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A Comprehensive Guide To The 340B Drug Pricing Program

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Introduction / Overview

Equipped with the right information, personnel, technology and program partners, your health system can optimize the benefits of a well-run 340B program — both in terms of the savings you'll generate, and the ability those savings will give you to maximize your mission of patient care and satisfaction.

Many of the hospitals who take advantage of the program's discounts save millions of dollars a year on their prescription costs. Savings and revenue which, for some of the hospitals VytlOne serves, literally make the difference between solvency and closure.

How two health systems use their 340B revenue

In a 2022 blog post, we profiled Directors Of Pharmacy at two health systems served by VytlOne's 340B team: Southwest Mississippi Regional Medical Center's Tiffany Poole and Conway [South Carolina] Medical Center's Andrew Wright.

Below are two excerpts from that post:

TIFFANY

“Our facility is the only option for so many patients. We have to find a way to serve them, and that takes our finance team and our patient care team creating a balance. That's the whole reason Congress started 340B — to increase access to healthcare for everyone, and spread scarce resources in our most underserved communities. Our relationship with VytlOne lets us spread those scarce resources further than we ever could on our own.”

ANDREW

“It's allowed us to expand into areas of medicine we never thought we could offer. We've added a cancer center, a pain clinic as part of our orthopedic practice, a dermatology clinic, and a women's center. We’re expanding our footprint, and we’re treating so many more patients than we used-to. Without VytlOne and 340B, that wouldn't have been possible.”

All of which begs the question:

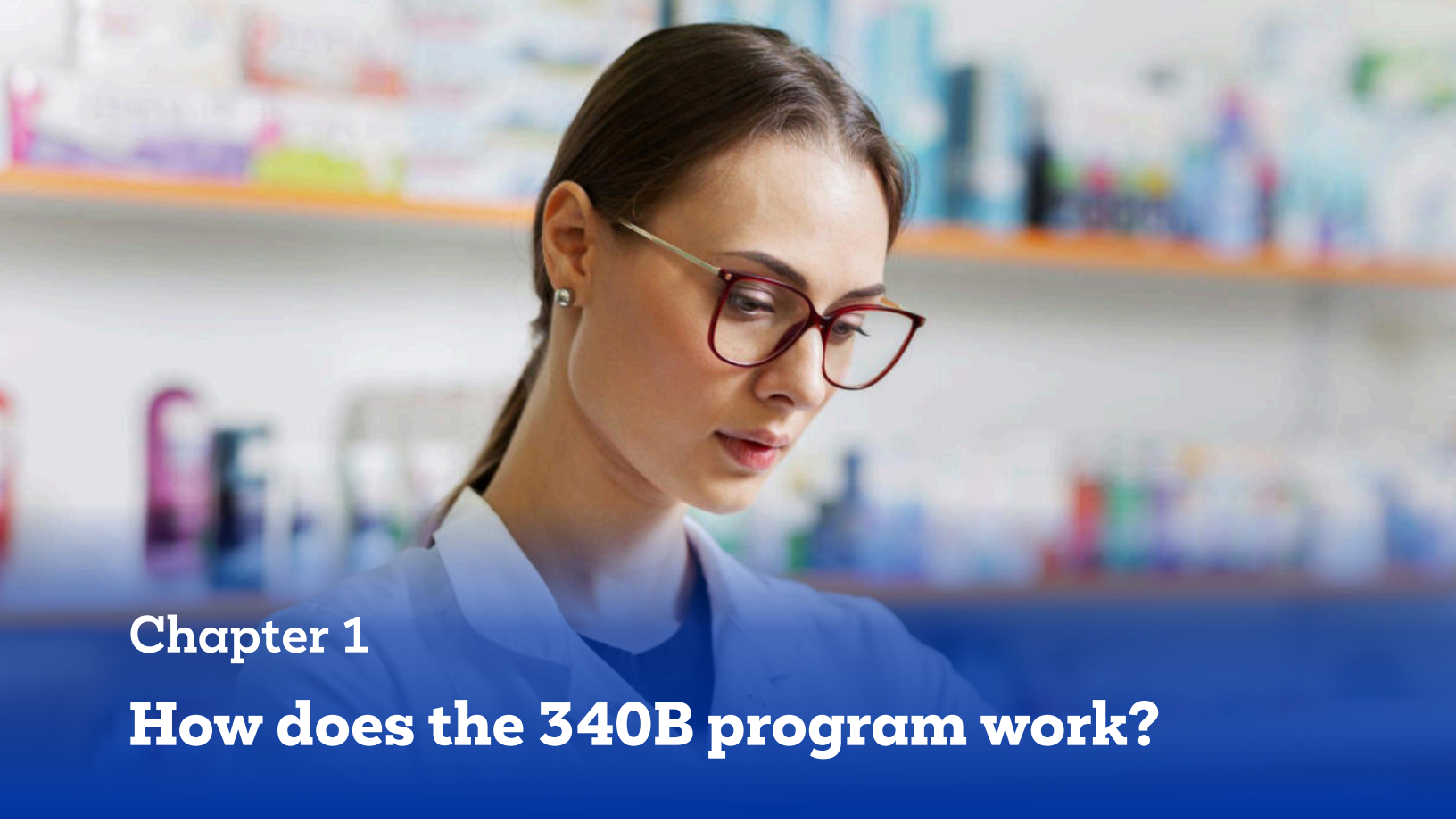
Why don’t all 340B-eligible hospitals and health systems take advantage of their legal rights to the program’s savings and discounts?

