HEDGEYE

Health Policy Explainer

The 340B Drug Program

Created in 1992, the 340B Drug Discount Program is a little-known program that's getting an increasing amount of attention from hospitals, Congress and pharmaceutical companies. The 340B Program requires that any pharmaceutical company participating in Medicaid (i.e., essentially all pharmaceutical companies) provide mandatory discounts for outpatient drugs to certain types of hospitals in order to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services," according to the HHS 340B program website.

The intent of the program, as reflected in the original list of eligible program participants – Ryan White Clinics, Federally Qualified Health Centers, for example – was to reduce the cost of drugs to these entities so they could direct scarce resources to the delivery of care to the uninsured. What has in fact happened is that nonprofit hospitals increasingly rely on their prescribing power and that of their physicians to enhance their income statements.

History and Background. Historically, eligible entities – known as covered entities or CEs – included nonhospital clinics that receive one of 10 types of federal grants aimed at low-income, uninsured individuals (e.g., community health centers, hemophilia treatment centers, etc.). and certain nonprofit hospitals that serve a high inpatient proportion of low-income Medicare and Medicaid patients. These hospitals are known as disproportionate share hospitals or DSH hospitals. In order to qualify for the discount, a DSH hospital must meet a minimum DSH threshold and one of the following criteria:

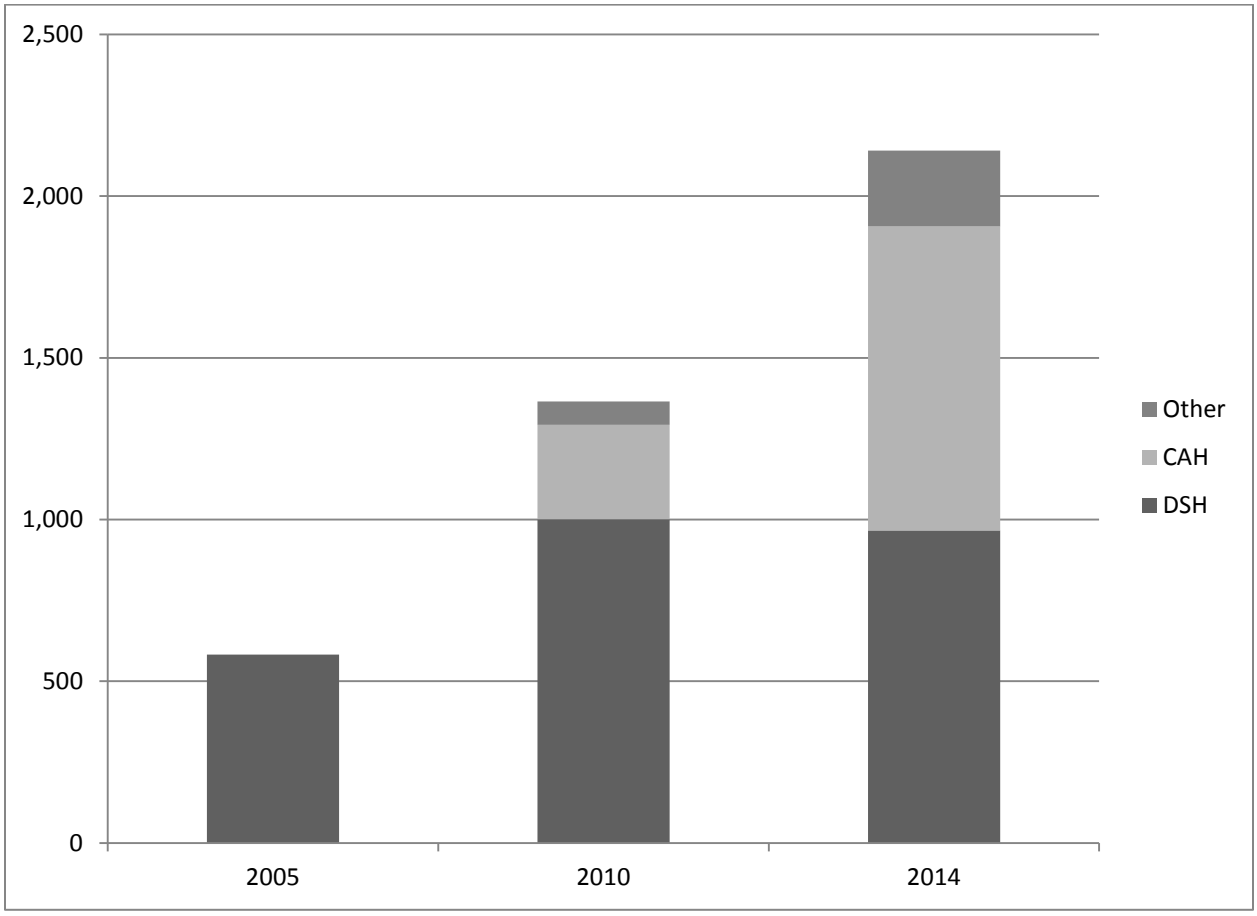
- Owned or operated by a State or local government;
- A private, nonprofit hospitals with a contract with a State or local government to provide health care services to low-income individuals not entitled to Medicare or Medicaid;
- A public or private nonprofit hospital that has been formally granted governmental powers by a State or local government;
- Nonprofit critical access hospitals;
- Nonprofit sole community hospitals
- Nonprofit children's hospitals;
- Nonprofit rural referral centers; and
- Nonprofit freestanding cancer hospitals.

