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Patient-Centered Reform of the 340B Drug Pricing Program

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Key Points

- The 340B Drug Pricing Program began with a laudable goal—helping certain safety-net organizations stretch scarce resources to provide needed services to vulnerable patients.
- What was initially intended as a support program narrowly focused on certain hospitals and providers has grown to include a sizeable portion of U.S. pharmacies, including major pharmacy chains.
- Unclear legislative parameters, informal regulations, a lack of transparency, and inadequate oversight and enforcement authority have cast doubt on whether the program is functioning as originally intended.
- The program's good intentions will not be fully realized without meaningful reform that adequately addresses the program's current shortcomings.

The 340B Drug Pricing Program began with a laudable goal, helping providers to offer needed services to vulnerable patients at safety-net organizations (U.S. House Committee on Veterans Affairs, 1992). Although the program continues to engender bipartisan support, it has become a controversial issue in healthcare. (U.S. House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, 2017). Proponents argue that the program allows safety-net organizations to provide medications and other needed services to low-income and uninsured patients (Slafsky et al., 2018). Critics say the program has grown far beyond the original intent and that inadequate oversight and lack of accountability have allowed covered entities to profit from the program (Conti & Bach, 2014). The available evidence suggests that, to some extent, both are correct. Although the program has undoubtedly helped many vulnerable patients, substantial program growth in the face of unclear legislative parameters, informal regulations, a lack of transparency, and inadequate oversight and enforcement authority have cast doubt on whether the program is functioning as originally intended. Substantial reform of the 340B program, which includes shifting the focus to patients rather than participating entities, is essential in order to reduce unnecessary spending on pharmaceuticals and ensure that the benefits are passed through to the patients the program was meant to help.

History

Medicaid Drug Rebate Program

Attempts to reduce the cost of prescription drugs for vulnerable patient populations predate the 340B program. The Medicaid Drug Rebate Program (MDRP), which was created by Congress in the 1990 Omnibus Reconciliation Act (Omnibus Budget Reconciliation Act, 1990) as a response to rising drug prices and increasing Medicaid spending (U.S. Senate Special Committee on Aging, 1989), lowered the cost of drugs reimbursed by state Medicaid agencies by requiring pharmaceutical companies that want their drugs covered under Medicaid to enter into a rebate agreement with the secretary of the Department of Health and Human Services. Under the agreement, the drug manufacturer must pay rebates to state Medicaid programs for "covered outpatient drugs," as defined in the MDRP statute (Social Security Act, 1990), and the states are to share the rebates with the federal government based on the state's federal medical assistance percentage (FMAP). Whereas prior to the MDRP, drug manufacturers had voluntarily offered large discounts to Department of Veterans Affairs (VA) hospitals and other safety-net medical providers serving uninsured and indigent populations, under MDRP, manufacturers were now required to provide rebates to Medicaid programs on covered outpatient drugs. As an unintended consequence, manufacturers began to limit discounts to safety-net providers not

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covered by MDRP in order to offset the erosion of Medicaid drug prices (O'Neill-Hayes, 2019).

Origins of 340B

Created in 1992, the 340B Drug Pricing Program gets its name from Section 340B of the Public Health Service Act, created under Section 602 of the Veterans Health Care Act of 1992 (Veterans Health Care Act, 1992). In addition to addressing unintended consequences of the MDRP program, Congress originally meant for the savings from 340B-purchased drugs to enable covered entities to stretch federal resources, allowing providers to offer needed services to the most vulnerable patients at safety-net organizations (U.S. House Committee on Veterans Affairs, 1992). However, the legislation establishing the 340B program, as well as subsequent guidance on its implementation, is focused on participating entities, rather than on uninsured, indigent, and other vulnerable patient populations.

Key Program Elements

Ceiling Price

Administered by the Office of Pharmacy Affairs (OPA), which is part of the Health Resources Services Administration (HRSA), the 340B program requires drug manufacturers to sell drugs to covered entities at a deep discount, known as the ceiling price. Similar to the MDRP, the rebates are based on the average manufacturer price (AMP), defined as the average price paid to the manufacturer for the drug in the U.S. by wholesalers and by retail community pharmacies that purchase drugs directly from the manufacturer. A unit rebate amount (URA) is then calculated for each drug based on an established formula (HRSA, 2015).