In our experience, the primary reason is fear of the consequences of non-compliance — coupled with a lack of administrative bandwidth to effectively develop and administer a 340B program.

That’s why we’ve created this comprehensive guide: To give eligible entities all the information they need to understand the 340B program’s requirements — and how to **1)** optimize their savings from 340B-elible medication replenishment and **2)** improve patient care & satisfaction, while **3)** still maintaining full compliance at all times.

The 340B landscape, and what it means for eligible entities in 2025

The 340B landscape continues to evolve rapidly, with ongoing 340B ESP and other manufacturer restrictions, new compliance hurdles, and increasing financial pressures on covered entities. Chief among those new challenges is HRSA’s Rebate Model Pilot Program — a program which, if expanded to include all 340B-eligible prescriptions, could literally have a catastrophic impact on every participating 340B health system’s finances, moving forward.



Chapter 1

How does the 340B program work?

When a patient receives a 340B-eligible prescription from an eligible entity, the entity is reimbursed for the full market price of the drugs, but pays only a fraction of the drugs' cost by replenishing the medication from the 340B catalog.

Who pays the 340B costs?

Manufacturers bear the burden of the cost and reimburse wholesalers for 340B discounts on 340B-eligible medications.

How does the 340B payment process work?

As a covered entity, you send your encounter (visit) data to your TPA, and your pharmacy sends the TPA the prescription data. Your TPA creates a match when it determines that 340B qualification criteria has been met, and your pharmacy then orders from your 340B account to replenish the drugs.

Clients served by VytlOne use a proprietary software system, which monitors every prescription their organizations fill, and identifies every eligible prescription generating sufficient savings to justify the time and effort to claim 340B savings. This extra layer of monitoring improves compliance, while hunting-down hidden opportunities for more 340B savings.

VytlOne works with each client to determine how aggressively they want to pursue 340B savings. We then maintain comprehensive records on every prescription applied for — always assuring clients of complete compliance.