There are over 36,000 CEs, of which 43 percent are DSH hospitals and their affiliated entities. These affiliated entities include outpatient centers for radiation therapy, cardiology and ophthalmology as well as other types of satellite locations. The roughly 16,000 individual CEs

represent 2,300 individual hospitals as defined by their Medicare provider number. These 2,300 hospitals represent almost half of all US hospitals and include virtually all major teaching and research hospitals.

With the passage of the Affordable Care Act which expanded the number of eligible CEs, the 340B program has exploded. The universe of hospitals now includes Critical Access Hospitals, Rural Referral Centers and Sole Community Hospitals. In 2005, there were approximately 583 DHS hospitals with unique Medicare Provider Numbers in the 340B program. Today there are 2,200. Chart 1 represents the number of hospitals added to the program since 2005.

Chart 1: Hospital Enrollment in 340B Program 2005-2013



Source: MedPAC

Not only has the number of hospital CEs grown in recent years – partly because of CE eligibility expansions included in the ACA - the universe of 340B-discounted drug spending has also grown. CE hospitals are capturing more patients eligible for 340B-discounted drugs not only through an arguably loose interpretation of how to attribute a patient under 340B but also by expanding outpatient departments through the acquisition of independent physician practices.

Furthermore, a recent study by the Government Accountability Office (GAO)[1] has suggested that 340B hospitals maximize the revenues made possible by the discount program through not only higher utilization of outpatient drugs but also the prescribing of more expensive drugs than their non-CE counterparts. Finally, since guidance changed in 2010, hospitals may contract with as many pharmacies as they like to dispense 304B discounted drugs to their patients, allowing CE hospitals to capture the revenues associated with patients no matter which pharmacy they use.

On average, CEs get savings of between 25 and 50 percent on outpatient drugs provided to virtually all of their patients (with the exception of Medicaid patients for whom a separate discount is mandated by law) regardless of their income and whether they are insured or not. This discount is established by the HRSA quarterly as the 340B ceiling price. This ceiling price is not disclosed to the purchasing hospitals. Hospitals that participate in the Prime Vendor Program may pay less for a drug than the 340B ceiling price. The OIG reports that in 2013, the HRSA Prime Vendor Apexus, had 7,000 drugs under contract at an average discount of 10 percent below the 340B ceiling price.

Medicare pays the hospital 106 percent of volume weighted average sales price of a drug regardless of what the hospital paid for the drug under the 340B program. [2] Medicare does not benefit from the discount and beneficiaries' cost sharing is not adjusted to reflect the lower drug price.

