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Impact of 340B drug pricing program on specialty medication access: A policy analysis and future directions

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Abstract

The 340B Drug Pricing Program, initially designed to assist healthcare providers in offering affordable medications to vulnerable populations, has increasingly come under scrutiny, particularly concerning its impact on specialty medication access. This review critically examines the program's effectiveness in improving access to high-cost specialty drugs, highlighting significant challenges such as program misalignment, economic pressures, and criticisms from the pharmaceutical industry. It further explores the regulatory landscape, stakeholder perspectives, and ethical considerations that shape the program's implementation. The paper proposes reforms to refine eligibility criteria, enhance transparency, and adjust pricing structures to serve better patients needing specialty medications. Additionally, it discusses innovative strategies like digital health integration and industry partnerships that could enhance the program's efficacy. The long-term implications of these proposed changes on healthcare systems, patients, and the pharmaceutical industry are considered, emphasizing the need for a balanced approach to sustain the 340B program's mission in the evolving healthcare environment.

Keywords: 340B Drug Pricing Program; Specialty Medications; Healthcare Policy; Program Reform; Pharmaceutical Industry; Patient Access

1. Introduction

The 340B Drug Pricing Program, established by the U.S. Congress in 1992, was designed to enable eligible healthcare providers, known as covered entities, to purchase outpatient drugs at significantly reduced prices (Pacheco, 2021). The program's primary objective was to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. This initiative arose from a growing recognition of the financial pressures faced by healthcare facilities that serve large numbers of low-income or uninsured patients (Greenwood, 2024). By requiring pharmaceutical manufacturers to provide outpatient drugs at discounted prices to these entities, the 340B program aimed to enhance the financial stability of these healthcare providers, thereby improving access to necessary medications for vulnerable populations (Kelsey M Owsley & Bradley, 2023).

The legislative framework underpinning the 340B program is detailed in Section 340B of the Public Health Service Act. The program is administered by the Health Resources and Services Administration (HRSA), which oversees the eligibility of covered entities, compliance with program requirements, and the registration of participating

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manufacturers (Ragni et al., 2023). Over the years, the 340B program has expanded in terms of the types of entities that qualify for discounts and the range of drugs covered. Despite its growth and broadening impact, the 340B program has faced significant scrutiny and debate, particularly concerning its effects on pharmaceutical pricing and the intended versus actual benefits for patients (Kelsey Marie Owsley, 2022; Ragni et al., 2023).

Specialty medications, often used to treat complex, chronic, or rare conditions, have become increasingly significant in modern healthcare. These drugs are typically high-cost and may require special handling, administration, or monitoring, making them distinct from traditional pharmaceuticals. The importance of specialty medications lies in their ability to offer effective treatment options for conditions that previously had limited or no treatment alternatives, such as cancer, multiple sclerosis, and certain genetic disorders. As a result, access to these medications is critical for improving patient outcomes, managing chronic diseases, and enhancing quality of life (Newman et al., 2020).

However, the high cost of specialty medications presents a substantial barrier to access, especially for patients who are uninsured or underinsured. This is where the 340B program becomes particularly relevant (Peter et al., 2022). By allowing covered entities to purchase these medications at discounted prices, the program theoretically improves access for patients who might otherwise be unable to afford them. The role of the 340B program in facilitating access to specialty medications is thus a critical area of focus, as it intersects with broader issues of healthcare equity, cost management, and patient care (Wu, Wang, Toh, Pisa, & Bauer, 2020).

The primary objective of this research is to analyze the impact of the 340B Drug Pricing Program on access to specialty medications. Given the growing reliance on these high-cost drugs in the treatment of serious and chronic conditions, understanding how the 340B program affects their availability to vulnerable populations is essential. This paper seeks to examine whether the program is meeting its intended goals in the context of specialty medications, identify the challenges and criticisms that have emerged, and propose potential policy reforms to enhance its effectiveness. By doing so, the research aims to contribute to ongoing policy discussions and provide recommendations for future directions that align with the original intent of the 340B program and the evolving needs of the healthcare system.

