The 340B Program, Contract Pharmacies and Hospitals: An Examination of the First 25 Years of their Increasingly Complex Relationship

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ABSTRACT
The 340B Drug Pricing Program, created by Congress in 1992 through the Veterans Health Care Act, has provided discounted drug prices to hospitals and other health care organizations serving a wide population of low-income patients. Some 340B programs use contract pharmacies, an arrangement whereby the hospital or health care organization signs a contract directly with a pharmacy to provide covered pharmacy services at discounted prices.

The federal 340B Drug Pricing Program has provided access to reduced price prescription drugs to over 35,000 individual healthcare facilities and sites certified by the U.S. Department of Health and Human Services (HHS), and clinics have served more than 10 million people in all 50 states, plus commonwealths and U.S. territories. The 340B program has increased profits for hospitals through contract pharmacies because they have still received the same reimbursement but acquired drugs at a lower rate.

Keywords
340B Program, Covered entities, Pharmacy contracts

1 INTRODUCTION
The Federal 340B Drug Pricing Program was created by Congress in 1992 through the Veterans Health Care Act and has provided discounted drug prices to hospitals and other health care organizations that serve a wide population of low-income patients (HRSA, 2017a). The 340B program offers discounts to hospitals for the purchase of outpatient drugs regardless of the patient’s ability to pay (Health Affairs, 2017). As many as one third of Americans living at or below 200% of the federal poverty level have struggled to afford even modest prescription drug expenses (Bright et al., 2010). 340B pricing has not been applied to generic drugs, but has been applied to over the counter drugs, if prescribed by a physician (Albrecht and Mudahar, 2015). The sole purpose of the 340B program has been to use its savings incentives to help safety net providers increase their amount of patient services (HHS, 2016). Initially, individuals with low income and/or uninsured were the main targeted patients (Conti and Bach, 2014).

Under the 340B Program, a contract pharmacy has been defined as the arrangement in which the covered entity signs a contract with a pharmacy to provide pharmacy services (Clark et al., 2014). Covered entities within the program have been considered as facilities or programs that have been deemed eligible in the 340B statute to purchase drugs with the 340B discount and have appeared within the Health Resources and Services Administration (HRSA) 340B Database (340B University, 2016).

Audits have been the mechanism that HRSA has used to ensure that more than 11,000 covered entities participating in the 340B drug program were in compliance with government regulations (Vogel, 2015). HRSA has developed a 340B-specific protocol involving a more in-depth review of 340B compliance: they have audited covered entities based upon risk and targeted approaches under three various risk categories. The first category included high risk, which has depended on the volume of purchases, increased complexity of program administration, and use of contract pharmacies. The second category has been lesser risk, which has been audited by the HRSA and covered entities have been chosen at random from program types that have been...
considered a lesser risk. Finally, the targeted category, where audits have been predicted to trigger allegations of 340B non-compliance, which have not been limited to whistleblowers, manufacturers or covered entities themselves (Ingram, 2012). The HRSA has managed the program and predicted in 2013 that approximately $3.8 billion would be saved on outpatient drugs and has also estimated that hospitals would have a minimum discount of 22.5% with the use of the prospective payment system (Kantarjian and Chapman, 2015).

That the 340B program is important and growing is indisputable. Between 2010 and 2015, the 340B program more than doubled in size and between 2013 and 2015 alone it expanded by 66%. The program is forecasted to exceed $23 billion in total sales by 2021 and will exceed 2014 Medicare Part B drug reimbursement that same year, with growth largely be driven by expanded utilization at existing 340B-covered entities through contract pharmacy programs and from practice acquisitions, physician practice affiliations, and patient referrals (Vandervelde and Blalock, 2016).

Given the substantial and increasing size and mandate of the federal 340B Drug Pricing Program, we examine how it has affected hospitals and contract pharmacies since its inception, and what might be required to better meet the needs of its intended target, low-income Americans.

2 RESULTS

340B Covered Hospitals

Covered entities include six categories of hospitals: disproportionate share hospitals (DSHs), children’s hospitals and cancer hospitals exempt from the Medicare prospective payment system, sole community hospitals, critical access hospitals, and rural referral centers (Brennan et al., 2015). The requirements for eligibility of each hospital are presented in Table 1.