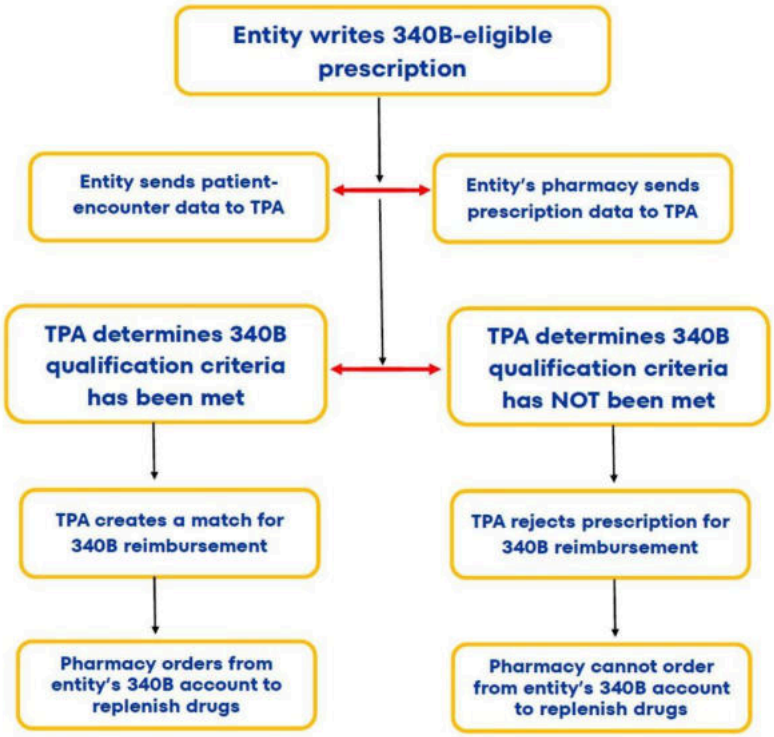
Which pharmacies can I use for 340B prescriptions?

340B-eligible hospitals can use the in-house (or on-campus) retail pharmacies they own and manage, as well as "contract pharmacies" — which can be both on-campus and off.

You can extend 340B eligibility to contract pharmacies (onsite or off) if they meet HRSA's requirements — which include the following: Your contract pharmacies must **1)** register for the 340B Program, **2)** be listed on the 340B OPAIS prior to dispensing 340B drugs on your behalf, and **3)** not use 340B drugs for Medicaid patients unless you have an arrangement in place with the state.

SIMPLIFIED PAYMENT PROCESS*

(No manufacturer restrictions)



*NOTE

The TPA steps described above are for off-site contract pharmacies, but aren't necessary for health systems' on-campus pharmacies.

What Are The Requirements For 340B Programs?

Covered entities must meet the following ongoing requirements:

- Keep 340B OPAIS information accurate and up to date.
- Register new outpatient facilities and contract pharmacies as they are added.
- Prevent diversion to ineligible patients.
- Maintain auditable records documenting compliance with 340B Program requirements.

As a covered entity, it's also your responsibility to notify drug manufacturers and wholesalers that you plan to purchase drugs at 340B prices. The wholesalers and manufacturers verify your enrollment on the 340B database and must sell their drugs to you — at or below the maximum price determined under the 340B statute.

How do I enroll in the 340B program?

To register, you need a 340B Office of Pharmacy Affairs (340B OPAIS) user account. To get started, visit the 340B OPAIS Registration page, and select the appropriate link toward the bottom of the page — either **Grantee Registration** or **Hospital Registration**.

The system should lead you through the process from there. It's important to know, in advance, that you must complete your registration in a single session. Which is why you'll need to have your latest filed Medicare cost report on-hand while you're completing the process.

You'll also you'll need to enroll your main location first, then add any Child Sites.

What is a 340B Child Site?

HRSA defines a 340B Child Site as an off-site outpatient clinic or location that uses, or purchases, 340B drugs for its patients. In general, "off-site" means a location has a separate physical address than the hospital parent site, and is not located within the main hospital.

Can my TPA apply for 340B discounts on my behalf?