2. Current Impact of the 340B Program on Specialty Medication Access

2.1. Analysis of Access Trends

The 340B Drug Pricing Program has profoundly impacted the accessibility and affordability of specialty medications for vulnerable populations. By allowing covered entities to purchase medications at discounted prices, the program has facilitated broader access to high-cost treatments that are often crucial for managing chronic, rare, or complex conditions (Faraj, Caram, Shahinian, & Hollenbeck, 2024). Specialty medications, which include biologics, cancer treatments, and drugs for autoimmune diseases, can be prohibitively expensive, sometimes reaching tens of thousands of dollars per treatment course. The 340B program's discounts, which can be as high as 50% or more off the list price, have enabled healthcare providers to offer these essential medications to patients who might otherwise be unable to afford them (Thomas & Schulman, 2020).

Data indicates that the 340B program has played a significant role in expanding access to these medications. For example, hospitals and clinics participating in the program have reported increased patient adherence to treatment regimens, particularly among low-income and uninsured patients. This improvement in adherence is critical because specialty medications often require consistent and prolonged use to be effective. The program's ability to lower out-of-pocket costs for patients has also contributed to reducing the financial burden associated with these therapies, making them more accessible to those who need them the most (Alhazami, Pontinha, Patterson, & Holdford, 2020).

However, the impact of the 340B program on access to specialty medications is not uniform across all covered entities. Larger hospitals, particularly those classified as disproportionate share hospitals (DSHs), benefit more from the program due to their higher patient volumes and purchasing power. These institutions can negotiate better prices and pass on more significant savings to their patients. In contrast, smaller clinics and rural healthcare providers, while still benefiting from the program, may not experience the same level of impact due to their limited resources and lower patient volumes. This disparity highlights the need for a more equitable distribution of benefits within the 340B program to ensure that all patients can access the specialty medications they require regardless of where they receive care (Cole, 2020).

2.2. Challenges Faced by Covered Entities

Despite the benefits provided by the 340B program, covered entities face several challenges in utilizing these discounts effectively, particularly when it comes to specialty medications. One of the primary obstacles is the complexity of managing the program's compliance requirements. The 340B program mandates that covered entities maintain strict records and documentation to ensure discounted drugs are only provided to eligible patients (Pacheco, 2021). This requirement is especially challenging when dealing with specialty medications, which often have stringent handling, storage, and administration protocols. The need for specialized staff, training, and infrastructure to manage these medications adds to the operational burden on covered entities, particularly smaller ones that may lack the necessary resources (Dzierba et al., 2020).

Another significant challenge is the rising cost of specialty medications themselves. While the 340B discounts make these medications more affordable, increasing drug prices in the specialty sector has strained the financial resources of covered entities. The savings provided by the 340B program may not always be sufficient to cover the full cost of care, especially for patients who require long-term or multiple specialty medications. This financial pressure can limit the ability of healthcare providers to expand services, invest in new technologies, or improve patient care, thus undermining the potential benefits of the 340B program (Ball, 2022).

The use of contract pharmacies to dispense specialty medications also presents challenges. Many covered entities rely on external pharmacies to manage the distribution of these medications, particularly in cases where the medications require special handling or storage that the covered entity itself cannot provide. While contract pharmacies can help expand access, they also introduce additional layers of complexity and potential compliance risks (Rough et al., 2021). Issues such as ensuring that only eligible patients receive the discounted drugs, maintaining accurate records, and managing the contractual relationships with pharmacies can be daunting for covered entities. Moreover, the reliance on contract pharmacies has been a point of contention, with some stakeholders arguing that it leads to less control over the program's benefits and potentially diverts resources away from patient care (Jolly, Pierson, & Pulvermacher, 2021).

2.3. Patient Outcomes

The 340B program's impact on patient outcomes, particularly for those needing specialty medications, has generally been positive but varies depending on the type of covered entity and the specific patient population served. The program has been a lifeline for many patients, enabling them to access critical medications for managing their health conditions (Levengood, Conti, Cahill, & Cole, 2024). By lowering the cost of these expensive drugs, the 340B program helps patients adhere to their prescribed treatment regimens, which is crucial for achieving positive health outcomes. This is especially important for chronic conditions, where consistent medication use is necessary to prevent disease progression and reduce the risk of complications (Pacheco, 2021).