<table>
<thead>
<tr>
<th>Type of Hospital</th>
<th>Definition</th>
<th>To be eligible to participate in the 340B Drug Pricing Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disproportionate Shared Hospitals (DSHs)</td>
<td>Serve a significantly disproportionate number of low-income patients and receive payments from the Centers for Medicaid and Medicare Services to cover the costs of providing care to uninsured patients</td>
<td>Must meet the requirements of 42 USC 256b(a)(4)(L)</td>
</tr>
<tr>
<td>Children’s Hospitals</td>
<td>Are inpatient facilities with predominantly serving ages 18 or younger</td>
<td>Must either have a disproportionate share adjustment percentage greater than 11.75% for the most-recently filed cost report; or be eligible under a separate indigent care calculation that meets specific criteria including location in an urban area, 100+ beds and net inpatient care revenues (excluding Medicare) for indigent care of more than 30% of net during the cost reporting period in which the discharges occur</td>
</tr>
<tr>
<td>Freestanding Cancer Hospitals</td>
<td>Independent, non-profit hospitals that treat patients with cancer</td>
<td>For-profit hospitals are not eligible to participate</td>
</tr>
<tr>
<td>Sole Community Hospitals</td>
<td>Designated by the Centers for Medicare and Medicaid Services</td>
<td>Must have a disproportionate share adjustment percentage equal to or greater than 8% for the most-recently filed Medicare cost report and meet the requirements of 42 USC 256b(a)(4)(L)(i)</td>
</tr>
<tr>
<td>Rural Referral Centers</td>
<td>Are high-volume acute care rural hospitals that treat a large number of complicated cases</td>
<td>Have a disproportionate share adjustment equal to or greater than 8% for the most recently filed Medicare cost report and meet the requirements of 42 USC 256b(a)(4)(L)(i)</td>
</tr>
<tr>
<td>Critical Access Hospitals</td>
<td>Designated by the Centers for Medicare and Medicaid Services</td>
<td>Must meet the requirements of 42 USC 256b(a)(4)(L)(i)</td>
</tr>
</tbody>
</table>

Source: (HRSA, 2017)
Hospitals in each of the categories are required to be (1) owned or operated by state or local government, (2) a public or private non-profit corporation which has been formally granted governmental powers by state or local government, or (3) a private non-profit organization that has a contract with a state or local government to provide care to low-income individuals who do not qualify for Medicaid or Medicare (340 Health, 2017). To have qualified for 340B eligibility, a DSH must have a patient population of 27.32% low-income patients, defined as Medicaid-eligible (but not eligible for Medicare Part A), or Medicare Part A eligible patients who also qualify for federal Supplemental Security Income payments (Gricius and Wong, 2016). These authors also suggested that rural referral centers and sole community hospitals have a threshold of 22.8%. Hospitals, which were 46% percent of 340B-covered entity sites, account for nearly 90% of 340B purchases (Fein, 2016). In 2013, hospitals received 340B discounts on an estimated 25% of their drug purchases, compared with only 3% of 2004 purchases (Fein, 2016).

The federal 340B Drug Pricing Program has provided access to reduced price prescription drugs to over 35,000 individual healthcare facilities and sites certified by the U.S. Department of Health and Human Services (HHS) as "covered entities." In turn, these organizations have served more than 10 million people in all 50 states, plus commonwealths and U.S. territories (NCSL, 2017). These authors have also stated that covered entities spent $7 billion in 2013 on 340B drugs, which was 3 times the amount that was spent 8 years prior (Brennan et al., 2015). The 340B Program was originally implemented into only low-income communities, however, research suggested that facilities that registered after 2004 have been in higher-income communities (Conti and Bach, 2014).

### 340B audit compliance

Since 2012, HRSA has conducted audits of covered entities to assess whether they complied with statutory prohibitions against diversion and duplicate discounts. The latest audit results have revealed noncompliance rates that exceeded 69% and have reflected challenges in covered entities’ ability to comply with statutory requirements and HRSA’s administration of the 340B program (HRSA, 2017).

In order to remain compliant with the 340B program, covered entities must have registered all the pharmacy locations with which the covered entity had a written contract in place to dispense drugs or provide services to patients of the covered entity under the contract (Apexus, 2018).

HRSA must approve eligible entities, and covered entities must recertify their eligibility annually. Each site within a multi-location health system must qualify independently. A 340B hospital’s outpatient facility can participate in the 340B program only if it is an “integral” part of the hospital, which HRSA defines as “a reimbursable facility included on the hospital’s Medicare cost report” (Fein, 2016, p. 198). Several key focus areas exist for compliance, as assessed from the recent HRSA audit findings: verification that the patient was eligible, that the prescribing provider was employed or under contract with the covered entity at the time the prescription was written, and that the treating facility was registered in the HRSA database (Davison, 2017).

In addition, all off-site facilities and pharmacy locations should be registered accurately in the HRSA database. Internal controls should be maintained for preventing duplicate discounts and diversion, such as a tracking system, standard reports, and a process for mitigating problems when they were identified. Lastly, facilities should conduct regular internal monitoring and/or an independent annual audit, or otherwise be able to demonstrate an adequate oversight mechanism (Pontell, 2014).