Yes. However, the work performed by TPAs has emerged as a distinct risk to Covered Entities — a topic we'll cover, in-depth, in **Chapter 3.**

NOTE: VytlOne is not a TPA. However, we work closely with our clients' TPAs, holding them accountable and ensuring that they maintain the same standards for 340B compliance that we do. To learn more about how VytlOne optimizes 340B savings and revenue, visit this page of our website.

How does the 340B program interact with the MDRP?

The Medicaid Drug Rebate program interacts with other programs receiving manufacturer discounts on drugs. As a condition of participation in that program, manufacturers must also participate in the 340B drug-discount program.

340B ceiling prices are calculated to match Medicaid prices, but manufacturers can (but rarely do) provide additional discounts to 340B providers that are not subject to the Best Price rule.

Safety net providers eligible for 340B discounts can choose whether or not they provide drugs purchased with the program discounts to Medicaid beneficiaries within state guidelines. This may not include drugs paid for by managed-care plans or those dispensed at contract pharmacies, but MCOs also are required to exclude 340B claims from reports they provide to states for rebate purposes.

Chapter 2

What entities, patients and drugs are 340B-eligible?

The following hospital categories are eligible for 340B participation

- Disproportionate Share Hospitals (DSH)
- Sole Community Hospitals (SCH)
- Rural Referral Centers (RRC)
- Critical Access Hospitals (CAH)
- Children's Hospitals (PED)
- Free-Standing Cancer Hospitals (CAN)

340B Eligibility Requirements: An Overview

In order for hospitals to qualify for the 340B program, they must meet the three requirements below — unless they are Rural Hospitals; in which case, they must meet only the first two requirements.

1. Government owned or government-controlled.

In other words, hospitals must be either **A)** Owned or operated by a state or local government, **B)** Public or private non-profit corporations which have been formally granted governmental powers by their state or local government, OR **C)** Private non-profit hospitals under contract with their state or local governments to provide health care services to low-income patients who are not entitled to Medicare or Medicaid benefits.

2) Disproportionate Share Hospitals.

Disproportionate Share Hospitals must have an adjustment percentage (or the percentage by which the hospital's allowable operating costs of inpatient hospital services exceeds the hospital's target amount) higher than 11.75% for the most recent cost reporting period ending before the calendar quarter involved. Sole Community Hospitals and Rural Referral Centers must have an adjustment percentage of greater than 8 percent.

Free-standing children's hospitals and free-standing cancer hospitals must have a payer mix that gives them a DSH percentage of greater than 11.75 percent. Critical Access Hospitals do not have a DSH adjustment percentage requirement.

NOTE: A hospital's DSH adjustment depends on the number of inpatient days of its Medicaid and Supplemental Security Income (SSI) patients.

3) DSH hospitals, children's hospitals and free-standing cancer hospitals meeting the first two criteria.

These hospitals are eligible to participate in the 340B program if they do not obtain covered outpatient drugs through Group Purchasing Organizations (GPOs), or through other group purchasing arrangements. At the same time, hospitals participating in 340B as CAHs, RRCs and SCHs are not subject to the GPO prohibition.

Hospital Categories Eligible for 340B Participation

Eligibility Requirements / Overview

1. Government owned or government-controlled.
2. Disproportionate Share Hospitals.
3. Children's hospitals & Free-Standing Cancer Hospitals meeting 1st two criteria.

Types of Facilities Included

- Freestanding acute care general hospitals
- Psychiatric hospitals
- Long term/continuing care nursing homes
- Home infusion therapy centers
- Hospices
- Federally qualified health centers
- Rural health clinics
- State mental institutions
- Indian Health Service facilities
- Federally Qualified Health Centers
- Community-based rehabilitation programs

Does HRSA Allow 340B Child Sites?

Yes. OPA requires that a covered entity register, as child sites, all offsite clinics, departments and services where 340B drugs are purchased or used, whether or not they are in the entity's primary campus.

