



Utilization of the 340B Drug Pricing Program in Rural Practices

Authors: Austin Gillard, Dennis Shelby and Karen White

I. Introduction

Beginning in 1992, the 340B Drug Pricing Program requires drug manufacturers to provide discounted drugs to certain health care providers, known as covered entities. Health care providers' ability to participate in the program is based on the type of provider and share of low income patients served. The 340B Drug Pricing Program, established as part of the Public Health Service Act, includes six hospital types – general acute care hospitals, children's hospitals, critical access hospitals (CAHs), freestanding cancer hospitals, rural referral centers and sole community hospitals, as well as certain federal programs including federally qualified health centers (FQHCs), Native Hawaiian health centers, tribal/urban Indian organizations, Ryan White grantees, black lung clinics, among others. Oversight and administration of the program rests with the Office of Pharmacy Affairs (OPA) at Health Resources and Services Administration (HRSA) within the Department of Health and Human Services (HHS).¹

Prior to the expansion of the Medicare Modernization Act (MMA) in 2003, few rural hospitals were eligible to participate in the 340B program. Rural participation further expanded in 2010 when CAHs became eligible as a part of the Patient Protection and Affordable Care Act.² A June 2018 study completed by the Government Accountability Office indicates that as of 2016, there are 2,399 hospitals participating in the 340B program with 62 percent of these hospitals located in rural areas. Of those participating rural hospitals, 93 percent are critical access hospitals.¹

The intent and purpose of the 340B Drug Pricing Program was rooted in providing savings so covered entities could expand services to meet the needs of more patients, especially the underserved and indigent populations. Savings generated from the 340B program come from discounted prices for outpatient drugs offered by manufacturers that are then sold to patients at a reduced cost. Section 340B of the Public Health Service Act specifies that as a condition for inclusion and participation in the Medicaid program, pharmaceutical manufacturers must participate in providing discounted outpatient drugs to covered entities. There are benefits for both manufacturers participating in 340B program as well as covered entities – by participating manufacturers have their pharmaceuticals covered by Medicaid and covered entities receive discounts between 25 and 50 percent of the average whole price for the covered pharmaceuticals.²



II. The 340B Program

The 340B program began after a Medicaid rebate program caused drug prices to spike dramatically for hospitals caring for low-income patients, threatening vulnerable hospital's solvency and patient access to needed care. The 340B program requires manufacturers to provide covered entities with discounted drugs. Covered entities must register with the OPA and adhere to comprehensive requirements to ensure compliance with program rules. Discounted drugs can be dispensed to patients with Medicare, private insurance, the uninsured, or those Medicaid patients for whom a Medicaid rebate was not already received. For privately insured patients, and in some instances Medicare patients, the full price of the drug is paid to the covered entity resulting in savings generated from the 340B program.

Critics of the 340B cite issues including the overall size of the program, including the number of "child sites" and how savings generated from the program are utilized by the covered entities, including the failure to pass along savings to patients. At the root of these issues is the ambiguity of Section 340B of the Public Health Services Act itself, Congress did not set requirements for how program savings must be used by hospitals, nor did they set requirements for detailing the use of savings, nor how the use of these savings are reported. While hospitals are not restricted in how the program savings are utilized, certain other covered entities, specifically Federal grantees, are required to utilize the savings in activities that are "federally approved as advancing their charitable mission of ensuring access to care for the underserved".^{1,3}

III. Problems with Measuring the Impact of 340B for Hospitals

Because of the lack of a clear definition of how funds are to be used, surrogate measures are sought to measure the extent to which 340B hospitals serve the indigent and underserved population the program was created to help. The most common surrogate measures that have been suggested are charity care, uncompensated care, and total unreimbursed and uncompensated care as a percentage of revenue. Data used for these measures are readily available from the Medicare cost report. These figures include charity care, bad debt, as well as those costs items excluded for reimbursement from Medicaid.⁴ However, due to the reporting burden, these measures are inconsistently reported among smaller hospitals as they have fewer resources to track the data that is the result of a complicated and burdensome process. Additionally, reporting of this data does not directly affect the reimbursement on the cost report, so there is little incentive to appropriate large amount of resources by small hospitals to track this data.