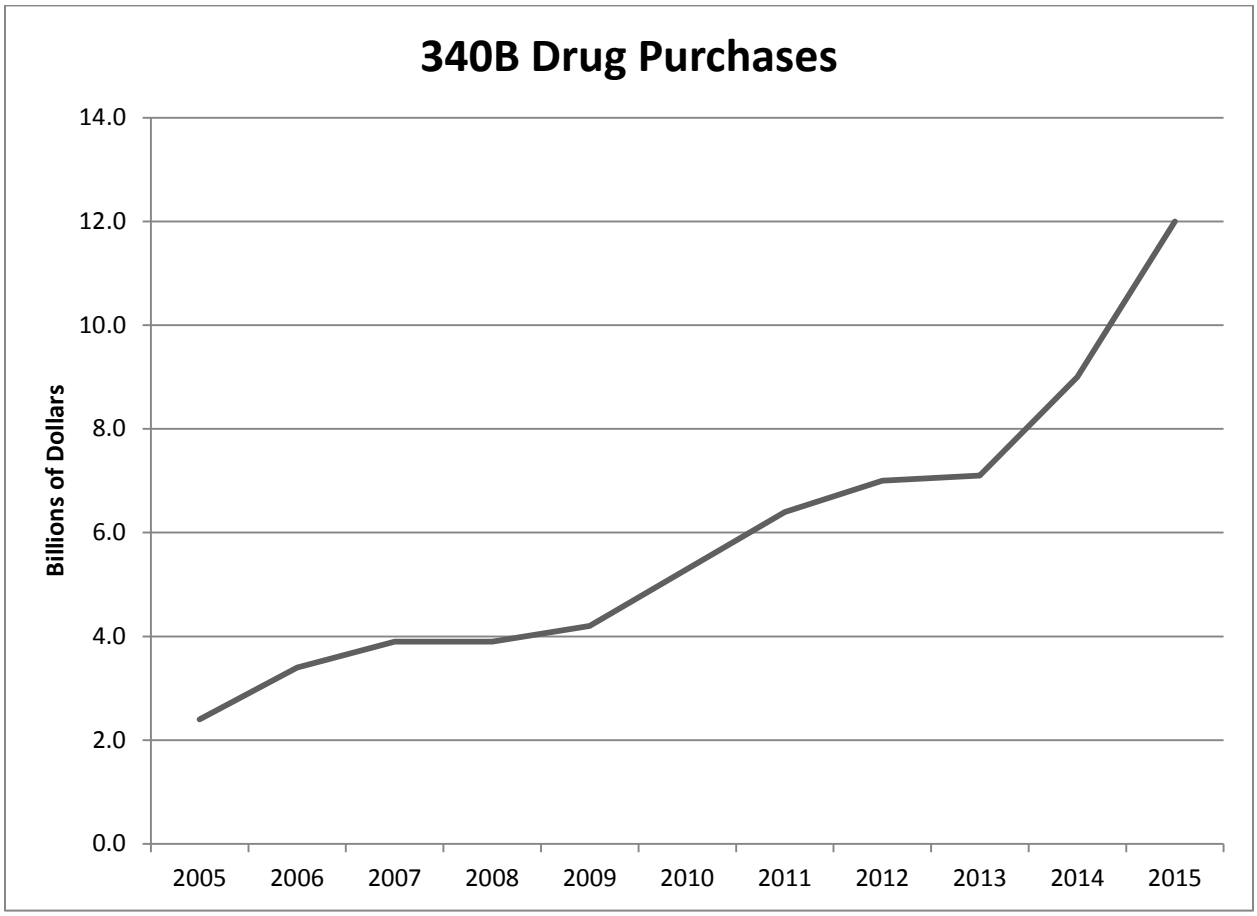
Drug companies currently rebate a portion outpatient drugs costs back to state Medicaid agencies. A hospital can opt to "carve-in" Medicaid patients and dispense 340B drugs in which case the cost savings from the 340B program is not added to the statutory rebate. However, the OIG found that about half the states required CEs to bill the state Medicaid program at the 340B discounted rate. CEs that opt to "carve-out" Medicaid patients do not dispense 340B drugs to those patients. For patients that are commercially insured, CEs may bill insurance companies for the full negotiated/reimbursable amounts – regardless of what the CE paid for the drug.

For most patients, 340B hospitals are able to capture the spread between the cost of the 340B drug purchase and the price they are paid by Medicare, Medicaid and commercial insurers. For that reason the 340B program has grown dramatically. In May 2015, MedPAC released a report providing an overview of the program and indicating that 340B drug purchases reached $7 billion in 2013. Since that report was released, Dr. Adam Fein, the host of the Drug Channels blog and a principal at Pembroke Consulting, has calculated that drug purchases through the 340B program totaled $12 billion in 2015. Chart 2 illustrates the growth in 340B drug purchases by covered entities.

[1] http://gao.gov/assets/680/670676.pdf

[2] Under sequestration still in effect, Medicare Part B pays 1.043 percent of volume weighted ASP

Chart 2. 340B Drug Purchases 2008-2015



Source: MedPAC and Drug Channels Blog

Assuming the lowest estimated discount rate in the 340B program of 25 percent, the undiscounted value of 340B drug purchases is in the neighborhood of $16 to $17 billion. The current estimate for 2015 drug spending is about $310 billion, according to IMS Health. As such, 340B drug purchases now account for about 5 percent of US prescription drug market.

