a challenge in determining how to maintain the

integrity of this program while addressing the numerous concerns raised. To aid in this process, we have evaluated the 340B program through multiple lenses and make specific recommendations regarding which areas of the program require refocusing and how to ensure against abuse.

Since the enactment of the Affordable Care Act (ACA) in 2010, Members of Congress have scrutinized the 340B program. Concerns about the growth of the 340B program as a revenue source for hospitals rather than its intended underserved populations have been raised by program stakeholders.

Congress has increased its focus on the 340B program by continuing to debate taking action on amending the 340B program this even though both the Senate and House have held hearings, the introduction of multiple bills and a detailed report from the House

²Reid, J. (2018, January 10). *House Energy and Commerce Report Calls for 340B Discount Drug Program Overhaul*. Washington, DC: Morning Consult. Retrieved from: <https://morningconsult.com/2018/01/10/house-energy-and-commerce-report-calls-for-340b-discount-drug-program-overhaul>. See Also United States 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>

Energy and Commerce Committee.³ The reasons for Congressional action vary, but can best be summed up as follows:

- First, some are arguing for greater transparency in the 340B program – how much program is generated by each covered entity, how it is re-invested into the program and how are people specifically helped.
- Second, the program has evolved since inception where today PBMs, Managed Care Organizations (MCOs) and states have all become involved in the program in ways that were not originally anticipated; and
- Finally, it is important that Congress examine all federal programs even those working to determine if the reasons they were originally created are still true today. The 340B program has been an enormous help to many people over the years, but it has also become a revenue target for some providers too.

³Energy and Commerce Committee. (2018, January 10). *Review of the 340B Drug Pricing Program*. Washington, DC: United States House of Representatives: Energy and Commerce Committee. Retrieved from: https://energycommerce.house.gov/wp/content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf

Background

Under the 340B program, drug manufacturers seeking Medicaid coverage for their products must enter into pharmaceutical pricing agreements with HHS in which they promise to sell outpatient drugs to eligible providers at prices not to exceed a price set by a formula.

Most drug manufacturers participate in this program. Facilities eligible to participate in this program, called “covered entities,” include certain hospitals and safety net clinics. Participating clinics are known as grantees because they typically receive federal grants and include many federally qualified health centers, Ryan White HIV/AIDS clinics, and hemophilia treatment centers. Certain types of non-profit hospitals are also potentially eligible for 340B. The vast majority (about 80 percent) of all 340B sales are to hospitals that qualify for 340B because they serve a disproportionately high proportion of low-income

Medicare and Medicaid patients (known as DSH hospitals).⁴ Children’s hospitals, certain rural hospitals, and freestanding cancer hospitals also may participate in 340B if they meet the eligibility criteria.

There are rules, regulations, and guidance that are supposed to provide parameters around the 340B designation. However, as the program has grown, the government agencies tasked with overseeing it has found that several keystone elements, such as the definition of who constitutes a 340B patient or the Covered Entities for preventing a drug from being subject to both a Medicaid rebate and a 340B discount, are vague and are likely undermining a program meant to help uninsured and vulnerable patients.⁵

The 340B program was created by Congress in 1992 to ensure that the uninsured and other financially vulnerable patients paying out of pocket would have access to needed

⁴Hatwig, C. (2016, July 10). *Apexus Update*. Presented at the 340B Coalition Summer Conference, Washington, DC.

⁵Centers for Medicare and Medicaid Services. (2018, November 13). *Medicaid Drug Rebate Program*. Baltimore, MD: Center for Medicare and Medicaid Services: Medicaid: Prescription Drug. Retrieved from: <https://www.medicare.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html>

medications through nonprofit healthcare providers. The 340B program was designed to assist savings for nonprofit healthcare providers by allowing them to purchase outpatient prescription drugs at discounted prices.⁶ To have their medications covered by Medicaid, manufacturers provide steep discounts to Covered Entities.⁷

Covered Entities are subject to some restrictions. They may only provide drugs purchased

otherwise) and other patient revenues into the federal grant project. The grantees also must report how they budget for and spend such “program income.”¹⁰

In contrast, current 340B program rules do not set any standards for how 340B discounts should be used by hospitals.¹¹ Hospital utilization of 340B is concentrated in the disproportionate share (DSH) hospitals that comprise 80% of all 340B sales.¹² The lack of transparency and program standards for how DSH hospitals use 340B discounts, combined with the significant growth of the program driven by these hospitals, has greatly eroded the 340B program’s initial vision. As a 2014 Health Affairs study on 340B put it, the program has evolved “from [a program] that serves vulnerable communities to one that enriches hospitals.”¹³

But, it is important that we also not ignore the positive impact over the years that the 340B program had on helping some hospitals treat the medication needs of the uninsured and under-insured. It allowed rural hospitals and large center city and county hospitals to have the additional revenue to cover the medication costs for the most vulnerable at a time when the federal government did little or nothing to help. With the passage of the Affordable Care Act and Medicaid expansion, many of these hospitals have received a financial boost. However, in some rural communities, increasing numbers of the uninsured and under-insured (those enrolled in high deductible health plans and/or Medicare Part-D) continue to present in hospital emergency departments. Administrators understand that increasing numbers of these individuals and families do not have the financial resources to pay for their medications. As a result, if the hospital

4 **The federal grantees, including federally qualified health centers, Ryan White HIV/AIDs clinics, and HTC’s must reinvest any revenues from the sale of drugs (340B or otherwise) and other patient revenues into the federal grant project.**

at 340B program pricing to patients who meet the patient definition (the diversion prohibition) and cannot bill Medicaid for reimbursement for 340B drugs if the drugs are subject to a manufacturer rebate. Duplicate discounts are prohibited under federal law. Disproportionate share hospitals (DSHs), children’s hospitals and freestanding cancer hospitals may not obtain covered outpatient drugs through a group purchasing arrangement (GPO prohibition).⁸ Freestanding cancer hospitals and rural hospitals are not entitled to 340B program pricing for drugs with an orphan designation – a designation from the Food and Drug Administration that a drug meets certain criteria for treating a rare disease or condition – (orphan drug prohibition).⁹

