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THE 340B PROGRAM, CONTRACT PHARMACIES, HOSPITALS, AND PATIENTS: AN EVOLVING RELATIONSHIP IMPACTING HEALTH CARE DELIVERY

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.

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 healthcare organizations that have served a vast population of low-income patients but later was expanded to include rural, HIV positive, pediatric, and other patient populations in which healthcare settings have a high percentage of uncompensated care.¹ Part of the original intent of this program was to help fill the void in prescription affordability in the uninsured population that did not qualify for state Medicaid programs. Initially, individuals with low income and/or uninsured were the central targeted patients and sliding scale pricing allowed these patients to receive prescription drugs at substantially reduced rates or for free.² The 340B program has offered discounts to hospitals for the purchase of outpatient drugs regardless of the patient's'

ability to pay with the most significant discounts being on branded drugs.³ 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.⁴ A secondary purpose of the 340B program was to allow providers to offset the cost of uncompensated care and use its savings incentives to help safety net providers to expand or improve patient services provided. 340B pricing has not been applied to generic drugs but has been applied to over the counter drugs, if prescribed by a physician.⁵ Programs have used 340B revenues to help safety net providers increase their amount of patient services or patient access to care.⁶ Initially, individuals with low income and/or uninsured were the principal targeted patients.⁷

At the program's initial conception, rules required qualified covered entities to only use an in-house pharmacy. In 2016, HRSA's Office of Pharmacy Affairs (OPA) published a Federal Register Notice allowing 340B covered entities to contract with an outside pharmacy to provide pharmacy services limited to one pharmacy per health care services site.⁸ 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 340B pharmacy services.⁹ 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.¹⁰ With the expansion of the program, HRSA has been attempting to ensure integrity in the program by discouraging and preventing diversion of discounted drug products for nonqualified patients. Audits have been the primary mechanism that HRSA has used to ensure that more than 11,000 covered entities were participating in the 340B drug program complied with government regulations.¹¹

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 a 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.¹² HRSA has managed the program and predicted in 2013 that approximately \$3.8 billion would be saved on outpatient drugs and also has it has been estimated that hospitals would have a minimum discount of 22.5% with the use of the prospective payment system.¹³

Between 2010 and 2015, the 340B program more than doubled in size and between 2013 and 2015 alone it expanded by 66%.¹⁴ Also, the program has been forecasted to exceed \$23 billion in total sales by 2021 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 referral. This equates to more than 41 percent of all nonprofit and public general acute-care hospitals as participants.¹⁵ The purpose of this study was to evaluate the growth and effects of the federal 340B Drug Pricing Program implementation and to determine if it has decreased hospital expenditures.

METHODOLOGY

The methodology for this study was a systematic review approach. Electronic databases used included EBSCOhost, PubMed, Academic Search Premier, Google Scholar, and ProQuest. Government websites were also used. A total of 51 sources were referenced.

Step 1: Literature Identification and Collection

The electronic databases used include EBSCOhost, PubMed, Academic Search Premier, Google Scholar, and ProQuest. The terms searched within each database were: "340B drug pricing program" OR "340B program," OR "340B discounts" AND "pharmacy contracts" OR "covered entities" AND "340B audits". Journals cited included but were not limited to Journal of Managed Care and Specialty Pharmacy and other reliable medical and government websites. The search identified 209 relevant citations and articles were

excluded (n=159) if they did not meet inclusion criteria. Articles were included (n=51) if they described the 340B Program and Contract Pharmacies The PRISMA approach used is shown in Figure 1.

Step 2: Literature Analysis

In an attempt to collect the most recent data, sources older than ten years, 2008 or earlier, were removed from the search and only sources written in English were used. Primary and secondary data from articles, literature reviews, research studies, and reports written in the U.S. were included in this research. The systematic review included 37 references, which were assessed for information about this research project. The literature search conducted by MB, MK, HS, and validated by AC and DP, who acted as the second readers and double checked to ensure that references met the inclusion criteria.