Covered Entities

Although participation in the program is voluntary, incentives are strong for drug manufacturers since they must participate in the 340B program in order to have their drugs covered by Medicaid and Medicare Part B. In addition, most eligible entities participate in 340B to realize the significant savings from program drug price discounts, as well as generate revenue by purchasing 340B drugs that are dispensed to eligible patients whose insurance reimbursement exceeds the discounted price (Government Accountability Office [GAO], 2020a, p. 7). The 340B statute specifies which covered entities are eligible to participate in the program. There are six categories of hospitals and ten categories of non-hospital covered entities, and each covered entity category has its own eligibility requirements. Generally included are qualifying hospitals, certain federal grantees, the Centers for Disease Control and Prevention (CDC), the Department of Health and Human Services' Office of Population Affairs, and the Indian Health Service (HRSA, 2018b).

Child Sites

According to HRSA,

> *a non-hospital covered entity also may include associated health care delivery sites located at a different address. These associated health care delivery sites [are] listed on the public 340B database as able to purchase and use 340B drugs for their eligible patients if the non-hospital covered entity ('parent site') registers the associated sites and provides information demonstrating that each site is performing services under the main qualifying grant, contract, designation, or project. (*340B Drug Pricing Program Omnibus Guidance, 2015, p. 52301*)*

Once they are registered, the associated sites of the covered entity are termed "child sites."

Patients

Although the 340B program was created to provide low-income and uninsured patients with lower-cost drugs and other needed services, a 340B eligible drug can be dispensed to any patient who meets the following criteria (Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 1996):

> *The covered entity has established a relationship with the individual … the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements[1] … and the individual receives a health care service or range of services* (p. 55167)

that are consistent with those offered by the covered entity.

A patient does not qualify if the only service they receive from the covered entity is the dispensing of drugs.[2] A critical point is that patient income and insurance status are not determining factors in a patient's eligibility.

Contract Pharmacies

In 1996, HRSA issued guidelines that permitted covered entities participating in the 340B Drug Pricing Program to use a single point for pharmacy services, either an in-house pharmacy or, if the covered entity did not operate its own pharmacy, an individual third-party pharmacy (contract pharmacy), to provide services to the covered entity's patients (Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 1996). Beginning in 2001, a limited number of

1 Examples of other arrangements are referrals or consultations.

2 An exception is a state-operated or funded AIDS drug purchasing assistance program.

covered entities could apply for an Alternative Methods Demonstration Project (AMDP) and, if approved, were allowed to use other types of arrangements (Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 2010). Examples of these alternate arrangements would be allowing covered entities to contract with a non-hospital pharmacy to supplement an in-house pharmacy, allowing covered entities to contract with multiple pharmacies, or the development of a network of covered entities in order to serve patients in a geographically broad area (Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 2007). The result was a significant change in the composition of the pharmacies that participated in the program. For one thing, there was now greater participation by national pharmacy chains, and a greater number of participating pharmacies were located at a distance of more than 10 miles from the covered entity (Vandervelde et al., 2020, p. 4).

Program Expansion

In 2010, the Affordable Care Act (ACA) greatly expanded 340B program eligibility,[3] and, although 340B enrollment grew steadily before the ACA, it greatly accelerated following passage of the legislation, so that by 2014 nearly 45% of all Medicare acute care hospitals were covered by the program (Medicare Payment Advisory Commission [MedPAC], 2015). In addition, HRSA issued guidance effective on April 5, 2010, allowing 340B covered entities to use an unlimited number of contract pharmacies and eliminating the limitation that only 340B entities that lack an on-site pharmacy could utilize contract pharmacies (Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 2010). Consequently, according to the Government Accountability Office, by 2017, more than 12,000 covered entities participated in the program, and the number of contract pharmacies grew from about 1,300 in 2010 to approximately 20,000 by 2017 (GAO, 2018b, pp. 1-2).

It has been estimated that 340B hospitals contract with 22 pharmacies on average, the largest networks consisting of as many as 250 pharmacies, with a portion of the pharmacies at a considerable distance from the covered entity (Vandervelde et al., 2020, pp. 4, 7). However, since HRSA does not require a covered entity to register pharmacies with each of its affiliated sites, the actual number of contract pharmacy arrangements is unknown and likely to be considerably larger. GAO reported that, as of 2017, approximately 75% of 340B contract pharmacies were chain pharmacies,[4] even though chain pharmacies represented only about one half of all pharmacies in the U.S. (GAO, 2018b, pp. 20-21).