The federal grantees, including federally qualified health centers, Ryan White HIV/AIDs clinics, and HTC’s must reinvest any revenues from the sale of drugs (340B or

⁶Mulcahy, A.W., Armstrong, C., Lewis, J., & Mattke, S. (2014). *The 340B Prescription Drug Discount Program: Origins, Implementation, and Post-Reform Future*. Pittsburgh, PA: RAND Corporation: Content: Perspectives. Retrieved from: https://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE121/RAND_PE121.pdf

⁷United States Government Accountability Office. (2018a, May 15). *DRUG DISCOUNT PROGRAM: Status of Agency Efforts to Improve 340B Program Oversight* (GAO-18-556T). Washington, DC: United States Government Accountability Office. Retrieved from: <https://www.gao.gov/assets/700/691742.pdf>

⁸Code of Federal Regulations (annual edition), 42 C.F.R. § 256b(a)(4)(L)(iii) (2016).

⁹Code of Federal Regulations (annual edition), 42 C.F.R. § 256b(e) (2016).

¹⁰Code of Federal Regulations (annual edition), 45 C.F.R. § 75.2 (definition of “program income”) and § 75.309 (2002) (use of “program income”).

¹¹*National Commission on 340B*. 3 (2018, July 13) (Testimony of Rena M. Conti, Ph.D.).

¹²Alliance for Integrity and Reform of 340B. (2016). *BENEFITING HOSPITALS, NOT PATIENTS: An Analysis of Charity Care Provided by Hospitals Enrolled in the 340B Discount Program*. Washington, DC: Alliance for Integrity and Reform of 340B. Retrieved from: http://340breform.org/userfiles/2016_AIR340B_Avalere_Charity_Care_Study.pdf

¹³Conti, 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>

does not cover the expense, the patient will re-appear again and again in their Emergency Department. Many patients of FQHC's on high deductible plans and or Medicare Part-D cannot afford the cost of their prescriptions and are often forced to go without their medications, resulting in poor adherence and compliance which leads to uncontrolled/unmanaged diseases ultimately resulting in escalating healthcare costs.

Some argue that the program has become unrecognizable. For example, while it took 15 years for annual 340B sales to reach \$3.9 billion (in 2007), it was really after 2010 that sales at the 340B price grew by nearly 400% to reach 19.3 billion.¹⁴ The Med PAC May 2015 Report to Congress provides data showing that, between 2005 and 2013, 340B sales grew seven times faster than total U.S. Medicine spending.¹⁵ Between 2002 and 2017, the number of 340B designated contract pharmacy arrangements increased from 279 to 51,963. As of July 2017, there were 6,059 340B covered entities with 51,963 contract pharmacy arrangements.¹⁵ Nearly 90% of that growth followed HRSA's 2010 sub-regulatory guidance authorizing unlimited contract pharmacy networks. From 2013 to 2017, the number of hospital entities participating in the program tripled.⁷ Over that same period, 340B purchases as a share of hospitals' total drug purchases consistently and steadily increased,¹⁶ while hospitals' uncompensated care dropped.¹⁵

Discussion and debate have encircled the 340B program over the years. Over time, a series of questions have been asked that include:

- Has the program aided the efforts of Covered Entities to maximize limited federal resources, or has it become a piggy bank for some Covered Entities?
 - When created, who was the 340B program designed to help—at-risk Covered Entities or patients or both?
 - Today, who is truly benefiting—the patient—or the provider?
 - The 340B program was expanded since its inception, how have these expansions impacted the program? Patients?
 - In 2010, HRSA changed the 340B program to allow all Covered Entities an unlimited pharmacy network, has this development had a positive impact on patients?
- The real question and the ultimate challenge are to determine whether the 340B program should continue as currently designed? Federally Qualified Health Care Centers serve as the medical home for millions of patients providing them with quality care and to free or subsidized medications.
- Over the years the work of the FQHCs has been unparalleled. Similarly, Ryan White Clinics, AIDS Drug Assistance Programs (ADAPs), and Hemophiliac Treatment Centers have consistently delivered excellent care.
- Hospitals, both urban and rural, present an interesting challenge and healthcare dilemma, specifically, whether there should be different “intents” for different kinds of covered entities? Should Congress treat 340B clinics different from 340B eligible hospitals? Should there be a different standard for rural hospitals than urban facilities?
- Finally, is Congress willing and ready to address the even larger challenge of contract
- Is the program still benefitting patients?
 - What was the intended purpose of the program?

¹⁴Fein, A.J. (2018, May 07). *EXCLUSIVE: The 340B Program Reached \$19.3 Billion in 2017—As Hospitals' Charity Care Has Dropped*. Philadelphia, PA: Pembroke Consulting, Inc.: Drug Channels. Retrieved from: <https://www.drugchannels.net/2018/05/exclusive-340b-program-reached-193.html>

¹⁵Medicare 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>

¹⁶Fein, A.J. (2017, May 19). *340B Purchases Were More Than Half of the Hospital Market in 2016*. Philadelphia, PA: Pembroke Consulting, Inc.: Drug Channels. Retrieved from: <https://www.drugchannels.net/2017/05/340b-purchases-were-more-than-half-of.html>

pharmacies? How many is enough? Should Congress or HRSA regulate the fees charged by pharmacies (chain drug stores compared to independent pharmacies) to ensure that the 340B program is not being financially gouged?

The Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA) administers the 340B program.¹⁷ It argues that it has limited authority to regulate the program. The 340B statute only provides HRSA with the regulatory authority in three areas: 340B ceiling price calculation; manufacturer overcharge civil monetary penalties; and alternative dispute resolution. In other key areas, it can only issue guidance, including how to define a “patient” and contract pharmacy arrangements. To create new legally binding requirements, Congress could choose to change the 340B program, grant HRSA the regulatory authority to create additional rules governing it, or some combination of the two.

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¹⁷Sternfield, E.L. (2017, July 25). *Witnesses at Congressional Hearing on 340B Urge Congress to Give HRSA Broader Regulatory Authority*. Boston, MA: Mintz, Levin, Cohn, Ferris, Glovsky, and Popeo, P.C.: Insights Center: Viewpoints. Retrieved from: <https://www.mintz.com/insights-center/viewpoints/2017-07-witnesses-congressional-hearing-340b-urge-congress-give-hrsa>

⁷ **ISSUE 1: Clarifying the purpose and intent 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.”¹⁸ 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.¹⁹ 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 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.²⁰

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

¹⁸H.R.2890 - *Medicaid and Department of Veterans Affairs Drug Rebate Amendments of 1992*, H. Rept. No. 102-384 (Part 2), at 12 (1992).

¹⁹H.R. Rep. No. 102-384 (II), at 12 (1992). HRSA, OPA, 340B Program, at <https://www.hrsa.gov/opa/index.html>.

²⁰*National Commission on 340B*. 1 (2018, July 13) (Diane J. Nugent, MD).

been providing safety net entities before the unintended consequences from the passage of the Medicaid rebate law.²¹ In the years since 1992, uninsured rates steadily decreased²² while the number of individuals insured through Medicaid nearly tripled.²³ 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.²⁴

RECOMMENDED SOLUTIONS

- 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.”

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Congress could not have predicted the changes in the healthcare landscape over the last quarter of a century.

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.

²¹La 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/#ixzz5RBdIVfYC>

²²National 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

²³Medicaid 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>

²⁴Augustine, 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>

ISSUE 2: Should Covered Entities be accountable for how they use 340B program savings?

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 underserved population.²⁵

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.

²⁵*National Commission on 340B*. 9-10 (2018, July 10) (Sue Veer).

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

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 per Congressional intent. Most important, because of the nature of the disease state, the dollars are used for “multidisciplinary teams composed of physicians, nurses, physical therapists, social workers, health psychologists, pharmacists, genetic counselors, etc.”²⁸ 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.²⁹

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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.²⁶ Hospital groups counter that they treat more low-income patients than non-340B hospitals and provide more uncompensated care than their non-340B counterparts.²⁷ 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

²⁶Alliance 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

²⁷340B 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

²⁸National Commission on 340B. 4 (2018, July 13) (Diane J. Nugent, MD).

²⁹National Commission on 340B. 5 (2018, July 13) (Diane J. Nugent, MD).

RECOMMENDED SOLUTIONS

- Legislation introduced in the House and Senate 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.
- 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:
 - o State Boards of Pharmacy draft regulations regarding pharmacy oversight of 340B.
 - o Without regulations, hospital systems will not invest in pharmacy compliance costs;
 - o Hospital systems staff 340B pharmacies sufficiently. In pharmacy, the number one priority will always be an accurate dispense of medication promptly;
 - o 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
 - o Hospital systems offer 340B educational opportunities to their pharmacy staff.³⁰

³⁰National Commission on 340B. 6 (2018, July 13) (Diane J. Nugent, MD).

ISSUE 3: Has the program grown too rapidly or is it too large?

Critics of the 340B program have argued that program has grown too large, too fast. By certain metrics, the program began its most rapid growth around 2010.³¹ Some of the same analysts project additional expansion shortly. In part, growth is attributable to the expansion of contract pharmacy models (when HRSA issued new guidance in 2010) and a shift of care from the community setting to the hospital setting.

From 2013 to 2017, the number of hospital entities participating in the program tripled. Critics point to the fact that 340B sales have shifted over time, and today the clear majority of 340B sales are to hospitals. In 2004, originally intended grantees represented 55% of program sales¹⁵, while today, that figure has dropped to only 13%. Finally, they point to the fact that the volume of drugs and dollars flowing through the

program has grown: \$6.9 billion in sales at the 340B price in 2012 versus \$19.3 billion in 2017.³²

Growth in and of itself is not a problem. However, concerns arise once you layer on the amount of care, or lack thereof, these hospitals are providing to safety net populations the program was intended to serve. For example, the American Hospital Association's data shows that over the same period that hospitals' 340B sales have been increasing, the amount of uncompensated care hospitals provide has been declining.

Most hospitals qualify for the 340B program by having a DSH adjustment percentage derived by looking at low-income Medicare and Medicaid inpatient days – that exceeds a specific threshold. Some assert that Medicaid expansion under the ACA has allowed too many hospitals to qualify because more hospitals began treating more Medicaid-eligible

³¹Vanderveelde, A. & Blalock, E. (2017, July). *Measuring the Relative Size of the 340B Program: 2012-2017*. Emeryville, CA: Berkeley Research Group. Retrieved from: http://340breform.org/wp-content/uploads/2017/02/July-2017-BRG-White-Paper_Percent-of-Sales.pdf

³²Dickson, S., Coukell, A., & Reynolds, I. (2018, August 08). *The Size of the 340B Program and Its Impact on Manufacturer Revenues*. Bethesda, MD: Project Hope: The People-to-People Health Foundation, Inc.: Health Affairs: Health Affairs Blog: Drugs and Medical Innovation. Retrieved from: <https://www.healthaffairs.org/doi/10.1377/hblog20180807.985552/full/>

individuals in expansion states. Those critics believe a new metric should be used.