Step 3: Literature Categorization

The following subheadings were categorized into results: *340B Program Covered Health Care Entities*, *340B Program Audit Compliance*, *Contract Pharmacies*, and *340B and Health Care Entities*.

RESULTS

340B Program Covered Health Care Entities

Covered entities have included 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 reference centers.¹⁶ The requirements for eligibility of each hospital have been presented in Table 1.¹

Covered health care entities in each of the categories have been 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.¹⁷ 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 patient who also qualify for federal Supplemental Security Income payments.¹⁸ These authors also suggested that rural referral centers and sole community hospitals have a threshold of 22.8%, and hospitals, which were 46% of 340B-covered entity sites, account for nearly 90% of 340B purchases. In 2013, hospitals received 340B discounts on an estimated 25% of their drug purchases, compared with only 3% of 2004 purchases.¹⁹ In addition, hospitals received 340B discounts on an estimated 25% of their drug purchases, compared with only 3% of 2004 purchases.

By 2017, the federal 340B Drug Pricing Program 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.²⁰ In a report in 2015, covered entities spent \$7 billion in 2013 on 340B drugs, which was three times the amount that it was spent 8 years' prior.¹⁶ The 340B Program was initially implemented into only low-income communities; however, research suggested that facilities that registered after 2004 have been in higher-income communities with an increased percentage of private insurance coverage.²

340B Program 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.¹ Noncompliance has resulted from a lack of documentation, nonqualified patients receiving drugs, nonqualified physicians, or for other clerical reasons.²¹ In order to remain compliant with the 340B program, covered entities must have registered all the pharmacy locations with OPA and have placed a written contract covering all aspects of dispensing drugs, replenishment and compensation arrangement, as well as provide services to patients of the covered entity under the agreement.²²

HRSA must have ensured eligible covered entities, and covered entities have been required to recertify their eligibility annually, certifying that all listed information in the HRSA database is correct. Each site within a multi-location health system must have qualified independently. A 340B hospital's outpatient facility has only been eligible to participate in the 340B program if it was an "integral" part of the hospital, which HRSA has defined as "a reimbursable facility included on the hospital's Medicare cost report."¹⁹ Crucial several focus areas have arisen 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.²³ Moreover, this compliance has been particularly complicated and has required due diligence by covered entities to prevent diversion when patients have received care in areas with both inpatient and outpatient designations. Individual covered entities have been responsible for internally policing and auditing their processes and demonstrating how they rectify issues that arise.²⁴ It was reported that all off-site facilities and pharmacy locations must be registered accurately in the HRSA database.²⁵ Furthermore, internal controls have been 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 have conducted regular internal monitoring and/or an independent annual audit, or otherwise have been able to demonstrate an adequate oversight mechanism.²⁵

Contract Pharmacies

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.¹⁷ Initially, covered entities could only contract with one contract pharmacy. 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.²⁶ It has also benefited those covered entities that have had access to “in-house” pharmacy services but have wished to supplement these services.⁷ Additionally, contract pharmacies have helped covered entities that have wished to utilize multiple contract pharmacies to increase patient access to 340B drugs by giving patients more pharmacy choices.²⁷ Pharmacies have been 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.²⁸

340B and Health Care Entities

It has been reported 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.²⁹ Also, cash-paying patients' out-of-pocket costs have increased in some cases because costs have been shifted to consumers through increased cost of prescription drugs or increased copays from insurers, therefore in some cases, it has only benefited the hospital and a limited number of patients.

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.^{30;31} Although drugs dispensed to hospital inpatients have been 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, has been challenging to manage and diversion has occurred necessitating the need for constant audits by regulators and covered entities integrity teams.³² 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 has had the ability to “arbitrage” the system by buying drugs at the 340B rate and charging for these same drugs at the non-340B rate creating some degree of lack of transparency.³³ Medicare and commercial payers have not been able to identify the extent of the "excess," because providers have not been required to report the payer for 340B prescriptions.¹⁹ For example, it was reported that Duke