Provider and Patient Eligibility Issues. In addition to the issues raised by the GAO, HRSA, the OIG and members of Congress have noted certain problematic practices with the way CEs determine patient eligibility. The current 1996 guidance subjects 340B hospitals to a broad two-pronged test under which an individual must have their health care records maintained by the CE and receive care from a provider either employed by or with some "arrangement" with the CE. Over the years, this guidance proved unclear and hospitals were taking significant liberties with their interpretation of it. In 2007, HRSA released new guidance on patient eligibility.

The 2007 notice laid out more specific patient eligibility parameters, which HRSA made clear they thought were consistent with the intent of the 1996 criteria, but also provided a number of specific examples of "problematic" activities that provide insights into the practices hospitals were – and presumably still are – deploying. Some of the "problematic" activities that HRSA identified:

- Hospitals using case management or call center arrangements in which they have access to a patient health record but don't actually provide outpatient services linked to the prescriptions for which they are capturing 340B discounts.
- Hospitals creating loose affiliation networks for outpatient services via simple one-page "contracts" with outside providers to capture 340B discounts on a broader swath of patients.
- Hospitals using 340B discounts to dispense drugs to employees for which they provide health care coverage but not necessarily health care services.

The crux of the 2007 clarification was that HRSA felt that all 340B drugs should be linked to a specific prescription associated with a specific outpatient service provided by a provider with a valid, binding and enforceable contract between the CE and prescribing power. Well, HRSA received so many negative comments on the clarification that it withdrew the proposed guidance a couple of years later – presumably letting these "problematic" activities continue and grow.

Members of Congress have taken issue with the number and type of entities eligible to participate in the 340B Program. Senator Chuck Grassley, in response to an article in the Charlotte News Observer sent a letter to three North Carolina Hospitals inquiring about their 340B programs. Included in the letter was a question related to payer mix. The three hospitals provided their payer mix as listed in Table 2.

Table 2: Payer Mix for Three North Carolina Hospitals, 2009-2012

	Carolinas Health System				University of North Carolina				Duke University Health System			
	Medicare	Medicaid	Self-pay	Commercial	Medicare	Medicaid	Self-pay	Commercial	Medicare	Medicaid	Self-pay	Commercial
2009	24.2%	18.5%	11.5%	42.2%	27.5%	10.3%	20.0%	27.9%	14.0%	7.0%	5.0%	74.0%
2010	24.4%	18.2%	11.3%	42.6%	16.8%	7.2%	10.3%	28.0%	17.0%	10.0%	5.0%	69.0%
2011	25.6%	18.3%	11.3%	41.9%	23.1%	9.7%	12.0%	22.6%	19.0%	8.0%	4.0%	58.0%
2012	No Data				32.9%	12.5%	13.7%	29.6%	19.0%	9.0%	5.0%	67.0%

Source: Letters from Duke University Health System, University of North Carolina Health System and Carolina Health System to Senator Charles Grassley, 2012

Senator Grassley followed up on his letters to the North Carolina hospitals by asking HRSA for information over oversight while pointing out that Duke's patient population was only 5 percent self-pay or uninsured.

Since, the North Carolina Hospitals provided the information requested by Senator Grassley, the ACA has gone into effect. Not surprising, self-pay has dropped to 3.3 percent of Duke's payer mix, as disclosed in their FY 2015 Audit Financial Statements. The self-pay percentage at Carolinas Health System dropped to 9.7 percent. There is no 2015 data available for UNC.

The point of Senator Grassley's question was to clarify the extent to which hospitals actually need to the 340B discounts to support care for the uninsured. Duke responded with a list of indigent care programs it conducts primarily in the Raleigh Durham area.

Use of Contract Pharmacies. Perhaps one of the most interesting aspects of the 340B program is CEs' utilization of contract pharmacies to maximize revenues of the 340B program. In 1996, HRSA issued guidelines stipulating that CEs should use a single pharmacy – either in-house or via a contract with an outside pharmacy – to provide services to its patients. For the first time, HRSA explicitly allowed CEs to contract with outside pharmacies to provide 340B-discounted drugs.

To fully understand the thinking behind this change, recall the original class of covered entities. In addition to nonprofit DSH hospitals, the program was originally established for small, often disease/service-specific health clinics funded primarily with federal dollars for low-income individuals. Even now, many of the CEs, include Black Lung Clinics, Hemophilia Treatment Centers, Health Care for the Homeless Programs, Title X Family Planning Clinics, Ryan White HIV/AIDS Programs, and Community Health Centers.

