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# UNPRECEDENTED GROWTH, QUESTIONABLE POLICY: THE 340B DRUG PROGRAM

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## INTRODUCTION

The Affordable Care Act changed the landscape of American health care in many significant ways, with much of it receiving high levels of scrutiny. However, the expansion of a little-known federal program for hospitals – a result of Congress’s mission to increase care provided to the uninsured – has largely remained under the radar. It merits attention, however, because this change will cause unanticipated complications for patients and physicians, while likely increasing overall healthcare costs.

The program, 340B, is a popular one among hospitals and pharmacies, because it forces pharmaceutical manufacturers to provide markdowns to certain nonprofit hospitals (referred to as “covered entities”), with discounts ranging from 30% to 50%. Even better for the 340B facilities, they get to hold on to those savings, and are not required to pass along the reduced drug prices to any patients, whether they have insurance or not.

Thanks to expansions, such as a decision in 2010 from the federal government that allowed 340B facilities to contract with multiple pharmacies, the program has exploded. And it will only continue growing, as Medicaid eligibility is expanded to 133 percent of the federal poverty level, potentially impacting an estimated 9 million additional people this year, according to estimates from the nonpartisan Congressional Budget Office. That number is only expected to grow to a total of 12 million new Medicaid enrollees by 2019.

So why is 340B growing along with the Medicaid population? Because the statute behind 340B requires all newly-eligible facilities, like “sole community hospitals” and “critical access hospitals,” to cross a threshold set by a formula that uses Medicaid enrollees as a key factor. In other words, more Medicaid patients means more hospitals qualify for the 340B program.

340B was originally intended to meet a valid need: Total hospital margins in 2011 were around 7%, according to the latest data from the American Hospital Association, and nearly 25% of hospitals had negative operating margins in that same year.<sup>1</sup> That some hospitals are struggling to stay afloat is not surprising, as the rate of growth in national health care spending has slowed significantly since the 2008 recession.

But if the federal government wants to provide assistance to hospitals that serve the uninsured, this level of expansion the 340B drug program is not the right policy, nor is allowing entities benefiting from the program to remain unchecked. It arbitrarily lines hospital and pharmacy bottom lines, without improving patient care or physician access. It makes it difficult for local, smaller entities, particularly physicians with their own practices, to compete, since they cannot qualify for the 340B program on their own. And, in increasing numbers, this is leading to hospital acquisition and absorption of independent physician practices, causing the closure of community cancer clinics across the country. In the end, this policy will ultimately end up increasing health care costs for everyone, as patients are shifted from cheaper, community-based care to more expensive hospital settings and unnecessarily prescribed the most expensive drugs so 340B facilities capture the largest profits.

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<sup>1</sup>American Hospital Association. “Chartbook: Trends Affecting Hospitals and Health Systems.” <http://www.aha.org/research/reports/tw/chartbook/ch4.shtml>

The following paper explores how the 340B program has exploded, and the perverse incentives the program has that creates negative impact that has on patients and physicians.

### **EXPLODING GROWTH: FROM TARGETED PROGRAM TO ONE-THIRD OF U.S. HOSPITALS**

The 340B program was established by Congress in 1992, with an aim to help federally-funded clinics and public hospitals that serve a large uninsured population cover the cost of drugs. The program, named after the section of the law it was passed in, requires drug companies to give significant discounts, often ranging from 30% to 50%, to certain health care entities when they fill prescriptions for outpatients. At the time, the aim of the program was to help maintain outpatient services at hospitals and clinics that served large uninsured populations.