### Contract pharmacies in hospitals

Many 340B covered hospitals have elected to dispense 340B drugs to patients through contract pharmacy services in order to improve access and patient care: 72% of hospitals have elected to partake in this program to increase available resources and have preceded to meet the needs of their low-income and rural patients (340 Health, 2017). The ability to dispense 340B drugs to patients through contract pharmacy services has helped facilitate program participation for those covered entities that have not had access to available or appropriate “in-house” pharmacy services (Wakefield, 2010), as well as those covered entities that have access to “in-house” pharmacy services but have wish to supplement these services (HRSA, 2018). Additionally, contract pharmacies have helped covered entities that wish to utilize multiple contract pharmacies to increase patient access to 340B drugs by giving patients more pharmacy choices (NCPA, 2017). Pharmacies can be an expensive proposition: prescription expenditures in clinics and nonfederal hospitals totaled $63.7 billion (an 11.9% increase from 2015) and $34.5 billion (a 3.3% increase from 2015), respectively (Schumock et al., 2017).

### 340B and hospitals

Research has proved that the 340B program has increased profits for hospitals through contract pharmacies because they have still received the same reimbursement but acquired drugs at a lower rate. Patients’ out-of-pocket costs have increased, therefore in some cases, it has only benefited the hospital and not their patients (Conti and Bach, 2013).
It has been suggested that hospitals could retain the profits they have received on drugs purchased through contract pharmacies under the 340B Program by dispensing these drugs at full price to fully insured patients (House Energy and Commerce Committee, 2018; Kelly, 2014; Wright, 2014). Although drugs dispensed to hospital inpatients are supposed to be ineligible for purchase through the 340B program, the tracking mechanism regarding how and for how much these drugs were purchased, and to whom and at what price they were dispensed, is simply inadequate. Because 340B prescriptions purchased from contract pharmacies cannot be identified at the time of payment, third-party payers are forced to reimburse 340B and non-340B outpatient prescriptions at the same rate. Therefore, a 340B entity can “arbitrage” the system by buying drugs at the 340B rate and charging for these same drugs at the non-340B rate. Medicare and commercial payers would not be able to identify the extent of the “excess”, because providers are not required to report the payer for 340B prescriptions (Fein, 2016). For example, Conti and Bach (2014) reported that Duke University Hospital profited $282 million in 5 years through outpatient departments and other affiliated clinics from their participation in 340B. Duke University Hospital’s reply - “It is very difficult ... to accurately calculate gross or net revenues from outpatient pharmaceuticals due to many factors, including the complicated reimbursement models for pharmaceuticals” (Alexander, Neff and Garloch, 2015) – appears to support Fein’s (2016) concerns. While Duke University Hospital’s response may well be accurate, it does not say anything positive about the ability of hospitals to track the costs of their pharmaceuticals or how they may be participating in the 340B program. In any event, only 5% of the patients treated at Duke University Hospital were uninsured, so the other 95% had some sort of insurance coverage; i.e., Medicare, Medicaid, or private insurance (Stern, 2014).

It has also been noted that, because physicians in private practice are ineligible to purchase drugs for their private patients through the 340B program, they have found it increasingly difficult to compete with hospital-based oncology practices, and consequently many are selling their practices to hospitals which do to participate in the 340B Program. This practice would potentially provide the physicians with anti-cancer drugs at a greatly reduced price due to the 340B drug discount, improving the profit margin of the oncology practice and the hospital which owned that practice, while also greatly expanding the oncology patient population served by the 340B hospital regardless of that patient population’s financial status. For example, Pollack (2013) noted that a single practicing oncologist whose practice was acquired by a 340B hospital could gain an additional $1 million profit by purchasing oncology drugs at a discount through the hospital’s participation in a 340B program. Since the average profit margin in 2015 on 340B oncology drugs was 49% (Vandervelde and Blalock, 2016), it is not surprising that hospitals see a clear financial incentive to aggressively obtain and market oncology services (Lagasse, 2018). Thus, the acquisition of oncology practices by hospitals participating in the 340B Program has accelerated. In 2012 and 2013, 75% of community oncology practices were purchased by hospitals with 340B programs (Community Oncology Alliance, 2014). Community Oncology Alliance (2016) notes the continuance of this trend, with the rate of closing of community oncology practices having increased 87% per month, which Hagen (2016) continues to attribute to the difficulties which community oncology practices have in try to competing with the lower drug acquisition costs of hospitals participating in the 340B Program. These findings are disheartening from a financial perspective, as Winfield and Muhlestein (2017), in a recent systematic literature review of 10 studies using either Medicare or commercial claims datasets consisting of cancer diagnoses between 2011 and 2016, found that the average cost of cancer care was 38% higher for patients treated in hospital-based practices compared with those treated at community clinics.