University Hospital profited \$282 million in 5 years through outpatient departments and other affiliated clinics from their participation in 340B.² Duke University Hospital replied by stating that accurately calculating gross or net revenues from outpatient pharmaceuticals has been tight due to many different variables, one of which included pharmaceutical reimbursement models.^{34;35} It was also noted that, because physicians in private practice have been ineligible to purchase drugs for their private patients through the 340B program, many have been selling their practices to 340B hospitals which do participate in the program. This practice has potentially provided the physicians with anti-cancer drugs at a significantly reduced price due to the 340B drug discount, improved their profit margins, and also greatly expanded the oncology patient population served by the 340B hospital when drugs were administered at the hospital's sites. Conti and Bach² verified that a single practicing oncologist was able to profit \$1 million for a hospital by purchasing drugs at the 340B discounted price. Since the average profit margin in 2015 on 340B oncology drugs was 49%, it was not surprising that hospitals have sought financial incentives to aggressively obtain and market oncology services.^{14;36} In 2012 and 2013, 75% of community oncology practices were purchased by hospitals with 340B programs.³⁷ Furthermore, the continuance of this trend, with the monthly rate of closing of community oncology practices have increased 87%, which have been attributed to the difficulties which community oncology practices have when trying to competing with the lower drug acquisition costs of hospitals participating in the 340B Program.³⁸ These findings were discouraging from a financial perspective, as another study found in a systematic review of 10 studies using either Medicare or commercial claims datasets consisting of cancer diagnoses between 2011 and 2016, that the average cost of cancer care was 38% higher for patients treated in hospital-based practices compared with those treated at community clinics.³⁹

There has not been any specific HRSA requirement that covered entities spend any savings from the 340B program directly on patients, let alone on low-income patient,^{40;41} or even an obligation that hospitals have to report how the savings have been spent.^{42;43} In fact, in a study of general acute care not-for-profit hospitals with 50 or more beds and a DSH percentage \pm 10% of the 11.75% eligibility threshold,

there was 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.⁴⁴ Also, because of this lack of transparency in where funds have been applied, there has been an increasing drumbeat by manufacturers, lobbyists, and insurers to end the program. It should be noted; however, that target areas for many facilities spending has been free or discounted medications for patients, medication reconciliation services, "meds-to-beds" program for improved transitions of care, and for support of comprehensive care of patients with HIV.⁴⁵

Questions have been raised as to whether profits achieved as a result of the 340B Program have been used appropriately to serve the needs of the nation's most vulnerable.^{46;47;48} Hospitals, on the other hand, have claimed that the program has been serving its intended purpose, has helped keep hospitals in the black that otherwise would not have been able to operate, and the drugs have been provided to low-income vulnerable patients expanding their access to care and that analyses claiming otherwise have been based upon faulty or inappropriate data.^{49;27} The Government Accountability Office (GAO) 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.⁵⁰ Similarly, another study reported 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 has been transformed from one that attends to susceptible patients to one that enhances hospitals and their clinics in affiliation.² More currently, based upon FY 2012-2014 Medicare cost reports, it was reported that 64% of 340B hospitals (all of which have been not-for-profit) have provided less charity care than the national average for all hospitals, including for-profit hospitals.⁵¹

DISCUSSION

The growth and effects of the federal 340B Drug Pricing Program implementation were examined, and it was suggested that the program has decreased hospital expenditures related to prescription drugs and increased margins related to prescription drugs and overall operations. As a result, the 340B program continues to grow well beyond its original intended scope.⁴⁰ It was estimated that the program had grown 60% of all hospital outpatient drug spending as late as 2015 nationwide.¹⁵

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, more and more patients in the US have continued to receive these benefits.⁵²

In order for the 340B Program to better demonstrate compliance with federal regulations, a stricter internal auditing process, and publically visible reporting should be established. The 340B statute explicitly authorized HRSA to audit covered entities to be sure they have been compliant with the program. The internal auditing has helped with compliance issues that may have been overlooked otherwise. The authorizing officials at 340B-covered entities must have attested to full compliance with the 340B program during recertification, including compliance at contract pharmacies and demonstrate how they have complied with the spirit of the program by utilizing funds generated from the program. Also, as part of recertification, covered entities should self-report to HRSA when they have uncovered a breach of 340B program requirements.