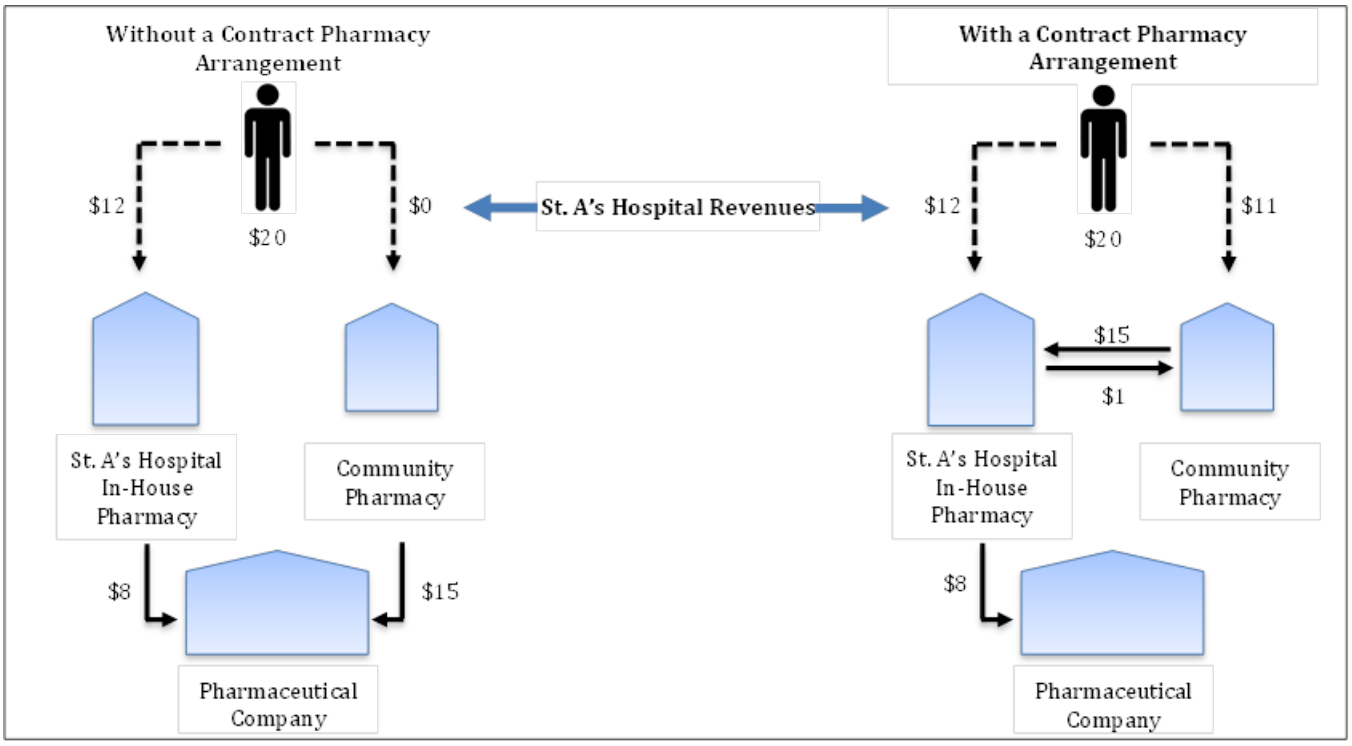
Many of these types of disease and service specific entities did not have in-house pharmacies. So in order to provide their low-income patients with access to discounted drugs, it was imperative that they make arrangements with an outside pharmacy. HRSA allowed for a limited number of arrangements with multiple contract pharmacies on a case-by-case demonstration basis. Under this demonstration, the contract pharmacy arrangements were to be independently audited every year.

HRSA approved 18 of these demonstrations and found no evidence that the arrangements ever ran afoul of program laws and guidance. In 2010, HRSA issued a revision its long-standing policy lifting the single-pharmacy restriction and allowing CEs to use multiple contract pharmacy arrangements. HRSA dropped the annual audit requirement but insisted that contract pharmacies comply with the program's laws and guidance (via CE self-policing). By allowing eligible hospitals to contract with multiple external pharmacies, participating hospitals were provided with the opportunity to capture even more 340B drug revenues.

Chart 3 below provides a graphic illustration of how contract pharmacy arrangements work. In the absence of a contract pharmacy arrangement, a CE is only able to capture the revenues that are generated between the discounted price at which they purchased an outpatient drug and the amount a patient or his/her insurance pays when that patient fills their prescription at the CE's in-house pharmacy. In our example, the patient's insurance pays $20 for a drug for which the hospital pays $8. If that patient gets their prescription filled at the hospital's in-house pharmacy, the hospital walks away with $12 in revenues it can spend elsewhere. If the patient, however, goes to a community pharmacy, the hospital gets nothing.