"Offsite" generally means a location has a separate physical address than the hospital parent site. A hospital does not need to register outpatient clinics, departments or services located within the entity's main hospital — but may do so if they appear on a reimbursable line of a hospital's most recently-filed cost report.

Applicable hospitals should ensure that their policies and procedures address qualification of 340B drugs dispensed at Child Sites for services not yet included in the most recently filed Medicare Cost Report, based on whether those locations meet Medicare provider-based requirements, whether the 340B covered entity maintains the responsibility and records of the patient's care, and whether the health care professionals prescribing 340B drugs have relationship with the 340B covered entity.

Which patients are covered under 340B?

Covered entities can dispense 340B-eligible prescriptions to patients who (1) Have established relationships with the covered entity, such that the entity maintains records of the patient's care; (2) Receive care from a professional employed by the covered entity, or under contract or other arrangements (e.g., referral for consultation) with the covered entity, such that responsibility for the care remains with the covered entity; and (3) Receive health services from the covered entity that are consistent with the services for which grant funding has been provided to the entity.

Under these guidelines, an individual is not considered a covered entity's patient if the only health care service received by the patient from the entity is the dispensing of a drug for subsequent self-administration — or administration in the home setting.

Are 340B prices available for inpatient prescriptions?

No. 340B pricing applies to covered outpatient prescriptions only. Covered entities must therefore maintain appropriate tracking systems to ensure that covered outpatient drugs purchased through the 340B Program are not used for hospital inpatients — and it is the responsibility of health systems in the program to ensure that appropriate safeguards are in place to prevent these diversions.

What prescription drugs are eligible for 340B Savings?

In general, 340B eligibility involves both prescription medications and the covered entity writing the prescriptions. Here's a simple checklist for determining whether drugs are eligible.

- As a covered entity, you have a relationship with the patient and maintains records of care.
- The services are provided by a healthcare professional who is either employed by, or contracted with, you.
- The responsibility for care rests with you, the covered entity.
- The services are within the scope of project for grantees and designees.
- The service provided must be more than just dispensing medication.
- The drug is administered in an eligible outpatient location or dispensed by one of your 340B contract pharmacies.

General drug exceptions to 340B eligibility

There are a few 340B-eligibility exceptions. These include vaccines and Orphan Drugs (which are, by definition, medications specifically developed to treat rare diseases or conditions — and drugs that have only recently been granted New Drug Status by the FDA).

Eligible drugs frequently NOT submitted for 340B savings

While narcotic medications are included among 340B eligible drugs, covered entities often choose to exclude them from their programs — due, primarily, to the complexity of procuring these medications for replenishment. That procurement complexity adds-up to significant time-and-effort costs. And of course, there's no point in utilizing 340B discounts for medications when the time-and-effort costs exceed the savings generated.

About 340B Orphan Drugs

For the following covered entities, 340B-covered drugs do not include any drugs designated by the Secretary under Section 526 of the Federal Food, Drug, and Cosmetic Act for rare diseases and conditions:

- Free-standing cancer hospitals
- Rural referral centers
- Sole community hospitals
- Critical access hospitals

ADDITIONAL READING

What Drugs Are Not Eligible For 340B Savings?

Chapter 3

Optimizing savings and patient care through 340B

Why you should optimize, and not maximize, your 340B program

For the health systems VytlOne serves, we pursue a policy of optimizing 340B savings that's both aggressive and conservative. In other words, we believe you should aggressively pursue 340B savings for every prescription that's worth pursuing.

An ideally optimized 340B program generates a net savings on every eligible prescription claimed.

Two key elements of our optimized 340B programs

An unblemished record of performance

Whether you manage your entire 340B program in-house, or you use an outsourced partner for support, be sure your people have the skillsets — and, ideally, the track records — to ensure that you maintain compliance at all times. It's worth noting that VytlOne has served dozens of health systems, and not once has a client of ours ever been fined for a 340B violation.

