Big Pharma's Efforts to Kill 340B: Background and Tactics for Hospitals

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Overview

The pharmaceutical industry has long opposed the 340 B program, particularly the explosion in contract pharmacies. Recently the industry's efforts have intensified. Since July 2020, several large drug manufacturers have attacked the 340B program in 3 ways:

1. Eliminating Contract Pharmacies
2. Mandating New Data Requirements
3. Replacing 340B Discount Pricing with Asynchronous Rebates

This paper reviews the actions of Big Pharma, describes their potential impact on Covered Entities, and suggests some tactics for health systems to consider. As this situation is constantly evolving, we will update this document on a regular basis.

Background

The 340B program was enacted by a bipartisan Congress as part of the Veterans Healthcare Act of 1992 and signed into law by President George H. W. Bush. [1] In 1996, Health Resources and Services Administration (HRSA) released a notice in the Federal Register[2] that defined eligible patients, providers, and settings for participation in the 340B program.[3] Part of this guidance allowed Covered Entities (CEs) "without an on-site pharmacy to contract with one off-site pharmacy". In 2010, HRSA released a notice in the Federal Register that removed this limit of one pharmacy location per CE, thereby allowing CEs to have multiple pharmacies (on-site pharmacies, off-site CE-owned pharmacies, and non-CE pharmacies).[4]

Since 2010, the pharmaceutical industry has worked to shrink the program through various means. In 2015, it lobbied for the "340B Drug Pricing Program Omnibus", which would limit hospital and patient eligibility. After almost three years of trying to enact this so-called "Mega Guidance", the Federal Office for Management and Budget withdrew it.[5] In 2018, Senator Chuck Grassley of Iowa requested a Senate committee hearing on the 340B program. Others have also tried to create bills to limit the 340B program by tying 340B discounts to the percentage of a hospital's uninsured patients, increasing audit requirements, and mandates for 340B providers to pass on all savings from 340B discounts to low-income patients. To date, none of these attempts have been successful.[6]

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[1] https://www.340bhealth.org/members/340b-program/overview/

[2] Federal Register, Volume 61, Number 207, October 24, 1996

[3] http://340breform.org/userfiles/FINAL.The%20Impact%20of%20Growth%20in%20340B%20Contract%20Pharmacy%20Arrangements.%20AIR%20340B.%20July%2014,%202014.pdf

[4] Federal Register, Volume 75, Number 43, March 5, 2010

[5] https://www.jdsupra.com/legalnews/340b-program-omnibus-guidance-withdrawn-71891/

[6] https://www.grassley.senate.gov/news/news-releases/grassley-introduces-bill-bring-transparency-340b-prescription-drug-program

Recent Actions and Threats by Manufacturers

1. Eliminating Contract Pharmacies

In August, AstraZeneca took issue with HRSA's 2010 guidance that allowed a CE to have more than one pharmacy (including on-site) by sending a letter to all 340B CEs stating:

> *"AstraZeneca to date has processed chargebacks associated with Contract Pharmacy arrangements consistent with the approach proposed in HRSA's April 2010 guidance. Beginning October 1, 2020, AstraZeneca plans to adjust this approach such that AstraZeneca will only process 340B pricing through a single Contract Pharmacy site for those Covered Entities that do not maintain their own on-site dispensing pharmacy."*
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> *"To implement this new approach, AstraZeneca will stop processing 340B chargebacks for all 340B Contract Pharmacy arrangements effective October 1, 2020. Any 340B Covered Entity that does not have an outpatient, on-site dispensing pharmacy should contact AstraZeneca to arrange for a Contract Pharmacy of its choice to be eligible to receive 340B pricing on behalf of the Covered Entity."*[7]

Eli Lilly, which had stopped distribution of Cialis to 340B contract pharmacies in July 2020, shortly followed suit and issued a notice to CEs that:

> *"Effective September 1, 2020, Eli Lilly is limiting distribution of all 340B ceiling priced product directly to CEs and their child sites only. Covered entities will not be eligible to purchase Eli Lilly products at the 340B ceiling price for shipment to a contract pharmacy. CEs that do not have an in-house pharmacy may contact Eli Lilly regarding the exception process to designate one contract pharmacy location."*[8]

According to Eli Lilly, "there is no *statutory* obligation to provide 340B priced product to contract pharmacies. The statue requires that manufacturers must offer 340B ceiling prices to CEs, which Lilly is continuing to do." This policy covers all Eli Lilly products except for insulin.