One analysis of covered entity and contract pharmacy data reported a 4,228% increase in contract pharmacy arrangements from 2010 to 2020 (Vandervelde et al., 2020, p. 4). According to an analysis by IQVIA, 340B program sales continued to increase by 18.1% in 2020, considerably faster than the overall pharmaceutical market growth. This includes a substantial growth in 340B mail pharmaceutical sales that did not appear to be related to shifts in treatment caused by the COVID-19 pandemic (Martin & Hasan, 2021).

Although the overall details of 340B revenues are proprietary, discounts on drugs purchased through the program are substantial. HRSA (Department of Health and Human Services [HHS], 2019) reported that total 340B sales in 2017 amounted to approximately $19 billion, or about 4.3% of the U.S. drug market (p. 286). Conservative estimates of discounts on covered drugs range from 25% to 50%, and there are few requirements on how the revenue generated from these discounts is to be used (MedPAC, 2015, p. 8). Recent reports from Milliman (Bunger et al., 2019) and the Berkeley Research Group (Vandervelde et al, 2020) suggest that the savings and profit margins on 340B purchased medicines dispensed through contract pharmacies may be substantially higher.

Issues

Duplicate Discounts

The provisions of the 340B law prohibit states from billing manufacturers for Medicaid rebates for drugs that have already been discounted under the 340B Program. However, the number of Medicaid managed-care beneficiaries, as well as the growing number of prescriptions filled at 340B contract pharmacies, has made avoiding duplicate discount billing substantially more challenging. In 2018, the GAO reported that HRSA lacked a process for auditing duplicate discounts in Medicaid managed care (GAO, 2018b), and in January 2020, GAO reported that due to ongoing limitations in federal oversight, "HHS does not have reasonable assurance that states and covered entities are complying with the prohibition on duplicate discounts" (GAO, 2020a, "What GAO Found" section). To address this issue, on January 8, 2020, CMS published an informational bulletin outlining regulatory strategies that states can consider using to help prevent duplicate discounts in both Medicaid Fee-for-Services (FFS) and Medicaid managed care organization

3 The ACA expanded 340B eligibility to the following categories of hospitals: critical access hospitals, sole community hospitals, rural referral centers, free-standing children's hospitals, and free-standing cancer hospitals.

4 The five largest chains—CVS, Walgreens, Walmart, Rite-Aid, and Kroger—represented a combined 60%.

(MCO) programs (Center for Medicaid & CHIP Services, 2020).

Diversion

An additional concern about the 340B program is the issue of diversion, which occurs when a 340B-priced drug is dispensed to an ineligible patient. Diversion includes dispensing 340B drugs at an ineligible site, from a prescription written by an ineligible provider, or to an individual who does not meet the standard of being a patient of the covered entity. Diversion has become a challenging issue to address. For example, many providers work at a 340B-eligible hospital and at their private practice on the same day, making it difficult to pinpoint the exact circumstances under which a 340B drug was prescribed and dispensed. The extent to which diversion occurs and the overall cost of diversion within the 340B program are difficult to quantify since direct data are lacking.

340B and Insured Patients

The 340B law prohibits the resale or transfer of discounted outpatient drugs to anyone other than an eligible patient. However, although a key focus of the 340B program is on entities that provide services to patients regardless of their ability to pay, the 340B statute only vaguely defines the criteria for patient eligibility. Therefore, drugs purchased at the 340B discounted price can be dispensed to insured patients, and the purchaser can bill the insurer, including Medicare, the full negotiated amount with the covered entity keeping the difference. Covered entities are not required to report to HRSA on the insurance status of their 340B patients, although the portion of insured patients who receive drugs purchased at 340B-discounted prices is likely to be substantial (Fein, 2013).

Use of 340B Savings

As noted above, the 340B program was originally meant to enable covered entities to stretch federal resources, allowing providers to offer needed services to the most vulnerable patients at safety-net organizations. However, there are no clear parameters about how the savings from the program are to be used, and, although the 340B discount is an important subsidy for safety-net providers, there is no clear connection between the savings and the patients who are meant to benefit from the program. This has left the program open to criticism, especially in light of program expansion and the proliferation of contract pharmacies. For example, a 2018 study in the *New England Journal of Medicine* found the 340B program to be associated with increased hospital-provider consolidation and greater financial gain by hospitals but without clear evidence of expanded care or improvements in mortality among low-income patients (Desai & McWilliams, 2018). Another analysis by Rene Conti and Peter Bach found that, beginning in 2004, newly registered 340B DSH hospitals tended to be in higher-income communities when compared with those that joined the program in prior years (Conti & Bach, 2014).