The ability to mine your records for 340B-eligible prescriptions: Present and Past.

VytlOne's proprietary 340PRO software not only identifies current and past reimbursable prescriptions for our new clients, it automatically applies for those reimbursements. Typically, we'll mine new clients' prescriptions written up to one year prior to the date we started our service for them.

Get the most from your contract pharmacies

Contract pharmacies are critically important for optimizing the savings and revenue that your health system can generate with a well-managed 340B program. They're also an important extension of your overall care of, and for, your outpatients. Increasing the number of independent pharmacies serving as contract pharmacies enhances your ability to offer your outpatients options and convenience in filing their prescriptions.

That said, some contract pharmacies cost hospitals more (in fees) than they generate in 340B savings and revenue. What's more, it's often not for lack of prescription volume, but rather because those pharmacies simply won't qualify many 340B-eligible medications.

Optimizing the quality and number of your contract pharmacies

The simple truth is, we've never served (or seen) a 340B health system with adequate in-house resources to do just that. The typical number of quality 340B contract pharmacies we've added to the networks of health systems we serve is five to ten. For the network of one health system in South Carolina, we added nearly thirty contract pharmacies in just two years.

The challenge of building a contract pharmacy network

As any experienced professional will tell you, "sales" (for lack of a better term) ultimately comes-down to the number of calls you make. That's partly how we've done it for the health systems we serve. Everyone on our 340B team is trained to make inquiry calls to prospective contract pharmacies, and we make those calls armed with reams of data analytics.

Factors to consider for your 340B contract pharmacy network

Pharmacy fees

Pharmacy fee structures can vary wildly from pharmacy to pharmacy.

TPA fees | TPA compatibility with your 340B contract pharmacies

In addition to pharmacy fees, TPAs often charge for simply attempting to process 340B prescriptions — whether they're eligible or not.

340B Manufacturer restrictions

Many manufacturer restrictions limit 340B replenishment for certain medications to just one pharmacy per health system. Pick the wrong pharmacy for a particularly costly manufacturer-restricted drug that your providers routinely prescribe, and the consequences for your 340B savings can be catastrophic.

Negotiated pricing for specialty drugs

Fees from specialty pharmacies also vary for 340B prescriptions. Some charge cost-plus percentage, some charge flat rates.

What should you avoid in your 340B pharmacy contracts?

The answer is complicated. And it typically applies on a market-by-market basis. In our experience, here are three primary situations you should avoid:

- Processors who charge on a per-claim basis, coupled with high-volume pharmacies — which will lead to excessive transaction fees for your health system.
- Contract pharmacies with low participation rates in allowing replenishments — picking and choosing which medications you've already approved.
- Remotely-located pharmacies offering very few of your patients proximity convenience.

At the same time, hospitals can compromise the potential of their 340B programs by setting Dispensing fees set too low — which lowers local pharmacies' incentive to partner with you in the program.

Audit requirements

In order to maintain 340B compliance, your health system is required to provide oversight of all contract pharmacies — while maintaining auditable records. You're also expected to conduct annual audits of your contract pharmacies. Audits which should be completed by an independent auditing firm.

That said, when you authorize VytlOne to manage and/or oversee your contract pharmacy agreements, we'll give you complete support in maintaining auditable records, and conducting your annual audits.

ADDITIONAL READING

Are Your Contract Pharmacies Optimizing Your Hospital's 340B Savings?

Your Hospital's 340B Contract Pharmacy Network Is Not What It Should Be.

Take full advantage of specialty drug discounts

Specialty drugs constituted about 50% of the overall prescription drug market's expenditures (some $161 billion) in 2020. That's a 29% increase of total expenditures over 2015. What's more, 8 out of every 10 new drugs approved by the FDA in 2020 were specialty drugs. All of which makes specialty drugs the fastest-growing, and largest part, of the prescription-drug market.