It has been suggested that tighter oversight of existing hospital eligibility criteria is needed.³ Hospitals note that the program is working exactly as Congress intended (albeit a different Congress in 2010 than the one reviewing the program today).

Some critics, including private oncologists, believe the 340B program is creating incen-

smaller portion of the total 340B drug-spend nationally.¹⁹ Rural hospitals are also rarely criticized, though numerically they represent the largest segment of Covered Entity growth since the passage of ACA, which made sole community hospitals, rural referral centers, critical access hospitals and freestanding cancer hospitals all eligible for the program.³⁶

RECOMMENDED SOLUTIONS FOR HOSPITALS

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It has been suggested that **tighter oversight of existing hospital eligibility criteria is needed.**

tives for hospitals to acquire oncology practices that can no longer compete with their ability to purchase chemotherapy and other injectable drugs at lower prices.³³ To help address concerns that the 340B program was favoring hospital-based providers, in November 2017, CMS approved reductions to the 2018 Medicare Part B reimbursement for 340B-purchased administered drugs in hospital outpatient settings.³⁴

In December 2018, the US District Court for the District of Columbia reversed the cuts, as a result of a lawsuit filed by a group of hospital associations and nonprofit hospitals. This ruling only impacted the 2018 cuts, and it is unclear as to what impact it could have in 2019 and subsequent years. Nevertheless, some continue to call for reforms to remove any incentives to acquire infusion practices or establish infusion suites.³⁵ And, it cannot be overlooked that relocating infusion sites into hospitals may be less convenient and accessible to eligible patients creating greater access issues.

Criticism regarding the size of the 340B program is generally aimed at hospitals, as other grantees represent a significantly

- Slow down growth by imposing a moratorium on new hospital and new hospital site registration, as proposed by the PAUSE Act³⁷ and HELP Act³⁸.
- Develop a new, more restrictive hospital outpatient site standard, as recommended in the HELP Act.
- Prevent or limit registration of outpatient sites that primarily provide drugs, as opposed to other outpatient services (HELP Act).
- Alter the DSH adjustment percentage thresholds that currently exist but leave the mechanism in place.
- Cap the number of DSH hospitals eligible to participate using a set number with the highest DSH adjustment percentages.

³³Energy and Commerce Committee. (2018, January 10). *Review of the 340B Drug Pricing Program*. 66-70. Washington, DC: United States House of Representatives: Energy and Commerce Committee. Retrieved from: https://energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf.

³⁴Rege, A. (2018, September 06). *Hospitals refile lawsuit against CMS over \$1.6B in 340B cuts*. Chicago, IL: Becker's Healthcare: Becker's Hospital Review: Legal & Regulatory Issues. Retrieved from: <https://www.beckershospitalreview.com/legal-regulatory-issues/hospitals-refile-lawsuit-against-cms-over-1-6b-in-cuts-340b-cuts.html>

³⁵Community Oncology Alliance. (2017, April 01). *The 340B Program in Review: A Look at the Data and Evidence to Date*. Washington, DC: Community Oncology Alliance: Issue Briefs & Overviews, Publications, Studies & Reports. Retrieved from: <https://www.communityoncology.org/the-340b-program-in-review-a-look-at-the-data-and-evidence-to-date/>

³⁶McCaughan, M. (2017, September 14). *Health Policy Brief: The 340B Drug Discount Program*. *Health Affairs*. Retrieved from: <https://www.healthaffairs.org/doi/10.1377/hpb20171024.663441/full/>

³⁷Buschon, L. (2017, December 21). H.R. 4710 – 340B PAUSE Act. Retrieved from: <https://www.congress.gov/bill/115th-congress/house-bill/4710>

³⁸Cassidy, B. (2018, January 16). S. 2312 HELP Act. Retrieved from: <https://www.congress.gov/bill/115th-congress/senate-bill/2312>

14 **ISSUE 4: Growth of Contract Pharmacies**

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.³⁹ 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.⁴⁰ However, the agency established some minimum ground rules for the use of contract pharmacies.

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.⁴¹ 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).⁴²

Most importantly, this 2010 guidance did not continue the requirement for annual

³⁹Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 FR 43549, 43550 (1996, August 23).

⁴⁰See *Ibid.* generally.

⁴¹Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 FR 43555 (1996, August 23).

⁴²Vandervelde, 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

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.⁴³

Operationally, a 340B Covered Entity can purchase and dispense 340B drugs through retail pharmacies. Such contract pharmacies

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. 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

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Today, about **one-third of the more than 12,000** Covered Entities contract with contract pharmacies.

hold the “virtual inventory” of a 340B Covered Entity. In 2010, the Health Resources and Services Administration (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. Today, 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-simultaneous passage of the ACA and related expansion of the 340B program also contributed to that trend.

⁴³United States 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>

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, percentage-of-reimbursement fees, pre-determined 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.⁴⁴ 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 Government Accountability Office (GAO)⁴⁵ found weaknesses in HRSA's oversight of contract pharmacies that impede compliance. The GAO's analysis found:

- 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:

1. The Administrator of HRSA should require Covered Entities to register contract pharmacies for each site of the entity for which a contract exists.
2. 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

⁴⁴Conti, 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>

⁴⁵U.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>

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.

3. The administrator of HRSA should incorporate an assessment of Covered Entities' compliance with the prohibition on dupli-

the results of the entities' assessments of the full scope of noncompliance identified during each audit.

7. 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 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

While HHS agreed with four of the recommendations, it took **exception with three.**

cate 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.