As Congress explained in a report that accompanied the law in 1992, the program was set up to provide “protection from drug price increases to specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans.”<sup>2</sup>

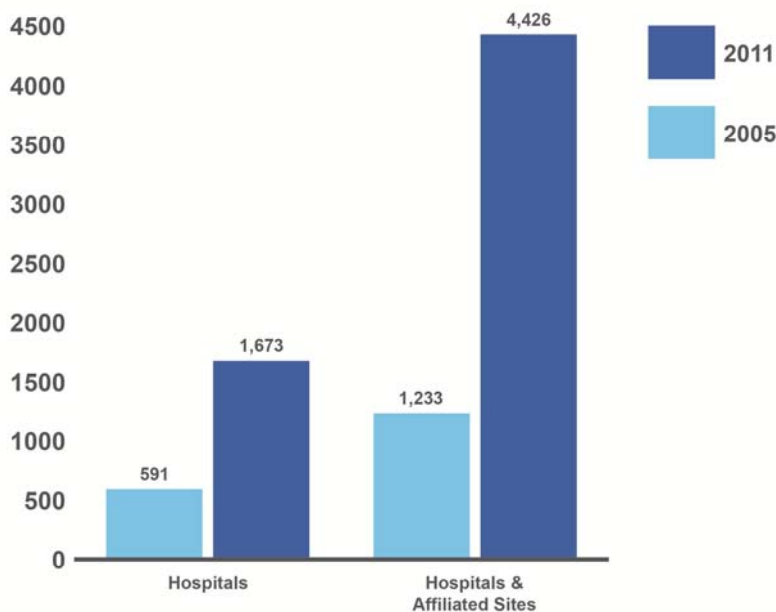
But that is not the path the 340B program has taken over the past two decades. According to the Government Accountability Office, the number of hospitals claiming 340B discounts doubled between 2009 and 2012, reaching 1,679 hospitals or a third of the hospitals in the United States. The overall number of facilities claiming 340B status has doubled since 2001, increasing from 8,605 facilities to 16,572 in 2011.<sup>3</sup> (A good portion of the overall growth came after the passage of the Affordable Care Act, which expanded which facilities would qualify for discounts.)

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<sup>2</sup> 32 U.S. House of Representatives Report accompanying H.R. Rep. 102-384 (II) (1992),12.

<sup>3</sup> Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement. (GAO-11-836). Washington, DC: US Government Accountability Office; 2011.

### Hospital 340B Participation More Than Doubles Since 2005; Will Only Increase With Medicaid Expansion



SOURCE: Government Accountability Office

A recent study from Avalere Health found that of the hospitals qualified for 340B, 267—one third of those in the program—reported uncompensated care that is below the 7% average of total revenues identified by the Internal Revenue Service. Put another way, that means that one-third of hospitals receiving major discounts on drugs are counting less uncompensated care than the average nonprofit hospital. That is a far cry from what the law intended.

The 340B program at hospitals also correlates with higher spending on drugs. Even though 340B hospitals make up a third of all of the hospitals in the U.S., they capture an outsize portion of drug spending, accounting for nearly half of drug spending among U.S. hospitals.<sup>4</sup> It makes sense that these hospitals would be spending more on drugs than facilities that are not part of the 340B program – the 340B hospitals get a discounted price on the drugs from the manufacturers, but get reimbursed at the regular rate by insured patients. The 340B hospitals keep the savings between the cost of the drug and the price they charged for it, making them more likely to prescribe more drugs in the future and making them more competitive against other hospitals.

As mentioned above, the number of 340B-eligible hospitals is only expected to increase as Medicaid expands under the ACA. The health reform law expands Medicaid access to childless adults making 133% or less of the federal poverty level. While the Supreme Court gave states the option to accept or reject this expansion, the nonpartisan CBO estimates that 9 million new people will be signed up for Medicaid this year.

<sup>4</sup> Avalere Health. “The 340B Drug Discount Program: A Review and Analysis of the 340B Program.” <http://www.bio.org/sites/default/files/340B%20White%20Paper%20FINAL.pdf>

As Medicaid enrollees increase, that means more and more hospitals will become eligible for the 340B program. That's because the formula used to determine whether new hospitals are eligible for 340B count the number of Medicaid patients in a key piece of the formula. So more hospitals will be eligible to buy discounted outpatient medicines, then keep the difference as they sell those medicines to insured patients.