Under a contract pharmacy arrangement, the hospital will buy discounted drugs on the pharmacy's behalf for the hospital's patients that use that pharmacy, and the hospital will pay the pharmacy some per-drug fee for its trouble. We have arbitrarily assigned a $1 fee for illustrative purposes. In our example, a patient can now go into either pharmacy and the hospital gets to keep the spread – $12 if the patient goes to the in-house pharmacy or $11 if it goes to the community pharmacy.

Chart 3: Contract and In-house Pharmacy Arrangements



Source: Hedgeye

There is an incentive for hospitals to maximize their relationships with pharmacies, and in fact, evidence suggests that some of the recent spikes in 340B drug utilization are as much – if not more – attributable to the 2010 pharmacy guidance change than to the eligibility expansions in the ACA. According to a 2014 HHS Office of Inspector General analysis, the number of unique pharmacies serving as 340B contract pharmacies grew by 770 percent and the number of contract pharmacy arrangements by 1,245 percent between March 2010 and May 2013.

In September of last year, we conducted our own analysis on the 340B program. In 12 months, the number of active contract pharmacy arrangements has increased from 38,000 to 63,000. The number of unique pharmacies involved in these contracts has increased from 17,000 to 22,000 and the number of unique contracting entities has increased from 5,300 to 6,300.

Table 3 and Charts 4 and 5 provide more detailed information on large national pharmacy chains' participation in 340B contract pharmacy arrangements and its growth in the last year.. Walgreens is easily the biggest player in the contract pharmacy arrangements – with over 27,000 arrangements in place with 1,500 CEs at 6,600 Walgreens locations. Over 80 percent of Walgreens stores have at least one contract pharmacy arrangement in place.

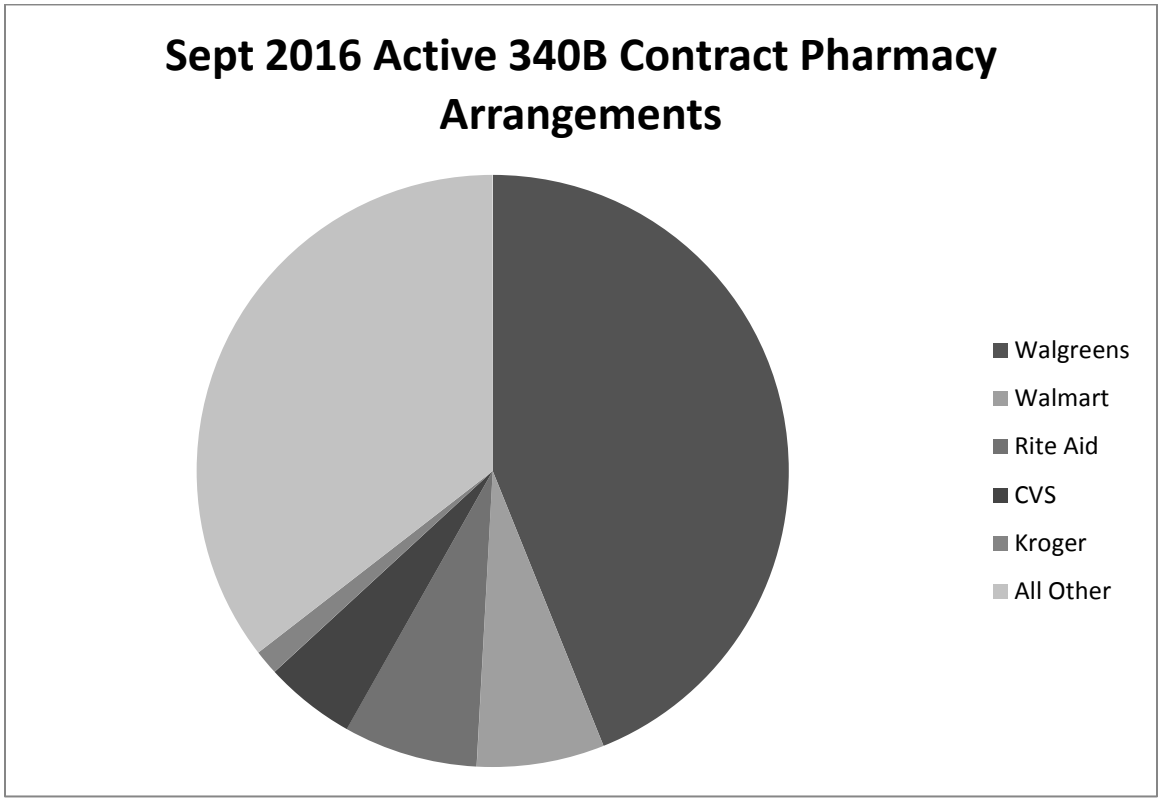
In fact, Walgreens comprises 44 percent of all 340B contract pharmacy arrangements – an increase of 4 percent in the last year alone. Walgreen's represents 30 percent of all unique pharmacies with at least one contract pharmacy arrangement in place, a decline of about 4 percent since last year, as other pharmacy companies have entered the market, especially Wal-Mart.