4. 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.
5. 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.
6. 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

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.⁷

Second, about 20,000 pharmacy locations now act as contract pharmacies for the hospitals and other healthcare providers that participate in the 340B program.⁴⁶

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.⁴⁷ Thousands of independent pharmacies and small chains participate, as well.

Dr. Adam Fein, Ph.D., in testimony before the National 340B Commission,⁴⁸ 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;⁴⁹

- 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).

RECOMMENDATIONS

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*,⁵⁰ 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.

⁴⁶National Commission on 340B. 4 (2018, June 13) (Adam J. Fein, PhD).

⁴⁷National Commission on 340B. 4 (2018, June 13) (Adam J. Fein, PhD).

⁴⁸National Commission on 340B. 4 (2018, June 13) (Adam J. Fein, PhD).

⁴⁹Fein, 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>

⁵⁰Office of Inspector General, U.S. Department of Health and Human Services, OEI-03-13-004e11G, February 4, 2014.

Contract Pharmacies deserve a careful and thoughtful reexamination. As a result, the Commission recommends:

- Require that all Covered Entities develop some type of enterprise charity care policy for contract pharmacy service similar to what FQHCs are currently required to do, such as a sliding fee scale and report the number of individuals that realized savings vs. the total eligible to receive the benefits. This could be

- o Explore HRSA creating a formula-based approach based on the size of the area or population served to determine the number of contract pharmacy sites.

The 340B Contract Pharmacy model is very challenging. Except for charitable care programs, which typically have established eligibility for Covered Entities, the eligibility is determined retrospectively by matching prescription attributes to data feeds from the covered entity. The process has a high incidence of errors and requires diligent auditing on behalf of the covered entity to prevent diversion. We recommend the creation of a new model based upon documented qualifying events rather than a matching algorithm.

The industry standard for a Contract Pharmacy (CP) is to use its regular inventory at the point-of-service and then determine eligibility post-adjudication through a verification process with the Covered Entity, third-party administrator and the Contract Pharmacy. Once 340B eligibility is determined and verified, then the Covered Entity will “replenish” the medication(s) initially dispensed by the CP with the Covered Entity’s 340B medication(s).

Additionally, another 340B regulation prohibits duplicate discounts under State Fee-for-Service (FFS), and managed care (MC) Medicaid programs. This prohibition has caused many State FFS and Managed Care Medicaid programs to mandate the use of the “Code 20” indicators by pharmacies using 340B drugs at the point-of-service. Since CP cannot verify, 100% of the time, eligibility for 340B, many CP and third-Party Administrators will not allow CP to participate in FFS and less commonly MC Medicaid program. This has hindered covered entities who serve patients who may not be able to afford the full cost of the medications or related copayments.

In the age of technology, we believe that it is possible to optimize the use of 340B medications for covered entities and their patients while preserving the integrity of the 340B regulations against duplicate discounts. One key factor in the 340B duplicate discount

The 340B Contract Pharmacy model is very challenging.

accomplished in contract pharmacies using a centralized processor.

- Require the disclosure of contract dispensing fees and all other fees to HRSA/OPA. Covered Entities would be required to explain whether the contract pharmacies are simply dispensing medications or providing additional services to warrant that specific fee.
- Establish safe harbor guidelines for the flat fair market value of contract pharmacy dispensing fees, considering a contract pharmacy’s margin loss, and increased cost of service as well as the projected entity cost associated with developing its distribution capabilities.
- Limit the use of hospital contract pharmacies. This could include:
 - o Geographic/radius limitations for 340B hospitals that take into consideration the unique needs of rural providers, grantees, and safety-net providers;
 - o Limiting the number of contract pharmacies to no more than five per registered site, though such a limit would penalize urban providers;
 - o Limit where the revenue can be spent. Specifically, Covered Entities could be required to use all revenue generated from a specific site in that geographical service area; and

regulation is that it is up to the manufacturers, states, and covered entities to settle any duplicate discount disputes. Additionally, States are increasingly concerned about duplicate discounts because they reduce the amount of their Medicaid rebates. And, this issue will continue to be a significant discussion point in Governor's offices and state legislatures.

To overcome the contract pharmacy adjudication chaos, we recommend the following:

- Establish a HIPAA compliant HUB for Covered Entities to send verified 340B drug usage files to the HUB, and for registered drug manufacturers to access and use the files to match against rebate requests.
- Establish a 30-calendar day limit for the date of notification turn around mandate for covered entities to submit 340B-eligible dispensing data files to the HUB from the date of service. (340B data aggregators exist and can meet this requirement. A 30 day turn around should accommodate any return-to-stock, etc. processes).
- Any entity serving as a contract pharmacy, TPA or PBM, must report its fees charged to a covered entity and submit the data to the Hub and HRSA. The fees must be provided to state Medicaid agencies and HRSA and the OIG at HHS.
- Hemophilia Treatment Centers in California, in collaboration with the state, created a specific coding system to distinguish 340B products from non-340B, to have a clear system of tracking product eligibility for pharmaceutical rebates to the state. Even though Recommendation Six creates a private sector response, the Commission recommends that Congress and specifically HHS and GAO review and comment on the California HTC system to determine whether this could address or solve the Medicaid and pharmaceutical industry concerns regarding duplicate billing.

21 **ISSUE 5: 340B and Medicaid Issues: Duplicate Discounts**

Background

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.

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.⁵¹

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 program management and oversight.

⁵¹United 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>

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.

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HRSA released duplicate discount guidance in 2014 that specifically excluded MCO utilization.

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.⁵² However, despite this requirement, the OIG recently found that states vary greatly in their methods of identifying duplicate discounts.⁵³

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

HRSA has interpreted the 340B statute, which states that a CE 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.⁵⁴ 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).