Contract pharmacies have served as a significant 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 the 340B Program. However, it has become apparent that a large percentage of the growth of the program has been fully insured patients generating additional revenues for the program versus improving access to lower cost prescription

drugs. Health-systems should be required to document in a publically viewable model as to how they have met the intent of the program with its generated savings.

A potential positive component to the 340B Drug Pricing Program was that hospitals have been able to access drugs at a discounted price but have kept the same reimbursement rate, therefore increasing their dispensing margin. The ability of these hospitals to obtain drugs at a lower price would potentially allow them to allocate their resources and services to more vulnerable patients or to provide compensation for what would usually be known as uncompensated care.¹⁵ How hospitals allocate funds has been left up to the individual covered entity and should be the focus of more oversight.

A negative component of 340B was that hospitals had received additional profits while patients' out-of-pocket costs have increased. Hospitals may have disregarded or de-emphasized the program's original intent of serving lower-income populations by registering new facilities in higher-income communities in order to gain a more substantial profit.

The exponential growth in the use of contract pharmacies and the revenue it produces has been the source of much of the manufacturer and regulator's calls for an end to the program or reigning in of the program. There are conflicting motives for scrutiny as manufacturers have to seek profit and it has been pointed out that funds may not be being directed where they should be applied which should be low-income patients. Finally, regulators have perceived an intensive hospital lobby, limited budgets, and lack of transparency in the drug pricing system.

This research study was not without its limitations. One barrier was that some hospitals have not implemented the 340B Program or have implemented it much later than others, so there was not consistent data regarding its participation rate and hospital profit margins. Another limitation was that some research has suggested that hospitals have utilized 340B based on its original intent to benefit low-income patients, whereas other studies suggested that hospitals have shifted its goal towards using it to increase their profit margins. This systematic review was restricted due to a small number of available articles, which may have

affected the quality of the information found during research. Other limitations included search strategy, number of databases used and researchers and publication bias.

This study revealed many practical implications proving that further investigation would be beneficial. 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 studies and or a meta-analysis of this topic would 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 have been registering healthcare settings in higher-income communities.

CONCLUSION

The federal 340B Drug Pricing Program has continued to grow since being signed into law, serving as a lifeline for safety-net providers and the patients they serve. The 340B program Has decreased drug expenses for hospitals and increased their margins generated from prescription drugs.

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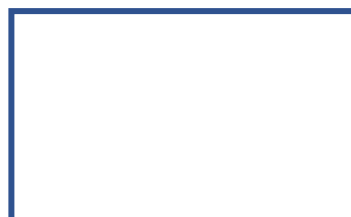
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Figure 1: Overview of citation evaluation.