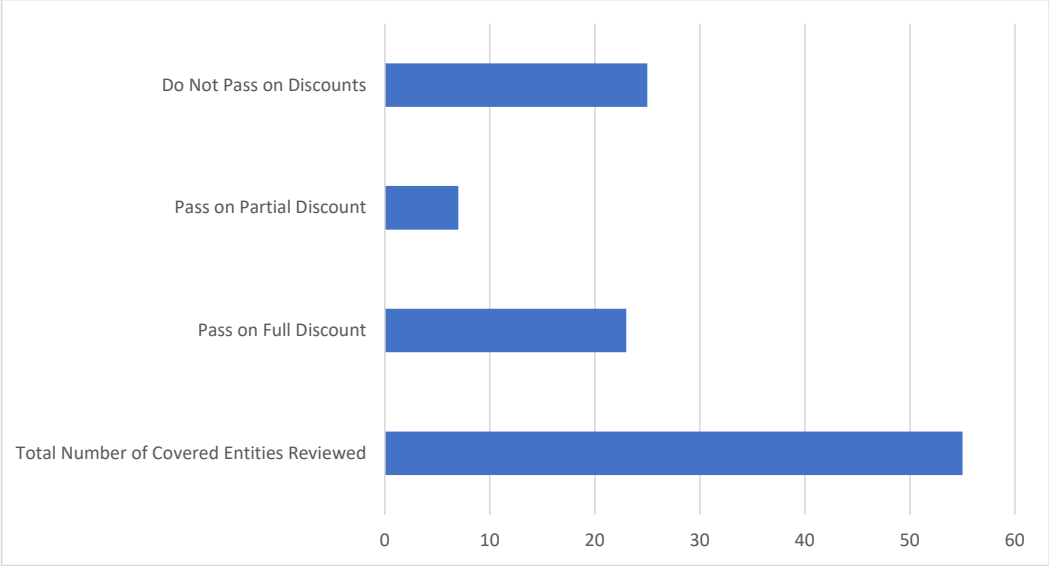
Although some safety-net providers, such as federally qualified health centers, are required to show evidence that they provide community benefits in order to qualify for and remain in the program, others, such as DSH hospitals, qualify for the program based on their provision of inpatient services to Medicaid and low-income patients. DSH affiliates are under no obligation to disclose information on their outpatient population or the provision of community benefits (Conti, 2018). This information is crucial since the number of DSH hospitals participating in the program nearly doubled between 2005 and 2014 (MedPAC, 2015, p. 10), and DSH hospitals continue to account for a majority (as much as 70%) of 340B purchases by dollar amount, even though they represent less than half of the total number of hospitals enrolled in the program and an even smaller portion of the total number of covered entities (McCaughan, 2017).

Since DSH hospitals and their affiliates are not required to demonstrate how they use 340B revenues to enhance safety-net care, data on this issue are inconsistent at best. A study by L&M Policy Research prepared for 340B Health, using FY 2015 Medicare Hospital Cost Reports, found that, on average, 340B DSH facilities provided 27.4% more unreimbursed and uncompensated care than the comparison acute care hospitals (L&M Policy Research, 2018). However, another analysis using the same data found that median uncompensated care among the 340B participants (3.4% of operating costs) was only slightly higher than the median for all nonprofit and public hospitals (3.0%). The study also reported a substantial amount of variation among the participants, with a quarter providing less than 1.9% (Nikpay et al., 2017).

Further evidence raises concern that vulnerable patients may not be benefitting from the program. In 2018, GAO conducted a review to determine the extent to which selected covered entities provide discounts on 340B drugs dispensed by contract pharmacies to low-income, uninsured patients. Of the 55 covered entities that responded to the survey, 30 reported providing discounts to low-income and uninsured patients on 340B drugs dispensed at some or all of their contract pharmacies, and 25 said they did not offer discounts at their contract pharmacies.[5] Of the 30 covered entities that reported offering the discounts,

5 Four of the covered entities that did not offer discounts at their contract pharmacies did offer discounts at their in-house pharmacies.