2. Mandating New Data Requirements

Merck and Sanofi have asked CEs to use a product called 340B ESP, which is provided by Second Sight Solutions. According to their website, 340B ESP allows 340B covered entities and pharmaceutical manufacturers to work collaboratively to resolve duplicate discounts. 340B covered entities upload 340B claims data every 2 weeks that originates from contract pharmacies and in-house pharmacies.[9]

Merck sent a notification to covered entities requesting that they share contract pharmacy claims data through 340B ESP starting August 14th. Merck claims that this is part of a new 340B integrity initiative and that participation is voluntary. However, Merck did say that "absent significant cooperation from covered entities, Merck may take further action to address 340B Program Integrity".[10] After Merck's announcement, Sanofi announced they will require CEs to submit contract pharmacy claims data to 340B ESP. In their announcement, Sanofi stated that

[7] AstraZeneca Letter to Covered Entities re: 340B Contract Pharmacy Pricing, August 17, 2020
[8] Eli Lilly Letter to Covered Entities re: 340B Distribution Notice, September 1, 2020
[9] https://www.rwc340b.org/sanofi-announces-340besp-participation-and-consequences/
[10] Merck Letter to Covered Entities re: 340B Contract Pharmacy Pricing, August 14, 2020

they would refuse to honor the ship-to/bill-to contract pharmacy arrangements with covered entities that did not comply with this requirement.[11]

Finally, Novartis also announced that it intends to begin collecting and analyzing 340B CEs' contract pharmacy claims data to mitigate duplicate discounts and "ineligible rebates". They have not announced whether they will be using 340B ESP like Merck and Sanofi, or what the penalty will be for CEs that do not participate. Up to six additional manufacturers reportedly will soon inform 340B CEs that they want to collect CE's contract pharmacy data.[12]

3. Replacing 340B Discount Pricing with Asynchronous Rebate

Vizient, a national health care performance improvement company, stated in their August 28th Pharmacy Solutions Update that pharma manufacturers intend to replace 340B discount pricing with 340B rebates. In this system, CEs would have to purchase drugs at the wholesale acquisition cost ("WAC") and submit for a 340B rebate through a third party.[13] This would introduce substantial delay to the financial savings of 340B, perhaps by 6 or more months. Such delays are common for rebate payments to PBMs and ultimately to payers/employers, and they would gravely affect the financial viability of many 340B-funded clinical programs.

Impact on Covered Entities

1. *Eliminating Contract Pharmacies:* AstraZeneca and Eli Lilly manufacture a large number and wide variety of drugs. Some examples of AstraZeneca and Eli Lilly's drugs include drugs that treat diabetes (e.g. Bydureon, Byetta, Onglyza, Farxiga, Trulicity, Jardiance), asthma and COPD (e.g., Bevespi, Symbicort, Pulmicort), and cancer (e.g. Faslodex, Tagrisso, Casodex, Almita, Cyramza). Depending on a CE and their eligible providers' specialties and prescribing habits, this may have a noticeable impact on margin. The margin impact of this will need to be analyzed on a CE specific basis.

   In addition, this limits access to specialty medications, which drive roughly 40% of all drug costs.[14] If a CE owns a pharmacy that cannot dispense specialty medications (e.g., lacks the license, capability, or access to limited-distribution medications), hospitals will not be able to order any AstraZeneca or Eli Lilly specialty products at 340B prices. Specialty medications are typically very expensive; excluding these drugs from 340B may limit or prohibit CEs from passing drug savings to patients.