For example, in the case of cancer patients, access to specialty oncology drugs through the 340B program has been shown to improve treatment adherence and outcomes. Patients who receive their medications at discounted rates are more likely to complete their treatment courses, leading to better survival rates and quality of life. Similarly, for patients with chronic conditions such as multiple sclerosis or rheumatoid arthritis, the ability to afford specialty medications through the 340B program has been associated with better disease management and fewer hospitalizations (Li & Xu, 2022).

However, the impact on patient outcomes is not uniform across all settings. In some cases, the benefits of the 340B program may be concentrated among certain patient groups, while others continue to face barriers to accessing specialty medications (Endriukaitis, Hayes, & Mills, 2021). For instance, patients in rural areas or those receiving care from smaller clinics may not experience the same level of access to specialty medications as those in larger urban hospitals. This disparity is partly due to the challenges faced by smaller covered entities in managing the complexities of the 340B program and the high cost of specialty drugs. Additionally, while the program has helped improve access to medications, there is ongoing debate about whether the savings are always being passed on to patients or are being used to subsidize other services within healthcare facilities (Faraj et al., 2024).

3. Policy Implications

3.1. Regulatory Landscape

The regulatory landscape of the 340B Drug Pricing Program is a complex and evolving framework that plays a crucial role in shaping access to specialty medications. Established under the Veterans Health Care Act of 1992, the program was designed to allow eligible healthcare providers, known as covered entities, to purchase outpatient drugs at

significantly reduced prices (V. Marshall et al., 2021). These savings are intended to support healthcare providers in expanding services and improving access to medications for underserved populations, including those requiring specialty drugs. However, the regulatory environment governing the program has become increasingly intricate, particularly as the healthcare landscape evolves and the demand for high-cost specialty medications grows (Armstrong & Lamm, 2024).

The Health Resources and Services Administration (HRSA) oversees the 340B program, ensuring that covered entities comply with program requirements, including maintaining accurate records and dispensing discounted medications to eligible patients. Recent regulatory developments have focused on tightening oversight and improving transparency within the program. For instance, HRSA has implemented measures to ensure that covered entities do not engage in "duplicate discounting," where a 340B discount and a Medicaid rebate are claimed for the same drug. Additionally, there have been efforts to clarify the use of contract pharmacies, which have become a critical component in distributing specialty medications (Knox, Kesselheim, & Sarpatwari, 2022).

Despite these regulatory efforts, the landscape remains contentious, particularly regarding the pricing and distribution of specialty medications. Pharmaceutical companies have expressed concerns that the program is being exploited, with some arguing that the 340B discounts are not always passed on to patients but are instead used to subsidize other operations within healthcare facilities (C. L. Marshall, 2022). In response, some drug manufacturers have sought to limit the distribution of 340B-priced drugs to contract pharmacies, arguing that this practice dilutes the program's intended benefits. This has led to legal challenges and ongoing debates about the appropriate balance between ensuring access to affordable medications and maintaining the financial sustainability of pharmaceutical companies (Knox, Wang, Feldman, Kesselheim, & Sarpatwari, 2023).

The regulatory landscape also faces pressure from changes in healthcare delivery, such as the increasing use of specialty medications and the growing reliance on telemedicine and other remote healthcare services. These developments have raised questions about how the 340B program should adapt to ensure it continues to fulfill its mission of improving access to essential medications, particularly as the cost of specialty drugs rises. As policymakers consider reforms to the program, they must navigate a delicate balance between protecting the interests of covered entities and ensuring that patients benefit directly from the discounts provided under the 340B program (Kumpunen et al., 2022).

3.2. Stakeholder Perspectives

The 340B program involves diverse stakeholders, each with their perspectives and interests, which shape the program's operation and impact on specialty medication access. Pharmaceutical companies, healthcare providers, and patients are among the most critical stakeholders, and their perspectives often reflect conflicting priorities that influence policy debates and reforms(Olatunji, Olaboye, Maha, Kolawole, & Abdul, 2024a; Osunlaja, Enahoro, Maha, Kolawole, & Abdul, 2024). Pharmaceutical companies are key stakeholders in the 340B program, as they are required to offer significant discounts on medications to covered entities. Many drug manufacturers have expressed concerns that the program has expanded beyond its original intent, with some arguing that healthcare providers are using the 340B discounts to generate revenue rather than directly benefiting patients (Ball, 2022). These companies have also raised issues about the use of contract pharmacies, arguing that it leads to a lack of transparency and accountability in the distribution of 340B drugs. As a result, some manufacturers have implemented restrictions on the distribution of 340B-priced drugs, particularly to contract pharmacies, which has sparked legal battles and further intensified the debate over the program's future (Thomas & Schulman, 2020).