The growth of the 340B program is not just in hospitals. The Avalere study found that there were 7,888 unique entities, from hospitals to pharmacies to outpatient cancer centers, participating in the 340B program as of July 2011.<sup>5</sup> That number has likely only increased since that date, as more facilities have qualified for the 340B program under the Affordable Care Act. But in 2011 the Health Resources and Services Administration (HRSA), which is responsible for 340B oversight, expressed concern that the statute outlining 340B qualifications was being so broadly interpreted that it included patients seen by providers who are "only loosely affiliated with a covered entity," which ultimately "does not actually have the responsibility for care."<sup>6</sup>

Some of the largest growth in the program has come from pharmacy contracts, which have increased at a rate of 43% annually since 2000.<sup>7</sup> A decision from HRSA in April 2010 allowing 340B entities to contract with multiple pharmacies increased the number participating in the program by a whopping 161%. That number is expected to grow, as hospitals and other 340B facilities have a financial incentive to encourage patients to use contract 340B pharmacies, which can purchase drugs at the discounted price.

In July, Senate Judiciary ranking member Chuck Grassley (R-IA) sent a letter to Walgreens requesting information on its 340B practice. According to the letter, 5,400 of the 7,000 contract pharmacies attached to the 340B program are Walgreens facilities, prompting questions on whether the program was passed to increase profits at a multimillion dollar corporation. Grassley contends that it was not: "The intent and design of the program is to help lower outpatient drug prices for the uninsured. It is not intended to subsidize pharmacies that team up with covered entities to turn a profit," he wrote.<sup>8</sup>

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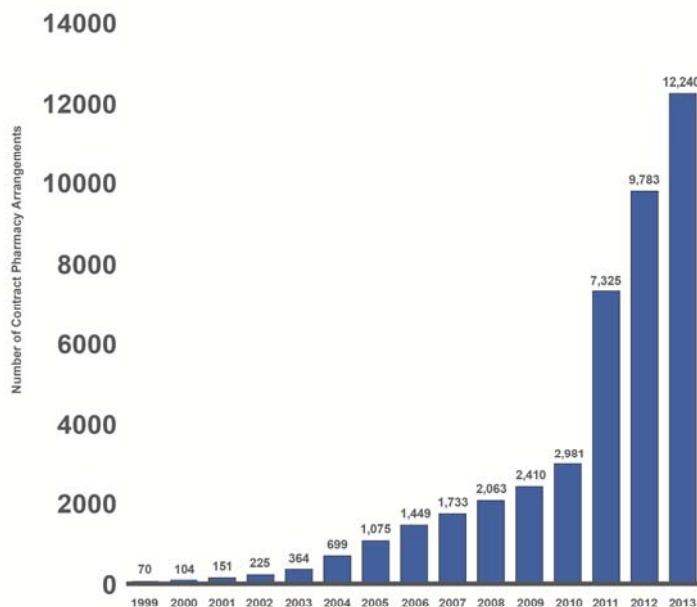
<sup>5</sup> *ibid*

<sup>6</sup> **Manufacturer Discounts in the 340B Program** Offer Benefits, but Federal Oversight Needs Improvement. (GAO-11-836). Washington, DC: US Government Accountability Office; 2011.

<sup>7</sup> Avalere Health. "The 340B Drug Discount Program: A Review and Analysis of the 340B Program." <http://www.bio.org/sites/default/files/340B%20White%20Paper%20FINAL.pdf>

<sup>8</sup> Sen. Chuck Grassley, (R-Iowa). "Letter to Walgreens President and CEO on 340B." [http://www.pembrokeconsulting.com/pdfs/Grassley\\_340B\\_Letter\\_to\\_Walgreens\\_31July2013.pdf](http://www.pembrokeconsulting.com/pdfs/Grassley_340B_Letter_to_Walgreens_31July2013.pdf)

## Pharmacy Contracts Explode Over the Past Decade



SOURCE: Avalere Health and HRSA

And it appears that the growth in 340B entities is not just for hospitals, clinics, and pharmacies. According to the National Community Pharmacists Association, at least one hospital has used its 340B status to get discounted drugs for patients in a long-term care (LTC) facility. The LTC in-house pharmacies that typically serve this population cannot compete, since they are not qualified to get the government discount on the drug.<sup>9</sup> That could put LTC pharmacies at risk, which serve nearly 2 million residents across the country.