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.⁵⁵ 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 a majority of 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.

⁵²Code of Federal Regulations (annual edition), 42 C.F.R. § 438.3(s)(3) (2016).

⁵³IBID

⁵⁴Health 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>

⁵⁵Health 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>

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).

For their part, states have expressed frustration in trying to identify 340B drugs billed to MCO and have considered changes such as mandatory carve-out of 340B or mandating that MCOs pay actual acquisition costs for 340B drugs (i.e., reduce reimbursement to replace the unavailable rebate).

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.

RECOMMENDATIONS

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 Office of Inspector General 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 Office of Inspector General 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:
 - o Could be funded with a user fee on Covered Entities that would be administered without the involvement of manufacturers; and
 - o Could be a private sector solution.

- Claims level data standards vary from states to manufacturers for Medicaid rebates. Right now, there are no standards on what the states have to supply, and as a result, manufacturers are playing catch up with limited data - thus making a recovery or prevention of duplicate discounts almost impossible. Today, Medicaid uses some combination of Medicaid Exclusion File and claims modifiers to prevent duplicate discounts. First, the states are not required to use any set format or form, thus requiring the entity to somehow manage a variety of different methods. Second, the MEF doesn't apply to managed Medicaid or contract pharmacies, thus limiting its utility. Third, the claims modifiers used by the various states require 340B awareness at the time of dispensing - which is not how 340B programs generally work. Finally - the states have effectively punted managed Medicaid and 340B to plans - who are the folks least likely to know how to manage 340B participation. So essentially the entire system is stacked against the manufacturers in this regard.
- To address this, someone should develop a claims clearing house platform for the covered entities and manufacturers (and plans and states) to share data under an antitrust safe harbor to prevent duplicate discounts proactively. This clearing house will collate the data from the participating parties and pass it back to the various parties in such a way that it will prevent duplicate discounts.

ISSUE 6: Payer Discrimination and 340B Discount Appropriation

Though there are competing views on what the intent of the 340B program should be, we believe that Congress did not intend for payers and PBMs to take advantage of Covered Entities' access to 340B drugs by paying those Covered Entities less than they pay similar non-340B providers. Unfortunately, the 340B statute does not provide the government, drug manufacturers or Covered Entities with the tools to prevent most payers from ratcheting down price spread reimbursement for 340B drugs. CMS has exacerbated the raid on the 340B discount by mandating that fee-for-service Medicaid programs pay no more than actual acquisition cost for 340B drugs,⁵⁶ and by reducing Medicare Part B hospital payments for 340B drugs to a proxy for actual acquisition cost.⁵⁷

The trend among private payers cutting reimbursement for 340B drugs has accelerated since the enactment of the ACA. PBMs

negotiate rebates with drug manufacturers that are paid based upon the achievement of certain criteria – like preferred formulary placement or market share. Just like manufacturers do not want to provide 340B discounts and Medicaid rebates on the same drugs, they do not want to provide PBM rebates on 340B drugs. Some manufacturers have begun refusing to pay PBM rebates on claims coming from 340B Covered Entities or their contract pharmacies. As a result, the payers have sought to make up the difference by reducing reimbursement for 340B drugs. In effect, the rebate that was paid by the manufacturer to PBM has been replaced by a discount provided by the manufacturer to the Covered Entity, which is then appropriated by the PBM and health plan.

Some Covered Entities have the wherewithal to push back against these reimbursement cuts. Federally qualified health centers have

⁵⁶Medicaid Program; Covered Outpatient Drugs, 81 FR 5169 (2016).

⁵⁷Medicare Program; Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 FR 59216 (2017, December 14).

statutory protections applicable to Medicaid Managed Care and Medicare Part D that prohibit payers from paying them less than they pay other service providers (albeit litigation will likely be required to enforce those fair payment rights).⁵⁸ Covered Entities, however, are typically not privy to the contracts between payers and contract pharmacies, and have no way of knowing when reimbursement is threatened in the contract pharmacy setting.

- HRSA should establish ceiling fees (CAPS) that a Third-Party Administrator can charge to manage an entities 340B program. This would include a maximum dispensing fee a contract pharmacy can be paid.

Covered Entities **should be free to choose** how to leverage the benefits of the 340B program.

Covered Entities should be free to choose how to leverage the benefits of the 340B program. A Covered Entity might pay service providers, including contract pharmacies or vendors that assist with compliance, using 340B program “savings” or “revenues.” A Covered Entity also might voluntarily agree to a lower reimbursement rate when negotiating with a payer. In those situations, the Covered Entity is choosing how best to deploy its resources, rather than being forcibly deprived of the discount Congress intended it to receive.

RECOMMENDATIONS

- Establish anti-discrimination provisions that apply to private payers and all Covered Entity types and require payers to reimburse 340B providers at rates comparable to non-340B providers.
- Provide HRSA with authority to regulate or oversee payer discrimination. Alternatively, allowing for a private cause of action.

⁵⁸Code of Federal Regulations (annual edition), 42 U.S.C. §§ 1396b(m)(2)(A)(ix), 1395w-27(e)(3)(A) (2016).

ISSUE 7: Giving HRSA / OPA Needed Authority

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.

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 GAO⁵⁹ as either being too vague (patient definition)⁶⁰ or leading to increased incidence of diversion and duplicate discounts (contract pharmacy).⁶¹

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.

⁵⁹United 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>

⁶⁰Examining 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.

⁶¹Office 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>

ISSUE 8: Patient Definition: Who Are 340B Patients?