Healthcare providers, particularly those serving vulnerable and underserved populations, view the 340B program as vital for improving access to medications, including specialty drugs. For many covered entities, the savings generated through the program are essential for maintaining financial viability and expanding services (Kennedy, 2024). Providers argue that the 340B discounts enable them to offer comprehensive care to patients who might otherwise be unable to afford it, particularly in the case of expensive specialty medications. However, providers also face challenges in complying with the program's complex regulatory requirements and managing the operational burdens of handling specialty drugs, which require specialized storage, handling, and administration (Levengood et al., 2024).

Patients, the ultimate beneficiaries of the 340B program, generally support the program's goal of improving access to affordable medications. For many individuals with chronic, rare, or complex conditions, the ability to obtain specialty medications at a reduced cost can be life-saving. However, there is concern that not all patients benefit equally from the program. Some patients, particularly those in rural or underserved areas, may still face barriers to accessing specialty medications despite the availability of 340B discounts. Additionally, there is ongoing debate about whether the savings

generated through the program are always passed on to patients in the form of lower out-of-pocket costs or whether they are being used to subsidize other aspects of healthcare delivery (Kelsey M Owsley & Bradley, 2023).

These differing perspectives highlight the complexity of the 340B program and the challenges involved in balancing the interests of various stakeholders. As policymakers consider potential reforms to the program, they must consider the needs and concerns of all stakeholders, ensuring that the program continues to fulfill its mission of improving access to essential medications while maintaining the financial sustainability of the healthcare system (Olaboye, Maha, Kolawole, & Abdul; Olatunji et al., 2024a).

3.3. Ethical Considerations

The ethical considerations surrounding the 340B Drug Pricing Program are multifaceted and deeply intertwined with healthcare equity, access, and the fair distribution of resources. At its core, the program is designed to improve access to medications for vulnerable populations, including those requiring specialty drugs, by providing covered entities with the financial resources to serve these patients. However, the ethical implications of the program's operation and its impact on different stakeholders warrant careful consideration (Maha, Kolawole, & Abdul, 2024; Olatunji, Olaboye, Maha, Kolawole, & Abdul, 2024b). One of the primary ethical concerns related to the 340B program is the issue of equitable access to specialty medications. While the program has undeniably improved access for many patients, there is evidence that the benefits are not evenly distributed. Larger hospitals and healthcare systems, particularly those in urban areas, tend to have greater resources and infrastructure to fully leverage the program, leading to potentially better outcomes for their patients (Chang, Karaca-Mandic, Nikpay, & Jeffery, 2023). In contrast, smaller, rural healthcare providers may struggle to manage the complexities of the program, resulting in less access to specialty medications for patients in these areas. This disparity raises ethical questions about the program's fairness and whether it is achieving its goal of improving access for all vulnerable populations (Knox et al., 2023).

Another ethical consideration is the transparency and accountability of how covered entities use 340B savings. The program was intended to help healthcare providers expand services and improve patient care, yet there is ongoing debate about whether the savings are always directed toward these goals. Some critics argue that in certain cases, the savings are used to subsidize other operations within healthcare facilities rather than directly benefiting patients. This raises questions about the ethical use of public resources and the responsibility of covered entities to ensure that the discounts provided through the 340B program are used in a manner that aligns with the program’s original intent.

The pricing and distribution of specialty medications under the 340B program also present ethical challenges. Specialty drugs are often expensive to develop and manufacture, and pharmaceutical companies argue that the steep discounts required under the 340B program can undermine their ability to invest in research and development for new therapies (Brokars, 2020). Balancing the need to provide affordable access to existing medications with the need to incentivize the development of new treatments is an ongoing ethical dilemma. Additionally, the restrictions imposed by some manufacturers on the distribution of 340B-priced drugs to contract pharmacies have sparked ethical debates about the role of profit in healthcare and the extent to which companies should prioritize public health over financial interests.