There is no requirement that hospitals spend any savings from the 340B program directly on patients, let alone on low-income patients (Gellad and James, 2018; Hayes, 2017), or even a requirement that hospitals report to anyone, public or private, how the savings are spent (Hayes, 2018; Teegardin, 2017). In fact, Desai and McWilliams (2018) in a recent study of general acute care not-for-profit hospitals with 50 or more beds and a DSH percentage ± 10% of the 11.75% eligibility threshold, found “no evidence of hospitals using the surplus monetary resources generated from administering discounted drugs to invest in safety-net providers, provide more inpatient care to low-income patients, or enhance care for low-income groups in ways that would reduce mortality.”

Questions have been raised as to whether profits achieved as a result of the 340B Program are being used appropriately to serve the needs of the nation’s most vulnerable (Freeman, 2017; Lee, 2014; Winegarden, 2017). Hospitals, on the other hand, claim that the program is serving its intended purpose, as the drugs are being provided to vulnerable patients or the money is spent on expanding low-income access to care and that analyses claiming otherwise are based upon faulty or inappropriate data (Testoni and Hart, 2014). However, the Government Accountability Office (GAO, 2015) found that “12% of hospitals which participated in the 340B program reported providing the lowest amounts of charity care across all hospitals in GAO’s analysis.” Similarly, Conti and Bach (2014, p. 1786) found that “hospital-affiliated clinics that registered for the 340B program in 2004 or later served communities that were wealthier and had higher rates of health insurance compared to communities served by hospitals and clinics that registered for the program before 2004, leading them to the conclusion that “the 340B program is being converted from one that serves vulnerable patient populations to one that enriches hospitals and their affiliated clinics.” More currently, the Alliance for Integrity and Reform (2016), based upon FY 2012-2014 Medicare cost reports, reported that 64% of 340B hospitals (all of which are not-for-profit) provide less charity care than the national average for all hospitals, including for-profit hospitals.
3 DISCUSSION
We examined the growth and effects of the federal 340B Drug Pricing Program implementation and determined that it has decreased hospital expenditures. Our literature review showed that 340B has decreased drug expenses for hospitals and increased their profit margins, and the 340B Program continues to grow, especially recently.

Six different types of hospitals have been covered by 340B, with each one having to have met a certain threshold for qualification. The 340B Program has been certified by the HHS and has allowed covered hospitals to have access to drugs at discounted prices. As a result of this program, over 10 million patients in the US have received these benefits.

In order for the 340B Program to better demonstrate compliance with federal regulations, a stricter internal auditing process should be established. The 340B statute explicitly authorizes HRSA to audit covered entities to be sure they are compliant with the program. The internal auditing helps with compliance issues that may have been overlooked otherwise. The authorizing officials at 340B-covered entities should be required to attest to being in full compliance with the 340B Program during recertification, including compliance at all contract pharmacies. In addition, as part of recertification, covered entities should be required to self-report to HRSA when they uncover a breach of 340B program requirements.

Contract pharmacies serve as a major component in the improvement of patient care and health care access. They have significantly increased the number of low-income and rural patients able to receive prescription drugs who were unable to do so before the implementation of 340B Program. However, many hospitals have also been found to provide drugs under the 340B Program to fully insured patients in order to gain a larger profit, rather focusing on lower-income patients who are uninsured.

Future research areas
Continual participation in the 340B Program by hospitals, and persistent research will be necessary to confirm if hospitals have neglected the program’s original goals and instead used the program becoming more profitable. The 340B Program has helped to offset hospitals’ expenditures, but the ongoing increase in patients’ out-of-pocket costs would imply that hospitals have used 340B to benefit themselves rather than their low-income patients. Additional data would obviously be helpful in determining where the additional funding associated with the 340B program payments to hospitals is being allocated by those hospitals. The practical implications of 340B will need to be more closely monitored as more hospitals register sites in higher-income communities.

4 CONCLUSIONS
The federal 340B Drug Pricing Program has continued to grow since being signed into law in 1992. Although it was originally designed to serve the needs of low-income Americans, it appears to have morphed into a mechanism for healthcare providers to enrich their bottom lines regardless of the income level of the population they serve, although the latter conclusion is disputable, depending on one’s point of view. Additional, more comprehensive data obtained using a better cost accounting system for providers and analysis by impartial parties will be necessary if the questions are to be resolved.

5 REFERENCES


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