In an October 24, 1996, Federal Register notice on the OPA website, HRSA defined eligible 340B patients using three criteria:⁶²

First, the individual must have an established relationship with the Covered Entity (CE) in which the CE maintains records of the individual's care;

Second, the individual must receive care from a professional employed by the CE, or under a contract or other arrangement (such as a referral consultation) in which the CE maintains responsibility for the care of the individual; and finally,

Third, the individual must receive medical services from the CE or a contractor of the CE that comply with the scope of services granted to that CE.⁶³ 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.⁶⁴

On August 27, 2015, HRSA released⁶⁵ 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.⁶⁶

Federal agencies such as the Government Accountability Office (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

⁶²Medicare 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>

⁶³Ibid at MedPac, pg. 8.

⁶⁴Ibid at MedPac, pg13. 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>

⁶⁵Morse, 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>

⁶⁶Johnson, 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>

was inadequate.⁶⁷ 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:⁶⁸

1. 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;
2. The individual receives a health care service from a health care provider employed by the CE, or who is an independent contractor of the CE, such that the Covered Entity may bill for services on behalf of that provider;
3. An individual receives a drug that is ordered or prescribed by the CE provider because of the service described in (2). An individual will not be considered a patient of the CE if the only health care received by the individual from the CE is the infusion of a drug or the dispensing of a drug;
4. 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];
5. 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 for the patient 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 CE will be considered a patient if the CE has clearly defined policies and procedures that it follows to classify such individuals consistently; and

6. The individual has a relationship with the CE such that the CE has a provider-to-patient relationship, that the responsibility for care is with the CE, and that each element of this patient definition in this section is met for each 340B drug.

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.⁶⁹ 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 healthcare coverage for Americans, it is essential that the 340B program evolve to recognize a

⁶⁷United 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>

⁶⁸340B Drug Pricing Program Omnibus Guidance, 80 FR 52300 (2015, August 28).

⁶⁹Luthi, 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>

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

referring CE.

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 meds 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.

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

We recommend the existing HRSA patient definition be left in place **but make the following modifications...**

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 CE. 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 CE cannot be broken. That patient must retain his or her patient status with the

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.

Conclusion: Growth, Oversight, and 340B Reality

Some have argued that HRSA has lost its ability to effectively oversee the 340B program.⁷⁰ In part, this is the direct result of the anemic response by HRSA and OPA to issue regulations and guidance to address the problems and challenges facing the 340B program. However, federal agencies cannot be completely held responsible, as they are operating with apprehension and are under-funded.

While HRSA/OPA has asked Congress to intervene with legislative authority, on August 27, 2018, U.S. House of Representatives Energy and Commerce Committee Chairman Greg Walden (R-OR), Energy and Commerce Committee Ranking Member Frank Pallone, Jr. (D-NJ), Senate Health, Education, Labor and Pensions (HELP) Committee Chairman Lamar Alexander (R-TN), and Senate HELP Committee Ranking Member Patty Murray (D-WA) sent a letter to OPA Director Krista Pedley regarding their failure to use their (OPA)

rulemaking authority to implement regulations to better administer the 340B Drug Pricing Program (340B Program). Excerpts from that letter include⁷¹:

“Given the important role the 340B Program plays in our nation’s health care safety net, it is critical that program rules be clear and consistent for all stakeholders,” the letter stated. “Unfortunately, the agency has faced significant impediments to appropriate oversight and enforcement given recent judicial decisions that, in effect, left the agency without broad rulemaking authority. HRSA has requested that Congress consider legislative action to give the agency broad rulemaking authority over the 340B Program,” the bipartisan leaders also wrote.

In testimony before the Senate Health, Education, Labor, and Pensions Committee this June and before the House Energy and Commerce Committee last July, HRSA stated

⁷⁰Medicaid and CHIP Payment and Access Commission, The. (2018, May). *The 340B Drug Pricing Program and Medicaid Drug Rebate Program: How They Interact*. 1, 6. Washington, DC: The Medicaid and CHIP Payment and Access Commission: Publications: Prescription Drugs. Retrieved from: <https://www.macpac.gov/publication/the-340b-drug-pricing-program-and-medicaid-drug-rebate-program-how-they-interact/>

⁷¹Letter from Congress to Krista Pedley, Pharm. D, MS, Captain, USPHS, Director, Office of Pharmacy Affairs, Health Resources and Services Administration. (2018, August 27). Washington, DC: Retrieved from: <https://energycommerce.house.gov/wp-content/uploads/2018/08/20180827HRSA.pdf>

that specific regulatory authority to conduct a rulemaking for all provisions of the 340B statute would allow the agency to oversee better and manage the program. Such specific authorities have been proposed in the president's budget as well.

The bipartisan letter also stated that:

“While HRSA has requested these additional authorities, the agency is not using its existing authorities. The [D.C. District] court ...did make clear that HRSA does have regulatory authority that includes (1) establishing and implementing a binding Administrative Dispute Resolution (ADR) pro Covered Entities for the resolution of certain disputes relating to compliance with 340B Program requirements, (2) providing for the imposition of civil monetary penalties (CMPs) against manufacturers that knowingly and intentionally overcharge a Covered Entity for a 340B drug, and (3) issuing precisely defined standards of methodology for calculation of 340B ceiling Covered Entities.”

“Additionally, the D.C. District Court has made clear that the agency has authority to issue guidance around other program requirements “to advise the public of its interpretation for the statute.” Unfortunately, HRSA has repeatedly delayed issuing rules and guidance regarding these important issues.” (footnote from a Congressional letter to Pedley)

The result of the bipartisan letter:

“While we appreciate that HRSA has requested these additional authorities, we remain concerned that the agency is not using its existing authorities. We believe

HRSA action to issue or implement final regulations in an open and transparent process, in collaboration with all relevant stakeholders, could help clarify and update program requirements in pursuit of strengthening access to necessary care and proper administration of the program,” the letter concluded.⁷²

Although it can be argued that HRSA/OPA work for Secretary Azar at HHS, it is likely that much of their work is, driven by the White House and Office of Management and Budget. Absent strong, clear guidance by the Secretary of HHS, some 340B issues, even simple solutions like duplicative billing will simply languish.