4. Challenges and Criticisms of the 340B Program

4.1. Program Misalignment

The 340B Drug Pricing Program was originally conceived to help covered entities—particularly those serving vulnerable and underserved populations—stretch scarce federal resources and provide more comprehensive care, including medications, to needy patients. However, as the healthcare landscape has evolved, so too have the challenges and criticisms associated with the program. A key area of concern is the perceived misalignment between the program's original intent and its current application, particularly concerning specialty medications (Pacheco, 2021).

The pharmaceutical market was markedly different when the 340B program was established in 1992. Specialty medications, now a significant program focus, were not as prevalent, and the financial pressures associated with providing these high-cost therapies were not as pronounced (Levengood et al., 2024). Today, specialty medications account for a substantial portion of healthcare spending, and their role in treating chronic, rare, and complex conditions has grown exponentially. However, critics argue that the 340B program, as it currently stands, is not fully equipped to address the unique challenges associated with these drugs (Taliaferro, Dodson, Norton, & Ofei-Dodoo, 2023).

One critique is that the program's benefits do not always reach the intended patient population. The original intent was to assist safety-net providers in offering affordable medications to low-income and uninsured patients. However, there

is evidence that some covered entities, particularly large hospital systems, may be using the savings generated by the 340B program to subsidize other areas of their operations rather than directly lowering drug costs for patients. This has led to concerns that the program's focus has shifted from its original mission, creating a misalignment between its goals and current impact.

Additionally, expanding the 340B program to include more covered entities and the increasing reliance on contract pharmacies have further complicated its alignment with current healthcare needs. While these developments have made it easier for some providers to access discounted drugs, they have also introduced new challenges in ensuring that the program benefits the patients who need it most. The proliferation of contract pharmacies, in particular, has raised questions about whether the program's savings are equitably distributed and truly enhancing access to specialty medications for underserved populations (Brokars, 2020).

4.2. Economic and Operational Challenges

The economic and operational challenges healthcare providers and pharmaceutical manufacturers face within the 340B framework are significant and multifaceted. For healthcare providers, particularly smaller clinics and rural hospitals, the financial pressures of participating in the 340B program can be overwhelming. While the program offers substantial discounts on medications, the costs associated with compliance, administration, and the provision of specialty medications can erode these financial benefits (Kelsey M Owsley et al., 2024).

One of the most pressing challenges is the complexity of the program's compliance requirements. Covered entities must adhere to strict guidelines to ensure that only eligible patients receive discounted medications and maintain detailed records to demonstrate compliance. This is particularly challenging in the context of specialty medications, which often require specialized handling, storage, and administration. The need for additional infrastructure, staff training, and ongoing monitoring can strain the resources of healthcare providers, particularly those with limited budgets. For smaller providers, the operational burden of participating in the 340B program may outweigh the financial benefits, leading some to question whether the program is sustainable in its current form (Kennedy, 2024).

Pharmaceutical manufacturers also face significant economic challenges within the 340B framework. The requirement to offer medication discounts can impact their revenue, particularly for high-cost specialty drugs. Manufacturers argue that the discounts mandated by the 340B program and the rising cost of drug development can limit their ability to invest in research and development for new therapies (Finley & Kruel, 2020). This is a critical concern in an industry where innovation is essential for addressing unmet medical needs and improving patient outcomes. The tension between providing affordable access to existing medications and funding future innovations is a central issue in the ongoing debate over the 340B program (Pacheco, 2021).

The operational challenges of distributing 340B-priced drugs through contract pharmacies also present significant concerns. While contract pharmacies have expanded access to discounted medications, they have also introduced new layers of complexity and potential compliance risks. Ensuring that these pharmacies adhere to the program's guidelines, particularly regarding patient eligibility and record-keeping, is daunting for many covered entities. The potential for intentional or inadvertent non-compliance has led to increased scrutiny and regulatory oversight, further complicating the economic and operational landscape for healthcare providers participating in the 340B program (Knox et al., 2023).

4.3. Criticisms from the Pharmaceutical Industry

The pharmaceutical industry has been one of the most vocal critics of the 340B program, raising several concerns and launching legal challenges that have shaped the ongoing debate over the program's future. Central to the industry's criticism is the argument that the 340B program has expanded beyond its original intent and is being exploited to undermine the financial sustainability of drug manufacturers and the broader healthcare system.