### PERVERSE INCENTIVES: INCREASED COSTS AND EXPENSIVE DRUGS

The savings available from discounted 340B drugs can incentivize hospitals and providers to change their behavior in order to reap financial benefits. For example, 340B conferences have encouraged facilities to change their admissions process so more patients were considered outpatients and therefore qualified for the discounted drugs, going so far in one case as to “discharge” transplant patients to a nearby townhouse so they could receive expensive drugs at the marked-down 340B price as outpatients. Of course, those savings were not passed along to the patients, but kept for the hospital.

These types of administrative changes are obviously not done with the patients’ best medical interests in mind. They are done for the best outcome of the hospitals’ bottom line. And patients can actually end

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<sup>9</sup> Avalere Health. “The 340B Drug Discount Program: A Review and Analysis of the 340B Program.” <http://www.bio.org/sites/default/files/340B%20White%20Paper%20FINAL.pdf>

up paying more, as higher co-pays and cost-sharing for drugs are common in an outpatient setting versus an inpatient setting.

Further, a recent article in the Journal of the American Medical Association points out that the profits providers can recoup on drugs, particularly in cancer treatments, can have an effect on what they end up prescribing.<sup>10</sup> Because physicians will, in general, make more money off the most expensive drugs in the 340B program, some will tend to prescribe those drugs more to increase profits.

The 340B program also seems to be contributing to the further consolidation of community oncology practices into hospitals. A 2013 study from the Community Oncology Alliance found that over the past six years, 1,338 oncology clinics closed, 469 practices signed an agreement with a hospital or were purchased, and 131 practices merged with hospitals. Over the past year, the group saw a 20% increase in the number of clinics that closed their doors, and a 20% increase in the number of practices that were purchased by a hospital or signed an agreement with one.<sup>11</sup>

As the JAMA article points out, hospital care, even when it is considered “outpatient” care, is often more expensive than treatments done at a physician’s office. Additionally, the further consolidation of cancer treatment options can end up increasing what hospitals can charge insurance companies, which ultimately drives up the cost of insurance premiums.<sup>12</sup>

## **CONCLUSION**

From unnecessary, expensive administrative changes, to the incentive to prescribe the costliest drugs, to continued consolidation of cheaper, local practices into expensive hospital settings, the 340B program is a loser for patients and physicians.

It is important that hospitals continue to care for the uninsured, and whether federal assistance to fund that task should continue in general is a different debate. But as more and more hospitals qualify for the 340B program, in large part thanks to the huge influx of Medicaid patients, it is clear that the 340B program is not the right policy to help hospitals and clinics who serve the uninsured. Instead, it has exploded into a free ride for hospitals that ends up driving up the cost of health care for the rest of us.

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<sup>10</sup> Conti, Rena, Bach, Peter. Cost Consequences of the 340B Drug Discount Program. JAMA, 2013; 309:1995-1996. Available from: American Medical Association, Chicago, Ill.

<sup>11</sup>Community Oncology Alliance. “Community Oncology Practice Impact Report 2013.”

[http://glacialblog.com/userfiles/76/Community\\_Oncology\\_Practice\\_Impact\\_Report\\_6-25-13F\(1\).pdf](http://glacialblog.com/userfiles/76/Community_Oncology_Practice_Impact_Report_6-25-13F(1).pdf)

<sup>12</sup> Conti, Rena, Bach, Peter. Cost Consequences of the 340B Drug Discount Program. JAMA, 2013; 309:1995-1996. Available from: American Medical Association, Chicago, Ill.