According to the estimates of several online sources, the average retail pharmacy prescription in 2020 cost $566 per month — while the average specialty drug prescription cost $6,565.

Implement a robust Meds To Beds program

Benefits of a Meds To Beds Program: Overview

On a purely practical level, a well-managed bedside prescription delivery program can improve your health system's pharmacy revenue.

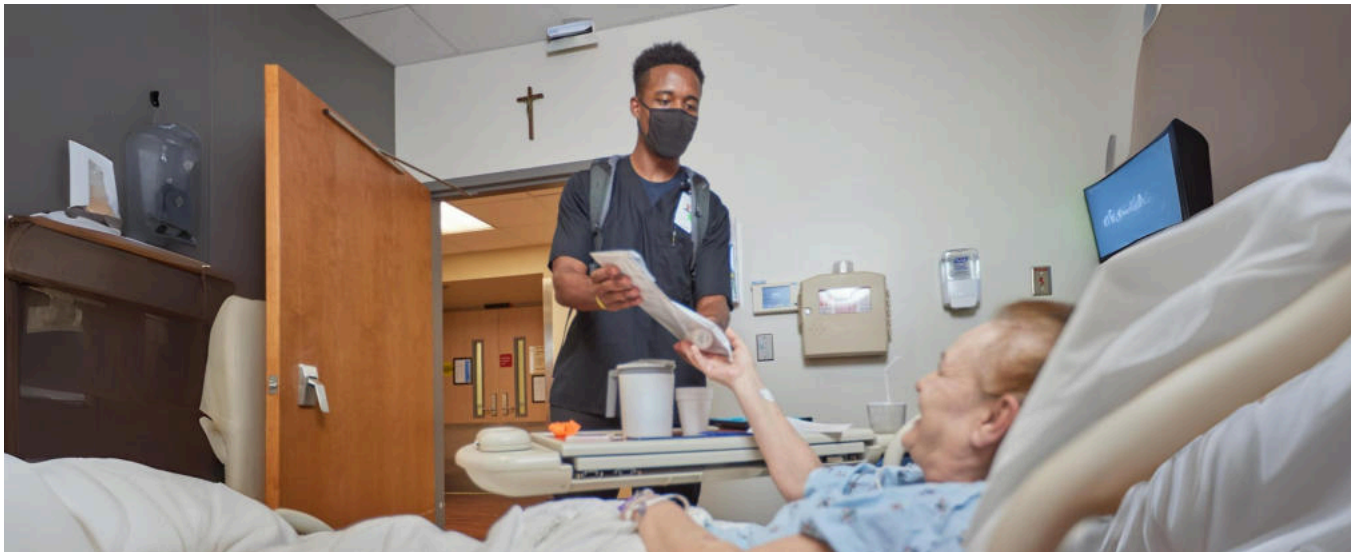
On the human level, Meds To Beds is more than a tangible sign of your system's care of, and for, the individuals & families you treat. It's your first line of offense in ensuring that your patients follow the prescription protocols you've given them — significantly decreasing the likelihood of their readmission while, in the process, improving your patient's satisfaction ratings.

In general, health systems fail to implement Bedside Prescription Delivery programs because of the costs of staffing and administration. In our experience, managing dozens of Meds to Beds programs, those costs are more than offset by the revenues generated. In one Mississippi health system alone, VytlOne filled over 18,000 outpatient prescriptions in just 12 months. During that time, the health system's pharmacy revenues increased 125%, while its readmissions decreased 79%.

How Meds To Beds benefits your 340B drug program

Bedside prescription delivery is arguably the most effective method for ensuring that your patients' prescriptions are captured before they leave your care.

Put another way, your Meds To Beds program should not only support your health system's mission of maximizing patient care, compliance and satisfaction while minimizing readmissions, it should serve as a funnel for directing patients into your 340B program.



How Meds To Beds benefits your 340B patients

Patients entered into your 340B program "funnel" generally receive superior ongoing professional care and support, after they are discharges.