One of the primary criticisms of the pharmaceutical industry is that the 340B program's discounts are not always reaching the patients who need them most. Manufacturers argue that some covered entities, particularly large hospital systems, are using the program to generate revenue rather than provide direct patient benefits (Knox et al., 2022). This has led to concerns that the program is being used as a financial tool rather than improving access to affordable medications. In response, some manufacturers have implemented restrictions on distributing 340B-priced drugs, particularly through contract pharmacies, arguing that these measures are necessary to protect the program's integrity (Thomas & Schulman, 2020).

The pharmaceutical industry has also challenged the 340B program's impact on drug pricing and innovation. Manufacturers argue that the deep discounts required under the program can reduce the resources available for

research and development, potentially slowing the pace of innovation in the pharmaceutical sector. This is a significant concern, as developing new therapies is essential for addressing emerging health challenges and improving patient outcomes. The industry contends that the 340B program, as currently structured, creates a disincentive for investment in new drug development, particularly for specialty medications that are costly to produce and require significant investment in research and development (Kates et al., 2021).

Legal challenges from the pharmaceutical industry have further complicated the regulatory landscape of the 340B program. Manufacturers have brought lawsuits challenging various aspects of the program, including using contract pharmacies and interpreting key regulatory provisions. These legal battles have highlighted the tensions between the need to ensure access to affordable medications and the need to maintain a viable and innovative pharmaceutical industry. The outcomes of these legal challenges could have significant implications for the future of the 340B program, potentially leading to changes in how the program is administered and its benefits are distributed (Ball, 2022).

5. Conclusion

The 340B Drug Pricing Program, while instrumental in expanding access to medications for vulnerable populations, requires reforms to address the evolving landscape of specialty medications better. One of the primary recommendations is to refine the eligibility criteria for covered entities and patients to ensure that the program's benefits reach the intended populations. Legislative changes could focus on tightening the definition of eligible patients, particularly those receiving specialty medications, to prevent potential program misuse. Another key reform could involve revising the oversight and transparency mechanisms to enhance accountability among covered entities. By mandating more detailed reporting on how savings from the 340B program are utilized, policymakers could ensure that these funds directly benefit patient care, especially in specialty medications.

Additionally, reforms could include adjusting the pricing structure for specialty medications within the 340B program. Given these drugs' high cost and complexity, a differentiated pricing model that reflects the unique challenges associated with their production and distribution could be introduced. This approach would balance maintaining affordable access for patients and ensuring that pharmaceutical companies are not disproportionately burdened by the discounts required under the program.

Beyond legislative reforms, there is potential for innovative strategies to enhance access to specialty medications through the 340B program. One such approach could involve leveraging digital health technologies to streamline the distribution and management of specialty medications. For instance, telehealth platforms and mobile health applications could be integrated into the 340B program to facilitate remote consultations, prescription refills, and patient monitoring, particularly for those in rural or underserved areas. This would improve access to specialty medications and ensure that patients receive continuous care without needing to travel to specialized healthcare facilities.

Another innovative strategy could involve establishing partnerships between covered entities and pharmaceutical companies. These collaborations could focus on creating co-payment assistance programs specifically for specialty medications, thereby reducing out-of-pocket patient costs. Furthermore, data-sharing agreements could allow covered entities and manufacturers to work together to monitor the real-world effectiveness and safety of specialty medications provided under the 340B program. This collaborative approach would foster a more integrated healthcare system where the benefits of the 340B program are maximized for both patients and providers.

The proposed reforms and innovative strategies could have significant long-term implications for healthcare systems, patients, and the pharmaceutical industry. For healthcare systems, introducing stricter oversight and more targeted pricing models could lead to a more efficient allocation of resources, ultimately enhancing the sustainability of the 340B program. For patients, particularly those requiring specialty medications, these changes could result in improved access to essential therapies, better health outcomes, and reduced financial burdens. However, these changes may also have complex implications for the pharmaceutical industry. While more refined pricing models could help mitigate the financial impact of the 340B program on drug manufacturers, they may also lead to increased scrutiny and regulatory challenges. The industry may need to adapt by exploring new pricing strategies and forming more strategic partnerships with healthcare providers to align with the evolving demands of the 340B program.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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