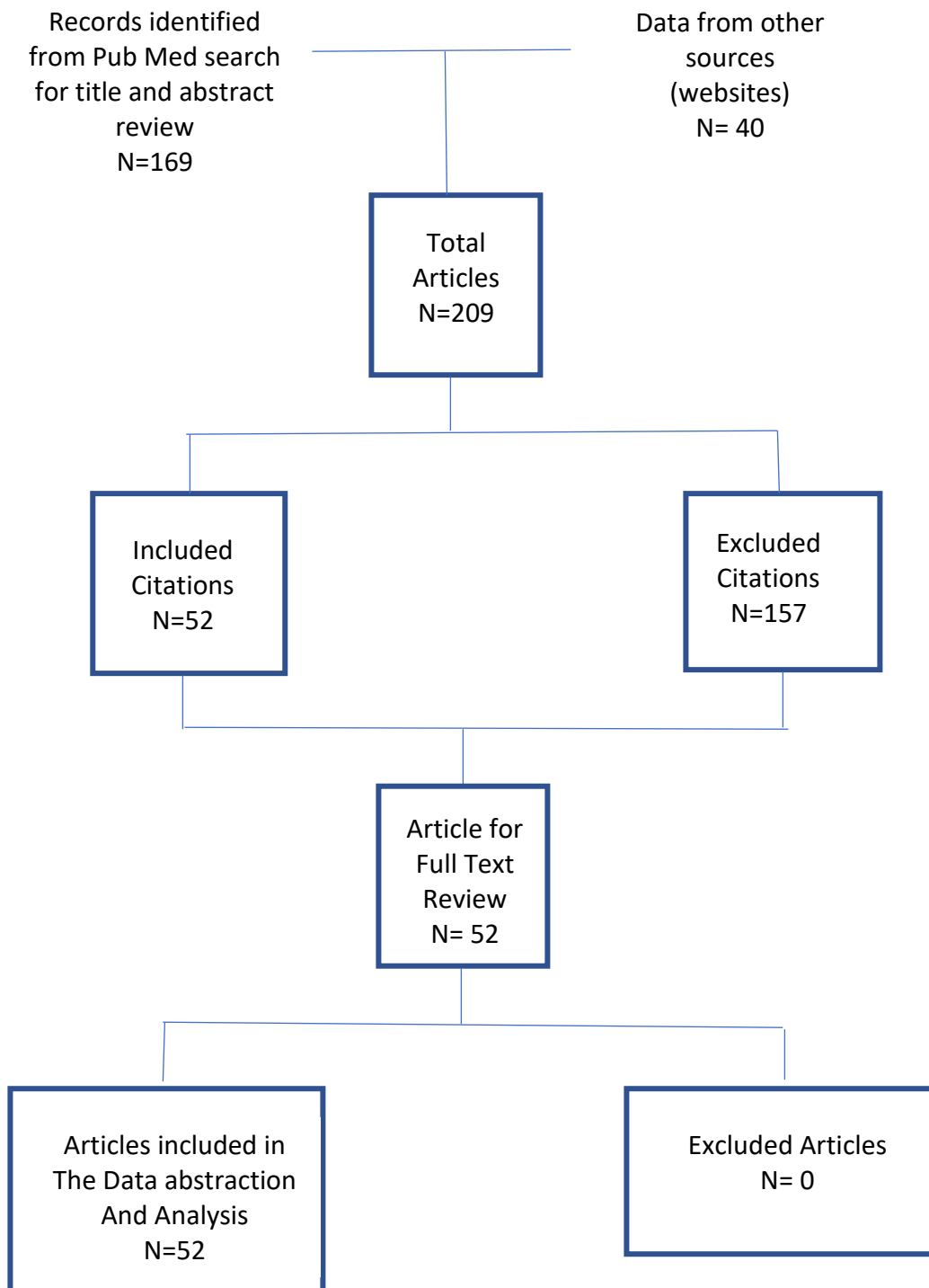


Table 1: Requirements for 340B Eligibility

Type of Health Care Entities	Definition	To be eligible to participate in the 340B Drug Pricing Program
Disproportionate Share Hospitals (DSHs)	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	Must meet the requirements of the 42 USC256b(a)(4)(L)
Children’s Hospitals	Are inpatient facilities with predominantly serving ages 18 or younger	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 with the discharges occur
Free Standing Cancer Hospitals	Independent, non-profit hospitals that treat patients with cancer	For-profit hospitals are not eligible to participate 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 Exempt from the Medicare Prospective Payment System
Sole Community Hospitals	Designated by the Centers for Medicare and Medicaid Services	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)
Rural Referral Centers	Are high-volume acute care rural hospitals that treat a large number of complicated cases	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)
Critical Access Hospitals	Designated by the Centers for Medicare and Medicaid Services	Must meet the requirements of 42 USC 256b(a)(4)(L)(i)
Federally Qualified Health Centers (FQHC)	Private nonprofit or public healthcare organizations located in or serving	<u>Health Center Program Statute: Section 330 of the Public Health Service Act (42 U.S.C.</u>

	federally-designated medically underserved areas or population.	<u>§254b</u>); Program: <u>42 CFR 51c</u> and <u>42 CFR 56.201-56.604</u>
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Source: HRSA, (2017a)