In testimony before the 340B Commission, Dr. Rena Conti (an economist and expert on drug pricing issues) shared three important points that underscore the crisis facing this program:

First, since its inception in 1992, the 340B program has grown from 50 acute care, not for profit hospitals to 1,279 in 2018; over 40% of all nonprofit and public hospitals and over half of all hospital outpatient drug spending.¹²

Second, these hospitals, with HRSA's blessing, have interpreted the program to allow them to dispense 340B medications to all patients, including people with private insurance. This means that hospitals have an incentive to attract and treat privately insured patients where their 340B margin is substantially larger.

Third, hospitals, unlike other safety net clinics, are not required to demonstrate how the program is used to benefit low-income and uninsured patients attending their hospitals.

⁷²Ibid. See Also Committee on Energy and Commerce. (2017, July 14). *Hearing entitled “Examining HRSA's Oversight of the 340B Drug Pricing Program.”*. Washington, DC: United States House of Representatives: Committee on Energy and Commerce: Meetings. Retrieved from: <http://docs.house.gov/meetings/IF/IF02/20170718/106269/HHRG-115-IF02-20170718-SD002.pdf>

Dr. Conti's insights are particularly important and valuable in two specific ways:

First, we should require all Covered Entities, regardless of size or type, to be 100% transparent; and

Second, all Covered Entities should be required to report all 340B revenue on an annual basis, and to explain how these funds are used to care for low-income patients (Medicaid, Medicare, those dually eligible,

the 340B equation is often lost.

Every 340B provider's success is built around the women and men who deliver quality care every day. They are the patient's medical home, their medical family. They are often the familiar face that greets the patient in the Emergency Department or at the local clinic. The 340B program has a human face – the patient and the worker. Perhaps some members of Congress and the federal bureaucracy should be reminded of this.

It is important that Congress take an important first step: ask every 340B Covered Entity in your state two simple but important questions. First, how much 340B revenue did you generate from 340B in the last calendar year? Moreover, how have you reinvested those dollars to increase or enhance patient care? Do uninsured and vulnerable patients benefit from 340B through a sliding fee scale? While the questions appear simple, the truth will be in transparency, that is whom willingly shares the information, how long does it take them to respond (time) and how detailed is their response.

Healthcare, like any other partnership, is not easy. However, with excellent communication, transparency, and honesty, it can, it must, it will get better.

We have struggled with the issue of who is a 340B patient not because it is complex or political, rather, because the healthcare world continues to evolve, and Covered Entities are not serving simply Medicaid and other low-income patients. Today, that reality has dramatically changed.

Covered Entities are serving and treating patients across all economic backgrounds. The greater the economic diversification of the Covered Entity, the financially healthier it may be in the long term. And, in rural America where access to doctors continues to decline, FQHCs and other 340B Covered Entities have become the medical home for more and more patients. And, this is not likely to change any time soon.

Additionally, with more and more Americans enrolled in high deductible health plans, they

Today, time and transparency are new battlegrounds facing hospitals participating in the 340B program.

the uninsured and underinsured) as well as patients suffering from the leading chronic disease conditions in that Covered Entity's geographical area.

A federal program called 340B was created in 1992 to reduce the cost of prescription drugs to hospitals, clinics and health systems serving low-income and rural patients.

Today, time and transparency are new battlegrounds facing hospitals participating in the 340B program. The good news is that many 340B providers have never been hesitant to share how they reinvest revenue to help patients. The bad news is that not all providers are so forthcoming, and their reluctance to show how their discounted rates help patients has raised a series of red flags among some in Congress, state legislatures, advocates and others.

Both the House and Senate have been holding hearings, digging into concerns raised by those who believe the 340B program needs to be changed. While some blame the pharmaceutical industry, that voice is only one among many asking Congress to look underneath the 340B covers.

As with many complex healthcare issues, it is easy to make simple, albeit ridiculous statements about solutions that in some cases have no place. When that occurs, providers worry and so do their staffs. The human element in

often seek providers who will address their medical needs. While Urgent Care Centers are certainly an option, the one primary benefit of an FQHC and other 340B Covered Entities is access to the most affordable medications available. For people with one or more chronic disease conditions and other medical care that requires an expensive specialty medication, the 340B acquisition price allows that patient the most affordable medication option they can find anywhere unless they are enrolled in a Patient Assistance Program or have access to a co-pay assistance card program.

The challenge facing many Americans is access to quality medical care. And, for those with one or multiple chronic disease conditions, the combination of access to medical care and affordable prescription drugs can be a long-term battle.

The question is whether and how the 340B program can and should realistically aid this effort? How can or should the program be positioned in the future to help and who should it help?

Congressional intent does not assist because, as a society, we did not anticipate or plan for a population of Americans with multiple chronic disease conditions. We never assumed that access to medical care would be so challenging, and in rural America, so desperate.

The Mega-Reg that was proffered under the Obama Administration offered a six-part definition for who was and was not considered a 340B eligible patient. And, like this report, the challenge is to determine who really should be eligible for the 340B program? Once you define who the patient is or is not, the challenges and objections to the program should resolve themselves.

But, as we and others have learned, when you talk about taking a careful and thorough look at the 340B program, people get scared or concerned. The diversity of the Commission was balanced, thoughtful discussions occurred, and this report is supported by all of its members. A wonderful example of bipartisanship, compromise, and leadership.

We salute our Commission colleagues who took the time to participate in this effort and thank each of them for their efforts and most importantly, their leadership.