2. *Mandating New Data Requirements:* On the surface, the new data process now required by Merck, Sanofi, and Novartis to report additional data has no additional cost associated with it. However, there are several concerns about this new mandate. The data required by Merck and Sanofi appears to contain PHI (e.g. patient name, date of birth, etc.), and contracted confidential information.[15] Second Sight Solutions does not appear willing to sign BAAs with CEs, therefore, by submitting the required data, CEs may be violating

[11] Sanofi Letter to Covered Entities re: 340B Contract Pharmacy Pricing, August 19, 2020
[12] Novartis Letter to Covered Entities re: 340B Contract Pharmacy Pricing, August 21, 2020
[13] Vizient Letter to Clients re: Drug Manufacturers Actions, August 28, 2020
[14] https://www.pharmacytimes.com/news/specialty-pharmacy-by-the-numbers
[15] https://www.blueandco.com/challenges-for-protecting-340b-program/

HIPAA and/or contracts. CEs will potentially be unable to comply with these requirements and will not be able to access 340B discounted Merck and Sanofi products.

This model is reminiscent of legislation in KY, introduced in October 2019, that would require contract pharmacies to identify at the point of sale if a prescription is 340B eligible (applying to Medicaid MCO patients only). All 340B eligible claims would be required to bill modifier 20 at the point of sale.[16] However, some 340B "compliance" vendors ("340B TPAs") are unable to determine 340B eligibility at the point of sale, meaning many contract pharmacies (and their CEs) could not dispense prescriptions at 340B prices to Medicaid MCO patients. This would effectively carve out all Medicaid MCO patients from the 340B program. After pushback from the Kentucky Hospital Association and CEs in the state, this legislation was placed on hold.

3. *Replacing 340B Discount Pricing with Asynchronous Rebate:* Delaying the financial savings of 340B would create a difficulty when passing discount pricing to indigent patients. Today, 340B savings are virtually immediate: when a CE purchases a drug under 340B, it is purchased at the discounted price. This makes it easy to determine discount pricing and make it available to indigent patients. However, if rebates are delayed by several months, this process becomes more difficult and would negatively affect 340B-funded clinical programs.

Response from 340B Health, AHA, and Others

Numerous industry advocacy/lobbying groups (e.g., 340B Health, the National Rural Health Association, National Association of Community Health Centers, and the National Health Care for the Homeless Council) have already asked the Department of Health and Human Services to prohibit Merck from imposing more burdensome requirements if covered entities do not voluntarily share contract pharmacy claims data through the 340B ESP platform and to intervene regarding Eli Lilly and AstraZeneca, claiming that their decision violates the 340B statute's requirement that manufacturers must offer 340B prices to eligible covered entities. 340B Health said it will pursue legal or legislative action if HRSA fails to address the violation.[17]

The American Hospital Association (AHA) wrote letters to the manufacturers discussed above to express outrage at the actions being taken, especially in the midst of the COVID-19 public health emergency. AHA urged the manufacturers to cease implementation of the new requirements and work to ensure that 340B drugs are available and accessible to vulnerable patient populations.[18]

HRSA announced on September 5th that they are evaluating potential sanctions including civil monetary penalties if the drug makers' actions violate 340B regulations.[19]

[16] https://chfs.ky.gov/agencies/dms/dpo/ppb/Documents/OnHold340BPolicyandProceduresManual.pdf
[17] https://www.340bhealth.org/newsroom/7-groups-representing-hospitals-and-pharmacists-ask-azar-to-enforce-340b-rules/
[18] https://revcycleintelligence.com/news/aha-slams-big-pharma-over-efforts-to-limit-340b-drug-discounts
[19] https://www.modernhealthcare.com/finance/hrsa-evaluating-drugmakers-340b-contract-pharmacy-crackdowns

Strategies to Minimize Impact for CEs

If the above actions and threats are actually upheld and implemented, there are several tactics a CE may employ to minimize their impact, including:

A. Build / expand CE owned pharmacy(s): A CE can open/expand its own retail pharmacy(s) and/or specialty pharmacy(s). Obviously, this tactic will require capital, time, and expertise. *Caveat:* Big Pharma will continue to try to limit each CE to only one retail pharmacy location (inclusive of its on-site pharmacy).