Within these areas, there are few guidelines regarding how 340B hospitals define charity care and there are inconsistencies in how financial assistance policies are written and applied leading to disparities in usage. Causing further confusion, the 340B



program metric used to determine eligibility for the program for hospitals is an inpatient measurement of Medicaid usage and admissions, which does not clearly represent the level of charity care, or even the 340B eligible patient population the hospital serves.²

IV. Charity Care

The proposal for participating 340B hospitals to have a certain amount of charity care listed on their Schedule H Form 990 is a flawed measure that does not actually provide the information the name implies. Charity care policies are different facility-by-facility. With the implementation of 501(r) mandated by the Patient Protection and Affordable Care Act, new rules have been established. These rules are also mandatory for governmental hospitals that have applied for 501(c) (3) status. Each hospital is required to meet several general requirements including:

- Establish written financial assistance and emergency medical care policies;
- Limit amounts charged for emergency or other medically necessary care to individuals eligible for assistance under the hospital's financial assistance policy; and
- Make reasonable efforts to determine whether an individual is eligible for assistance under the hospital's financial assistance policy before engaging in extraordinary collection actions against the individual.

Even with 501(r), patients are still required to complete a financial assistance application with the proper documentation asked within the application. This information can range from income statements, federal tax returns, or a basic understanding of the patients' monthly expenses. If the patient does not return the financial assistance application, no financial assistance is offered and the account eventually moves into bad debt. Accountability from the patient to complete the financial assistance application would be necessary, but unrealistic. Mandating this process to prove care was provided to individuals with no or little ability to pay is an undue hardship in the form of increased staff continually calling, helping, and monitoring financial assistance applications disbursed by the hospital.

The 340B statute does not require covered entities to track or report program savings or how they are used. The absence of reporting requirements in the 340B statute has resulted in a lack of data on how covered entities use the program and the value of the program, both to entities themselves and to the patients these entities serve.

V. Attempts to measure program impacts for hospitals do not work for rural hospitals

In 2015, the GAO found that about 40 percent of all hospitals participate in the 340B



program, and that the majority of 340B drugs are sold to hospitals.⁵ According to the Medicare Payment Advisory Commission, as of the first quarter of 2015, DSH hospitals represented about 78 percent of all 340B drug purchases.⁶ McKesson Corporation estimates that for each Medicaid prescription charged through 340B, the hospital would save more than \$7. For a large hospital or health system that bills for 500,000 Medicaid prescriptions a year, that is an annual savings of \$3.6 million.⁷ Aside from Medicaid prescriptions, the 340B program generates savings for covered entities by allowing them to purchase certain outpatient medications for less than they otherwise would pay - saving approximately 25 to 50 percent.⁸

With that said, we are still able to gather the financial impact of the 340B program through other sources not reported on the Medicare cost report, or covered entities reporting the program savings. HRSA estimates that covered entities saved \$3.8 billion on outpatient drugs through the program in FY 2013,⁹ \$4.5 billion in FY 2010,¹⁰ and approximately \$6 billion in Calendar Year 2015.¹¹ It is estimated that discounted drug purchases made by covered entities under the 340B program totaled more than \$16 billion in 2016 - a more than 30 percent increase in 340B program purchases in just one year.¹²

VI. Number of Hospitals do not tell the whole story

As of October 2017, 12,722 covered entities are participating in the program, and as of January 2, 2018, 743 pharmaceutical manufacturers are participating in the program.¹³ Furthermore, as of October 2017, 42,029 registered covered entity sites were participating in the 340B program, including 12,722 covered entity “parent sites” and 29,307 associated “child sites” are participating in the program.¹⁴ Looking at Exhibit 1, you are able to see the growth of hospital participation from 2005, 2010, and 2015. You will also notice the increase in CAHs participating in the program. In addition, by reviewing Exhibit 2, graphically you can see how much these entities spent from 2005 to 2013 on 340B qualified drugs.