Figure 1
GAO Review: Contract Pharmacies and Discounts to Low-Income, Uninsured Patients



Note. Data from *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, Government Accountability Office, 2018b (https://www.gao.gov/assets/gao-18-480.pdf).

23 indicated that they pass on the full discount to patients, meaning these patients pay the 340B price or less. In addition, the study found considerable variation in the methods used to determine which patients should receive the discounts (GAO, 2018b, pp. 30-31). Both the 340B statute and HRSA guidance fail to address whether covered entities must offer the discounts at their contract pharmacies and if the covered entities do not, the uninsured patients face the full non-340B price when filling prescriptions at these sites (Wright, 2014).

Impact on Pharmaceutical Costs

There is increasing interest in the impact of the 340B program on overall pharmaceutical costs. Some research suggests that the program provides financial incentives for hospitals to prescribe more expensive drugs to Medicare Part B beneficiaries, compared to non-340B hospitals. A 2015 GAO study indicated that in both 2008 and 2012, on average, Part B beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at non-340B hospitals in the analysis. The study also noted that this has implications not only for the Medicare program, but for patients as well, through their liability for larger co-payments (GAO, 2015). Concerns have also been raised that the program could cause manufacturers to increase list prices to offset revenue losses due to fewer drugs being sold at full price due to program expansion (Conti & Bach, 2013), similar to the response to enactment of the MDRP (CBO, 1996). However, some stakeholders argue that the 340B program has had little effect on overall drug spending (Dobson et al., 2017), and, without greater transparency and more meaningful data, the debate on this issue is likely to continue.

Oversight Inadequacies

From the creation of the 340B program in 1992 through 2010, there was no formal certification or listing requirements for purchasers, and this led to concerns that discounts were being used inappropriately. In response, the ACA established certification and audit requirements. In addition, HRSA drafted formal regulations for the program, including how to determine who counts as a "patient" of a 340B purchaser. However, prior to the regulations being issued, a federal court ruled that HRSA lacks authority to issue 340B implementing regulations, calling into question whether the agency could enforce program definitions even if regulations were finalized (McCaughan, 2017).

Because of the lack of clear regulatory authority, the 340B program has been operated largely through informal guidance from the HRSA Office of Pharmacy Affairs (340B Drug Pricing Program Omnibus Guidance, 2015). Following a recommendation from the GAO in 2012, HRSA has increased the number of annual audits to the current level of approximately 200 (GAO, 2020b). However, this represents only a tiny sampling (less than 2%) of participating covered entities (GAO, 2018a).

A 2018 GAO review found substantial weaknesses in HRSA's oversight of the 340B program that hinder the agency's ability to ensure that contract pharmacies are compliant with program requirements (GAO, 2018b, p. 38),

and in 2019, GAO also reported that HRSA's processes do not provide reasonable assurance that participating non-governmental hospitals meet eligibility requirements and made several recommendations to ensure that only eligible hospitals are allowed to participate in the program (GAO, 2019).

Policy Recommendations

Although the original intent of the 340B program is commendable, the focus on participating institutions rather than patients, without clear parameters regarding key elements of the program, including how program benefits are to be passed on to vulnerable patient populations, has plagued the program from the beginning. Meaningful, patient-centered reform of the 340B program needs to be based on three essential elements: legislative and regulatory clarity, greater transparency, and enhanced oversight. Clearly defined parameters in relation to program eligibility and reporting requirements will allow for greater transparency concerning important issues such as the role of contract pharmacies and how 340B savings are utilized. Greater transparency will then facilitate adequate program oversight, but only if supported by the statutory authority to enforce program compliance.

State-Level Policy Efforts

In a December 2020 decision, the U.S. Supreme Court ruled that the Employment Retirement Income Security Act (ERISA) does not bar states from regulating pharmacy benefit managers (PBMs) (*Rutledge, Attorney General of Arkansas v. Pharmaceutical Care Management Association,* 2020). Although the decision deals specifically with drug pricing, the ruling has a bearing on state oversight of PBMs and their role in the 340B program.

Recently, a number of states have enacted laws aimed at protecting 340B savings for covered entities. As of May 2021, at least 11 states had enacted legislation to protect against discriminatory pricing, whereby PBMs reduce reimbursement for 340B hospitals versus non-340B hospitals for the same drug (340BInformed, 2021). For example, legislation enacted in Montana in 2019 prohibits a plan sponsor not subject to the ERISA or a pharmacy benefit manager from providing payment to covered entities or their contract pharmacies for 340B drugs at less than the statutorily established price or imposing fees only on 340B covered entities (SB 335, 2019).