B. Develop Alternative Delivery Models: In addition to adding new physical retail pharmacies, CEs should consider several options to improve their ability to deliver 340B medications to patients:

a. Modifying the "meds-to-beds" program for discharge medications, from an "opt in" to an "opt out" model.
b. Offering patients "home delivery" through mail-order and/or courier service; State regulations apply.
c. Deploying an in-clinic prepackaged dispensing model (often called "physician dispensing"); State regulations apply.

C. Develop a Comprehensive Strategy for Specialty Medications: Specialty medications currently represent under 1% of all prescription volume but drive roughly 40% of drug costs, so accessing specialty medications at 340B prices is extremely important for the CE and its patients. Below is one PBM's data for a commercial population:

Drug Expenditures and 340B Impact by Script Type - Commercial Population
20,600 lives for 12-months ending May 31, 2020

Type	Scripts	share	$/script	Retail Cost	share	340B Savings		share
Specialty	**1,273**	**0.7%**	**$7,616**	$9,695,618	**40%**	**$5,614,384**	**58%**	**35%**
Brand	22,453	13%	$477	$10,720,081	44%	$8,674,550	81%	55%
Generic	155,319	87%	$24	$3,701,066	15%	$1,601,687	43%	10%
Total	179,045	100%	$135	$24,116,765	100%	**$15,890,621**	66%	100%

Source: PBM data; Progressive analysis

Health systems have several choices to ensure their access to specialty medications:

a. Develop a CE-owned specialty pharmacy, leveraging their existing retail pharmacy operations (i.e., their current on-site retail pharmacy). As this takes time, resources, and expertise, CEs should consider outsourcing all specialty pharmacy operations to an experienced firm.
b. Explore "partnering" with another CE that already owns and operates a specialty pharmacy. *Caveat:* Big Pharma will likely consider this relationship to be a "contract pharmacy" and thus subject to their limits on the number of contract pharmacies.

D. **Focus on high-value patients and patient segments:** From a financial perspective, not all 340B scripts and not all 340B-eligible patients are equal. As illustrated above, the

relatively few lives who are treated with specialty medications drive at least 35 percent of all 340B savings (as they are also prescribed brand and high-cost generics). Rather than attempting to leverage 340B for every possible script and patients, we recommend that CEs target "high-value" patients via focused clinical program development (e.g., Diabetes, Hepatitis C) or select specialties (e.g., rheumatology, gastroenterology), and then actively manage their medication treatment across the continuum.

E. **Deploy advanced IT infrastructure across the entire "pharmacy eco-system."** This includes:
    a. Determining "real time" eligibility for 340B (and Own Use) at the point-of-care in all pharmacies.
    b. Collecting all prescription data from ePrescribe applications at all 340B-eligible locations, so network capture rate and medication adherence rates can be measured and managed.
    c. Employing care management systems, so patients on high-cost meds or on many medications (particularly those with multiple providers in multiple practices) can be managed by clinical pharmacists.
    d. Deploying data analytics to manage this "eco-system" across the continuum of care, based on accurate and timely clinical data linked to financial impact.

F. Shift to Therapeutic Alternatives offered by "340B-friendly" Manufacturers: Providers (CEs) have significant influence on the usage and resulting market share of individual products. Consolidating use to products of "340B-friendly" manufacturers *when clinically-appropriate* (and if the cost to the patient and payor is not affected) would preserve the 340B discount for those clinical needs and encourage manufacturers to "remain" in the program as it has operated for 10+ years.

Given the importance of 340B to patients and to the financial viability of many health systems, we recommend that health system leaders evaluate the immediate applicability of the above solutions, as many of these tactics make sense regardless of the degree to which drug manufacturers are successful in minimizing the ease of using 340B. This approach is really an extension of what has been in place for many health systems during the pre-Summer environment. That is, health systems should have a medication dispensing and patient management care model that is tightly-managed with minimal reliance on Contract Pharmacies.

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