Exhibit 1:

The number of hospital organizations participating in the 340B program more than tripled, 2005-2014

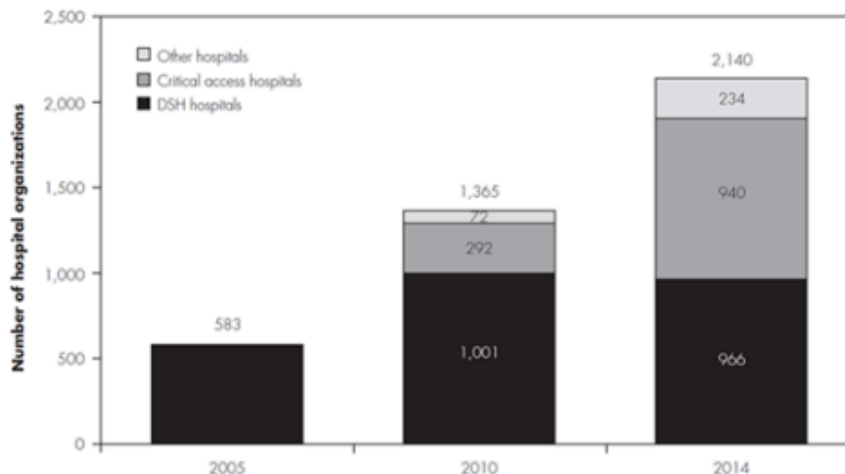
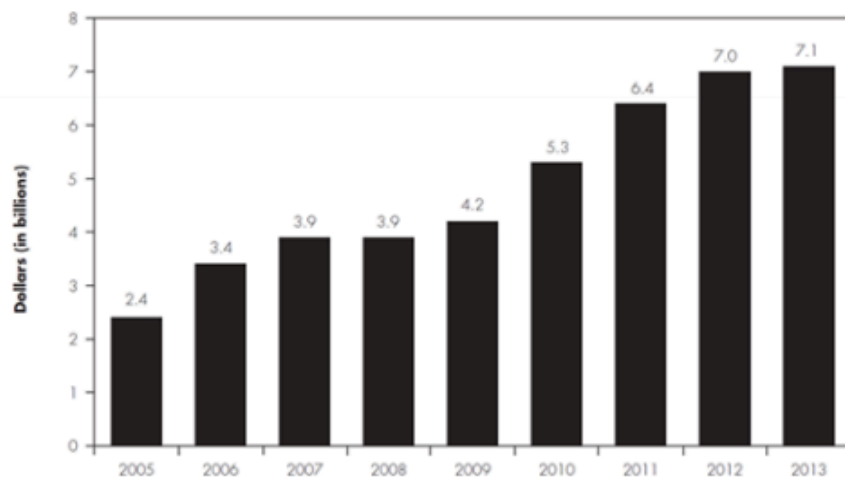


Exhibit 2:

Amount spent by covered entities on 340B drugs tripled, 2005-2013



The 340B program has expanded, as stated above. When pharmacy directors at 340B participating hospitals were asked to report what their hospitals did by purchasing discounted outpatient drugs, they mentioned offsetting the losses from providing pharmacy services (71 percent), increase and/or improve services at the hospital (51 percent), offset losses in other departments (41 percent), reduce medication prices to the patient (27 percent), and increase the quantity and/or variety of drugs available (16 percent).¹⁵



The loss of the 340B program would be detrimental to the portion of the healthcare system serving the most vulnerable patients. Congress created the 340B drug savings program to help those hospitals serving vulnerable communities expand access to prescription drugs and support essential services for their communities. The program constitutes less than three percent of the more than \$450 billion in annual drug purchases. Because the 340B program is funded by drug company discounts, not federal dollars, the 340B program does not cost the government any money – but it makes a big difference to vulnerable communities.

Improving the health of our communities is at the heart of every hospital’s mission, regardless of their form of ownership. Every year, tax-exempt hospitals demonstrate accountability to the communities they serve by filing a report on the benefits they provide to their community using the IRS Form 990 Schedule H and making it publicly available. In 2015 alone, the most recent year for which data is available, tax-exempt hospitals participating in the 340B drug savings program provided \$51.7 billion in total benefits to their communities, as seen in Exhibit 3.¹⁶

Exhibit 3:

340B Hospitals: Total Benefits to the Community

Type of Benefit* Provided	Percent of Total Hospital Expenses	Dollars Spent
Financial assistance, unreimbursed Medicaid, and unreimbursed costs from means-tested government programs	6.2%	\$25,267,225,086
Other benefits, including health professions education, medical research, cash and in-kind contributions to community groups	4.1%	\$17,079,563,560
FINANCIAL ASSISTANCE AND CERTAIN OTHER COMMUNITY BENEFITS	10.3%	\$42,346,788,646
Community-building activities	0.1%	\$319,162,052
Medicare shortfall	1.7%	\$6,900,205,440
Bad debt expense attributable to financial assistance	0.5%	\$2,143,469,669
TOTAL BENEFITS TO THE COMMUNITY	12.6%	\$51,710,148,846

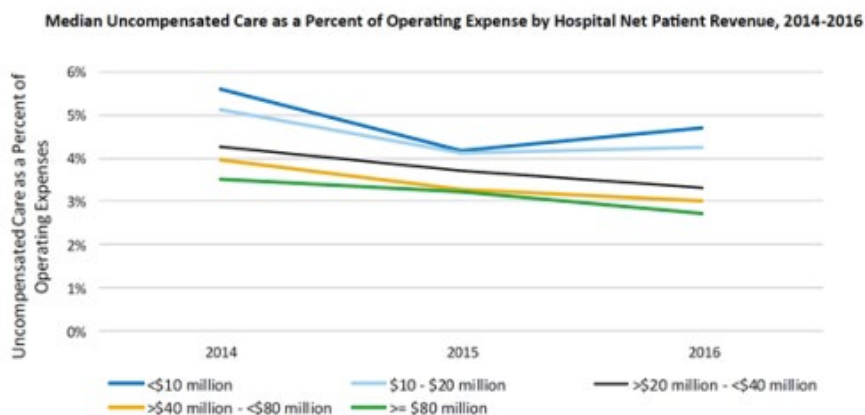
* Schedule H Part I.7, Part II, Part III A.3, B.7

VII. The rural safety net needs 340B

Rural residents are less likely than urban residents to have health care coverage through their employer, more likely to be low-income, and oftentimes are unable to afford coverage on their own.¹⁷ For hospitals that serve rural residents, this often means higher rates of uncompensated care compared to urban hospitals. After reviewing a

study by the North Carolina Rural Health Research Program regarding the median uncompensated care as a percent of operating expenses by hospital net patient revenue, Exhibit 4 shows that between 2015 and 2016, the median percentage of uncompensated care increased for hospitals with less than \$20 million in net patient revenue (n=894), whereas the median percentage decreased for hospital groups with more than \$20 million in net patient revenue (n=3,492).¹⁹

Exhibit 4:



VIII. Rural Community Benefits

For more than 25 years, the 340B program has been helping rural providers stretch scarce Federal resources as far as possible, to meet the needs of low-income citizens and improve and expand rural healthcare services. Ninety-five percent of the rural hospitals have been able to maintain or provide more uncompensated care services. The most powerful benefit is that 55 percent of rural hospitals reported that the 340B savings are used to keep the doors of their facility open. This is most definitely the greatest community benefit.²⁰ For those rural hospitals part of the 46 percent of operating at a loss, no additional documentation should be required to demonstrate that 340B program dollars are being used to provide a community benefit. The presence of a hospital is a well-documented benefit to the community. Some of the services available due to 340B are:

- Community health screenings
- Public wellness program and community outreach
- Expansion of rural health clinics to neighboring communities
- Free and/or deeply discounted medications
- Hospitals becoming certified trauma centers
- Transportation to medical appointments



This is just a sampling of the many services that 340B hospitals would not be able to provide unless other funding sources were secured. The best practice related to demonstrating the community benefit of the 340B program is to communicate the value of the program to the community annually.²¹ The American Hospital Association is asking that hospitals sign on to the 340B Good Stewardship Principles. They have templates for communicating the value of the 340B Program and disclosing hospital's 340B estimated savings.³² Another way to communicate the benefits is through an annual Community Benefits Report that most hospitals provide. Another report available is the Community Health Needs Assessment, which informs the public of unmet healthcare needs to which 340B funds could be applied. These same resources could be used by federal administrators seeking oversight into the use of 340B resources without any additional burden on participating hospitals. These documents are already public information that are available to HHS.