The recent activity at the state level reflects the increasing awareness of the need for reform of the 340B program. In addition, states should consider policies that include reporting requirements that enhance program transparency and that are not in conflict with the federal statute. However, comprehensive and meaningful reform is unlikely without policy changes at the federal level.

Legislative and Regulatory Clarity

Many of the issues that currently hamper the 340B program stem from ambiguities in the original legislation as well as the informal guidance for program implementation.

Patient Definition

As noted above, a key feature of the current program is that it focuses program eligibility on safety-net providers. The existing criteria regarding which individuals are "qualified patients" is broadly based on their relationship to the covered entity rather than individual patient characteristics (Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 1996, pp. 55156-58). Importantly, the patient's income or insurance status is not a determining factor. Although Congress's original intent for 340B may have been to help safety-net hospitals and vulnerable patient populations, drugs purchased at 340B prices can be dispensed to insured patients, and entities that purchase the drugs profit by billing payers, including Medicare, at the higher rates. The GAO has identified the lack of clarity regarding patient definition as a significant problem and noted that if the definition is interpreted too broadly, it can allow 340B drugs to be dispensed to individuals who were not intended to be eligible patients by HRSA, but who are also not clearly prohibited (GAO, 2011). Clear guidance is needed regarding the definition of an "eligible patient," to include information on the patient's income and insurance status, as well as the patient's relationship to the covered entity, so that drugs purchased through the program are dispensed to the patients that the program was designed to help.

Covered Entities, Child Sites, and Contract Pharmacies

The 340B legislation specifies which covered entities are eligible to participate in the 340B Drug Program (HRSA, 2018). In addition, HRSA allows covered entities to affiliate with multiple locations designated as child sites, including outpatient clinics that are not located at the parent site. However, HRSA does not have details about arrangements between child sites and contract pharmacies and this lack of crucial information greatly inhibits program oversight. Greater clarity regarding the eligibility and role of child sites, as well as specific parameters that address the varied and complex contract pharmacy arrangements, including fees paid to vendors and other parties involved in the purchase and dispensing of 340B drugs, is essential to program integrity. Better information about the practice of hospitals acquiring independent physician practices, enabling the practices to access the hospitals' 340B discounts, is also needed since this can drive up costs for patients and payers.

Use of Savings

As noted, covered entities may generate revenue by selling 340B drugs to individuals with insurance. This revenue is the difference between the 340B discounted price and the reimbursement the covered entity receives from insurance plans. Since there are no clear guidelines on how covered entities are to use this revenue, including no requirement to offer the 340B discount price to uninsured patients at their contract pharmacies, questions have arisen about whether the savings are fulfilling the original aims of the program. The revenue has been used by covered entities in a variety of ways. Although many covered entities use this revenue to enhance activities that address the mission of serving low-income and uninsured patients, program parameters do not preclude covered entities from using the revenue for general operations or other activities that have no clear relation to vulnerable populations. Some flexibility should be afforded to covered entities, but clear guidance is needed regarding how savings from 340B discounts are used to ensure that the benefits are passed through to the patients who are most in need of the services.

Transparency

The vague legislative language and unclear parameters that guide the implementation of the 340B program contribute to the lack of transparency and inconsistent reporting requirements regarding key aspects of the program.

Legislative efforts that attempt to address the lack of transparency include the 340B PAUSE Act (2017), sponsored by Representative Larry Bucshon [R-IN-8]), introduced in the U.S. House of Representatives in 2017, and the 340B HELP Act (2018), sponsored by Senator Bill Cassidy [R-LA]), introduced in the U.S. Senate in 2018. In addition to proposing a 2-year moratorium on approval of new DSHs, as well as any child sites, including clinics and contract pharmacies, both bills contain reporting requirements for the DSHs and their affiliates. Although the proposals differ in reporting details, such as whether the requirements apply to just the DSH, the DSH and affiliates, or just the affiliates, the combined requirements for DSHs and affiliates include reporting data on the number, percentage, and insurance status of patients receiving 340B drugs; costs and revenue for 340B drugs; and contracts with affiliated pharmacies and other entities that provide services associated with the program. The PAUSE Act would require additional information on DSH contracts with local and state governments, and the HELP Act places an emphasis on 340B claims modifiers as a way to more accurately assess revenue from 340B drugs as well as revenue obtained from physician-administered drugs. The reporting requirements in these proposals would substantially improve transparency and facilitate oversight of the program.