Table 3: Major Pharmacy Participation in 340B Program 2015-16

	Sep-15	Sep-16	Sep-15	Sep-16	Sep-15	Sep-16
	Active 340B Contract Pharmacy Arrangements		Unique 340B Contract Pharmacies		Unique 340B Covered Entities	
Walgreens	15,162	27,659	5,761	6,628	1,140	1,570
Walmart	3,000	4,393	401	1,995	1,028	1,280
Rite Aid	2,219	4,607	1,286	1,581	454	557
CVS	1,838	3,129	1,486	1,896	424	652
Kroger	631	851	466	561	154	193
All Other	15,366	22,364	7,477	9,388	2,132	2,207
Total	38,216	63,003	17,176	22,049	5,332	6,459

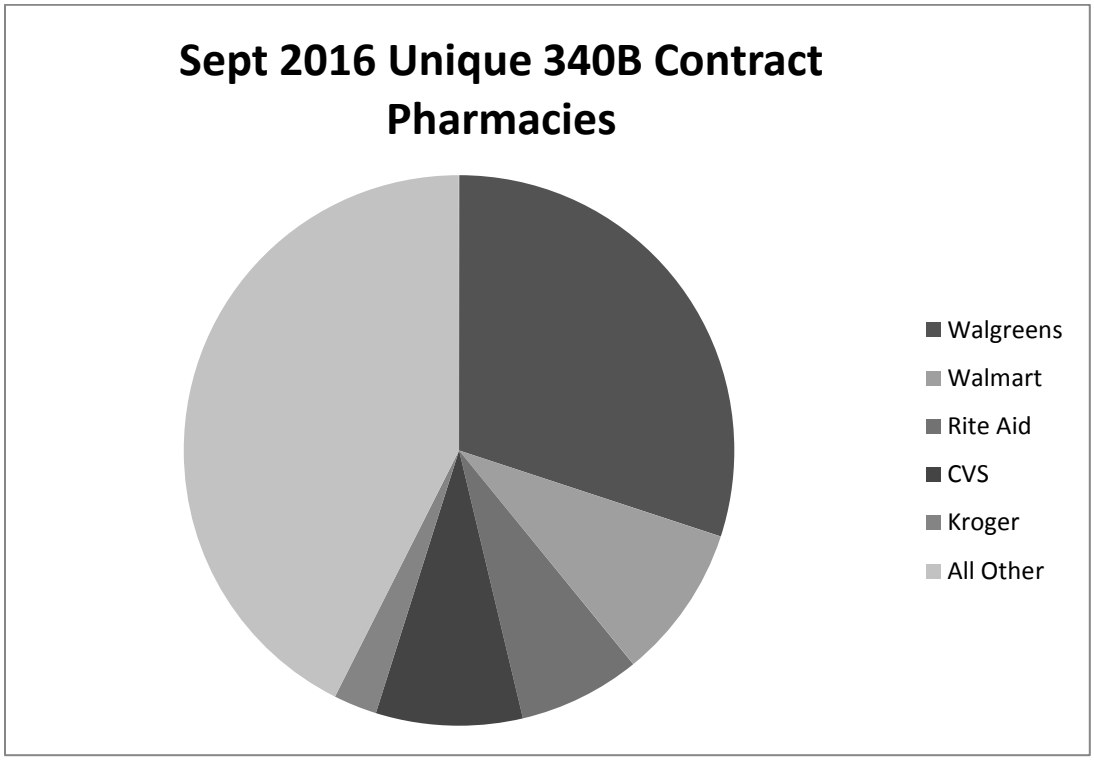
Source: HRSA database accessed Sept. 8, 2015 and Sept. 5, 2016

Chart 3: Active 340B Contract Pharmacy Arrangements as of Sept. 2016



Source: HRSA database accessed Sept. 8, 2015 and Sept. 5, 2016

Chart 4: Unique 340B Contract Pharmacies as of Sept. 2016



Source: HRSA database accessed Sept. 8, 2015 and Sept. 5, 2016

Implications for Hospitals. Like everything associated with the 340B Drug Purchase Program, it is nearly impossible to know exactly how much it may be reinforcing the income statements of nonprofit hospitals in the U.S. Drugs purchased at a discount through the 340B program would appear on the expense side of the ledger and would contribute to financial performance through the moderation in cost growth of drugs and supplies. What little data we have is provided by Senator Grassley's 2012 inquiry discussed above.