Another key partner in the rural safety net team includes the pharmacies and pharmacists who provide a critical role in not only dispensing medications, but also serve as support to hospitals and other healthcare facilities. As rural populations tend to be older and have more chronic health conditions than their urban counterparts, access to local pharmacy services is vital. Hospitals and other rural health providers depend on the 340B contract pharmacies to provide support for low-income patients with reduced drug prices. 340B rural contract pharmacies are vital because rural hospitals are less likely to maintain in-house outpatient pharmacies.³³

The intent of the 340B Program permits safety net providers to stretch scarce resources as far as possible, reaching more eligible patients and providing more comprehensive services.²² The resulting savings allows for greater reinvestment in charity care and enables covered entities to continue to provide services that otherwise would be eliminated due to lack of resources. "The program constitutes less than three percent of the more than \$450 billion annual drug purchases. Because it is funded by drug company discounts, not federal dollars, 340B program does not cost the government one penny, but it makes a big difference to vulnerable communities".²³

For rural hospitals, the estimated savings are between \$500,000 to \$1 million a year (24). Compliance costs for rural hospitals are close to \$100,000 a year, which eats up an average of 20 percent of the savings.²⁵ This results in a net savings for rural community hospitals of \$400,000 - \$800,000 to apply towards uncompensated care and to increase access and services for patients.²⁶

340B Health defines uncompensated care as the total charity care, bad debt, and underpayment from the public programs (excluding Medicare) provide in the last year. The uncompensated care calculation may not be the best way to reflect how hospitals increases access to care for lower income and/or rural patients. Each hospital must individually decide whether uncompensated care illustrates their hospital's unique 340B story.²⁷



- Charity Care: Services for which a hospital did not receive or expect to receive payment because the hospital determined a patient could not pay for the services.
- Bad Debt: Services that are often indistinguishable from charity care for which hospitals expected to be paid but were not reimbursed.
- Underpayments from Public Payers: Shortfalls in reimbursement from Medicaid and other state and local indigent care programs that do not cover hospital costs.²⁸

Rural hospitals have a disproportionate share of the sick and poor resulting in higher levels of uncompensated care. However, a single line on a Medicare cost report does not reflect the reality of a rural hospital's charity care and should not be used to exclude rural hospitals from this vital program.

IX. Summary

The 340B program has met an important objective: stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services, especially for rural providers where 46 percent are operating at a loss financially. The issues around the ambiguity of the act, financial impact of the program, community benefits, and the loss of the 340B program's effect on communities has been reviewed. One major conclusion is the lack of reporting requirements has resulted in a lack of reliable data surrounding utilization of the 340B program by approved entities. Reforming the 340B program to promote transparency and accountability will allow for an accurate accounting of the full scope of the 340B program, and will help promote integrity and oversight.²⁹ Until this happens, the authors of this brief suggest that covered entities follow the "Call to Action" recommended by the American Hospital Association and commit to good stewardship principles regarding the 340B program. There are tools available to help 340B entities demonstrate transparency.^{30,31} The 340B program is extremely valuable, affecting the lives of millions and allowing access to care that would not exist without the 340B program.



References

1. U.S. Government Accountability Office, Drug Discount Program: Characteristics of Hospitals Participating and Not Participating in the 340B Program, GAO-18-521R (Jun. 2018).
2. NORC Walsh Center for Rural Health Analysis, North Carolina Rural Health Research & Policy Analysis, Policy Analysis Brief, Rural Hospitals' Experience with the 340B Drug Pricing Program (Sept. 2007).
3. U.S. Gov't Accountability Office, Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement, GAO-11-836 (Sept. 2011).
4. U.S. Government Accountability Office, Drug Discount Program: Characteristics of Hospitals Participating and Not Participating in the 340B Program, GAO-18-521R (Jun. 2018).
5. U.S. Gov't Accountability Office, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, GAO-15-442 (Jun. 2015).
6. Medicare Payment Advisory Commission, Report to Congress: Overview of the 340B Drug Pricing Program, at 12 (May 2015).
7. McKesson, How Hospital Pharmacies Can Maximize on 340B Drug Savings (Dec. 4, 2017), available at <http://www.mckesson.com/blog/how-hospital-pharmacies-canmaximize-on-340b-drug-savings/>.
8. 340B Prime Vendor Program, 340B Price/Covered Outpatient Drugs (last accessed Dec. 1, 2017), available at <https://www.340bpvp.com/resource-center/faqs/340b-pricing--covered-outpatient-drugs/>.
9. Examining the 340B Drug Discount Program: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce, 114th Cong. (March 24, 2015) (statement of Diana Espinosa, Deputy Administrator, Health Resources and Services Administration).
10. Health Resources and Services Administration, U.S. Dep't of Health and Human Services, Justifications of Estimates for Appropriations Committees—Fiscal Year 2017 (2016), available at <https://www.hrsa.gov/about/budget/budgetjustification2017.pdf>.



11. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1227 (Jan. 5, 2017).
12. Aaron Vandervelde and Eleanor Blalock, Measuring the Relative Size of the 340B Program: 2012-2017, BERKELEY RESEARCH GROUP (July 2017), available at https://www.thinkbrg.com/media/publication/928_Vandervelde_Measuring340Bsize-July2017_WEB_FINAL.pdf.
13. U.S. House of Representatives, Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations, 115th Cong., Email from U.S. Department of Health and Human Services Staff to Committee Staff (Dec. 21, 2017); U.S. Dep't of Health and Human Services, Health Resources and Services Administration, 340B Drug Pricing Program Manufacturers (last accessed Dec. 13, 2017), <https://340bopais.hrsa.gov/manufacturerearch>.
14. U.S. Dep't of Health and Human Services, Health Resources and Services Administration, 340B Drug Pricing Program Covered Entities (last accessed Dec. 1, 2017), <https://340bopais.hrsa.gov/coveredentitysearch>; U.S. House of Representatives, Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations, 115th Cong., Email from U.S. Dep't of Health and Human Services Staff to Committee Staff (Dec. 21, 2017).
15. "Rural Hospitals' Experience with the 340B Drug Pricing Program." Rural Health Research Gateway, 2007, www.shepscenter.unc.edu/rural/pubs/finding_brief/FB82.pdf.
16. 340B Hospital Community Benefit Analysis | AHA. (2018, March). Retrieved from <https://www.aha.org/guidesreports/2018-03-01-340b-hospital-community-benefitanalysis>
17. Key Facts about the Uninsured Population (2017). Kaiser Family Foundation. Available at: <http://files.kff.org/attachment/Fact-Sheet-Key-Facts-about-the-Uninsured-Population>.
18. Banow T. Charity Care Spending Flat among Top Hospitals. Modern Healthcare, January 6, 2018. Available at: <http://www.modernhealthcare.com/article/20180106/NEWS/180109941>.
19. Garcia, K., Thompson, K., Howard, H., & Pink, G. (2018, June). Publication Details: Geographic Variation in Uncompensated Care Between Rural and Urban Hospitals - Rural Health Research Gateway. Retrieved from <https://www.ruralhealthresearch.org/publications/1186>



20. Results from 340B Health's 2017 Annual Survey, 340B Health, June 2018
21. <https://www.aha.org/initiativescampaigns/2018-09-12-call-action-hospitals-committment10/1/2018>
22. H.R. Rep. No. 102-384(11), at 12 (1992)
23. 340B Hospital Community Benefit Analysis American Hospital Association, March 2018 p.1
24. Evaluating 340B Hospital Savings and their use in serving low income and rural patients, 340B health. June 2018 page 9.
25. <https://340binformed.org/2018/06/survey>
26. 340B Oversight Best Practice Apexus 340B Prime Vender Program 06112018, p.2
27. 340B Health, Impact profile guide, p. 14
28. <https://340Binformed.org/2017/10/house-340b-hearing-set-for-oct-11/>
29. See 9 (after March 24, 2015), p.75
30. 340BSavings and Community Benefit Template, Apexus, 340B Prime Vendor Program, 6/11/18, p.1-3
31. 340b Health, Impact Profile Guide Chapter 3, The Impact of 340B in My Community, p.23
32. <https://www.aha.org/initiativescampaigns/2018-09-12-call-action-hospitals-committment10/1/2018>
33. 340B Health, 340B Hospitals Use Their Contract Pharmacy Benefit to Treat Low-Income