CMS needs the ability to accurately identify claims for 340B-purchased drugs and share this information with states and other program participants, in order to prevent duplicate discounts and diversion and ensure that vulnerable patients are charged appropriately for drugs purchased at 340B-discounted prices, even if this requires Congress to amend the statute.

The lack of program transparency has also added to the concerns regarding whether 340B savings are being used to provide care for vulnerable patients. Current measures of safety-net services, such as charity care and uncompensated care, may not adequately reflect the appropriate level of safety-net services provided (Conti et al., 2018) and better measures, as well as a better accounting method to link 340B savings to the provision of care to underserved populations, are needed to ensure that the program functions as intended.

Oversight

The GAO has repeatedly found inadequacies in 340B program oversight, which prevent the program from ensuring that contract pharmacies are compliant with the program requirements (GAO, 2018b) and may allow some hospitals to receive discounts for which they are not eligible (GAO, 2019). A major reason for the deficiencies in oversight is the lack of clear regulatory authority that has caused the 340B program to operate largely through informal guidance from the HRSA Office of Pharmacy Affairs. HRSA mainly relies on self-monitoring of participants and otherwise the agency engages in few activities to oversee the program. Currently, HRSA audits less than 2% of covered entities, and staffing levels at the agency have not kept pace with the dramatic increase in the number of program participants (GAO, 2018a). For adequate oversight to ensure 340B program integrity, Congress needs to give HRSA formal authority over program regulation, including specific reporting requirements for covered entities and their affiliates, tied to clear program goals, as well as the authority to enforce program compliance. In addition, adequate support is needed to allow oversight activities to match the growing level of program participation.

Conclusion

The 340B Drug Pricing Program is not the first attempt to mitigate the spiraling cost of prescription drugs for low-income and uninsured patients. Prior to the creation of the MDRP in 1990, drug manufacturers offered discounts to safety-net providers, but on a strictly voluntary basis. The MDRP was created to address rising Medicaid costs by requiring manufacturers to offer substantial rebates to state Medicaid programs as a condition of having their drugs covered by Medicaid. Not surprisingly, manufacturers

responded to this mandate by drastically limiting discounts to safety-net providers not covered by the program. To address those unintended consequences and with the laudable but vague intent of allowing certain providers to "stretch scarce federal resources" to help vulnerable patients, the 340B Drug Pricing Program was created by Congress in 1992.

Although well-intentioned, the 340B program, as currently designed and implemented, is fundamentally flawed and in need of major reform. For example, the focus on covered entities, rather than the patients the program is meant to help, allows drugs purchased at 340B discounted prices to be prescribed to fully insured patients, while at the same time, some uninsured patients may face the full price for their prescription drugs.

In addition, changes to the eligibility criteria, most notably following passage of the ACA, resulted in rapid program expansion, with the number of contract pharmacies increasing exponentially. What was initially intended as a support program narrowly focused on certain hospitals and providers has grown to include a sizeable portion of U.S. pharmacies, including major pharmacy chains. This growth has been both dramatic and largely unmanaged, as the statute failed to provide the necessary regulatory infrastructure, and, therefore, program integrity currently relies mainly on participants monitoring themselves.

The absence of formal regulations, including reporting requirements for many participants, has resulted in a lack of transparency that prevents adequate program oversight. Consequently, critical information, such as whether all providers participating in the 340B program and receiving discounted prices for drugs meet the statutory requirements for program eligibility or how the revenue from 340B savings are used, is unavailable. In addition, even if regulations were formalized, HRSA lacks the authority to enforce program compliance.

Reform of the 340B Drug Pricing Program needs to be patient-centered and based on three goals: legislative and regulatory clarity, increased transparency, and enhanced oversight. The program's good intentions will not be fully realized without meaningful reform that adequately addresses the program's current shortcomings. Fortunately, there appears to be bipartisan interest in seeing that happen.

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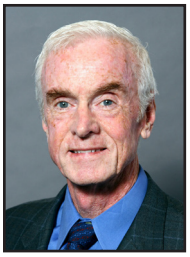

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