Included in his request was a question about revenues and expenses associated with the 340B program. The most comprehensive information was provided in Duke's letter to Grassley. Table 4 lists the 340B costs and revenues for Duke 2008 to 2012.

Table 4: Estimated Revenues and Expenses Associated with Duke Health System's 340B Drug Purchases, 2008-2012

	Estmiated Revenue	Estimated Expenditures	Spread	Gross Margin
2008	$ 83,341,864	$ 43,439,245	$ 39,902,619	48%
2009	88,953,570	42,363,667	46,589,903	52%
2010	109,700,404	50,728,709	58,971,695	54%
2011	131,759,091	54,848,988	76,910,103	58%
2012	135,539,459	65,882,189	69,657,270	51%
Total	**$549,294,388**	**$ 257,262,798**	**$ 292,031,590**	**53%**

Source: Letter from Duke University Health System to Senator Charles Grassley, October 23, 2012.
http://www.grassley.senate.gov/sites/default/files/about/upload/2012-10-23-Duke-to-CEG-340B.pdf

According to Dr. Fein, absent the 340B program Duke's gross margin on its drug purchases would have been 24 percent. For a $3 billion a year, health system like Duke, the nominal value of the captured spread many not be meaningful. However, since 2012, 340B drug purchases have grown 70 percent nationwide, suggesting there is a point at which it may become significant.

We also know that Erlanger Health System (TN) in its 2014 Final Official Statement listed implementation of the 340B program as a significant event in its financial turnaround.

Finally, since late 2015 when HRSA released its latest effort to reform the program, several hospital systems that have priced municipal bond deals have included changes to the program as a risk factor in their Final Official Statements. Deals listing changes to the 340B program as a risk factor include Vanderbilt University (TN), Oschner Clinic (LA), and Houston Co. (AL) Health Care Authority.

Not surprising, hospitals are fighting for the program. There are at least four groups – 340B Matters, Air 340B, 340B Facts and 340B Health, complete with their own twitter accounts – working in support of the program. The principal arguments they make are:

- The 340B Drug Program allows hospitals to use the spread to serve indigent populations
- The total amount of money – frequently quoted as $7 billion – is only 2 percent of all prescription drug spending

Implications for Pharmaceutical Companies. Pharmaceutical companies have about as much interest in disclosing the impact the 340B program as do the hospitals. While many state Medicaid agencies demand they pay no more than the 340B price, commercial payers are left to independently negotiate prices. Medicare, is of course, prohibited from any such negotiation. Pharma, then must make up for any margin deterioration resulting from 340B purchases with sales to non-340B entities like investor-owned outpatient hospital departments and retail pharmacies.

It may be just a coincidence but the acceleration of the 340B program's growth in the last several years has been accompanied by a dramatic increase in prescription drug spending across the board. The HHS Office of the Actuary reported a 12.2 percent increase in retail prescription drug spending in 2014. The increase for 2015 is expected to be slightly lower but still around 8 percent.

.Pharma has been pushing hard for reform to the program. Their main talking points are:

- Patient Definition: The definition of “patient” for purposes of the 340B program should ensure the program’s benefits flow to the individuals whom Congress sought to help, primarily vulnerable or uninsured patients.
- Hospital Eligibility Criteria: The qualifying criteria for 340B hospitals need to be calibrated to ensure proper identification of safety net facilities that serve large numbers of uninsured and vulnerable patients.
- •Contract Pharmacies: The use of contract pharmacies, which enable covered entities to contract with multiple outside pharmacies to dispense drugs that receive 340B discounts, should fulfill the intent of the 340B program and directly benefit vulnerable patients.
- Consolidation: The 340B program should be reducing prescription drug costs for patients, not increasing them. However, hospitals acquiring more independent physician practices, which enable the formerly independent practices to access the hospitals’ 340B discounts, can drive up costs for patients and payers, in addition to reducing patient access to community treatment options.
- Oversight: Increased government oversight of the 340B program is needed to ensure program requirements, including prohibitions on drug diversion, are being met. Entities participating in the 340B program must be fully and readily accountable for properly and safely handling and dispensing medicines and ensuring program integrity

Source: PhaRMA website