Statistical research conclusively demonstrates that two primary factors driving patient non-compliance are lack of education & understanding, and lack of access (both in terms of financial means and proximity) to pharmacies. Which is why many hospitals in the 340B program supplement their Meds To Beds programs by offering home delivery and prescription discounts to financially-challenged patients. Those health systems generally agree that the costs of additional patient support are more than offset by the benefits of superior post-discharge care — not to mention the savings that come with reducing readmissions.

According to a study published by Frontiers In Public Health, Meds To Beds programs have been shown to significantly reduce 30-day hospital readmissions — particularly among older adult patients.

ADDITIONAL READING

How Meds To Beds Can Drive Your 340B Savings

VytlOne's Impact© Readmission Reduction Program

In late 2023, VytlOne took all the fundamental components of its Meds To Beds programs, and developed a 30-day readmission reduction program we call Impact®.

Using a clinical pharmacist in collaboration with a health system's nursing team, the program emphasizes personal, one-on-one patient education and medication-compliance support. The program operates as a separate service from Meds To Beds prescription delivery, but it can easily work in collaboration with MTB. All that's needed to add Impact® to a Meds To Beds program is an onsite clinical pharmacist and a virtual team of nursing care coordinators.

When our initial Impact® program launched in November, 2023, South Carolina's Conway Medical Center had a baseline 47% readmission rate among MVP patients with three or more encounters. After 15 months, our program had enrolled and served 474 participants — and achieved a readmission rate of just 10.1%. Of those patients, past the 30 day mark, 379 patients "graduated" without readmission — and there were only 48 readmits, for an 88.5% graduation rate. Readmissions dropped 77% among patients with 3 or more encounters, and 93% among patients with uncontrolled A1C.

The savings CMC achieved in readmission avoidance costs, as a result of the program, was $1.25 million (based on the $15,200 readmission cost per patient cited above). What's more, patient satisfaction ratings with the program (142 survey respondents) was 9.77 out of 10 — nearly 50% higher than the national average of 6.6 for health system Hospital Consumer Assessment of Healthcare Providers and Systems Survey (HCAHPS) scores.

FOR FURTHER READING (AND A VIDEO):

How To Achieve Readmission Reduction, One Patient At A Time

Understand, and overcome, your TPAs' limitations

TPAs play a critical role in a 340B program. It's their job to "match" prescription claims from your contract pharmacies with patient data you provide, and then to determine the eligibility of those claims. Without a match, a prescription cannot be qualified for 340B eligibility and savings.

Your TPAs' ability to accurately qualify your 340B claims is only as reliable as the information you provide. Their systems simply aren't configured to monitor and spot mismatches in that data.

340B data mismatches can be extremely trivial.

One of the most common reasons 340B claims are misqualified — particularly with Medicare patients — is inconsistency in Date Of Birth entries. Patient Name mismatches is another common cause of misqualifications. For instance, you may have a patient registered as Bob in your pharmacy system and Robert on your hospital's system. That said, the more complex your 340B Program is, the higher the likelihood that your automated data submission process will be flawed.

Technology often causes 340B data mismatches

The process of monitoring a 340B program is especially difficult when you use multiple TPAs. Every TPA's proprietary software system's interface is unique. Making matters even more complicated, the reporting structure within TPA portals vary significantly from one to another.

How common are TPA 340B misqualifications?

Mismatch rates vary from health system to health system, but we can say this with confidence: If you have a 340B program already in place, it's probably a lot higher than you think.

One of the health systems VytlOne serves employs three experienced and well-trained full-time professionals — who monitor their system's 340B claims on a full-time basis. And yet, during the first six weeks VytlOne supported their efforts, we provided matching justification for, and generated $187,000 worth of, 340B savings that they'd overlooked.

ADDITIONAL READING

How And Why TPAs Misqualify 340B Prescriptions.

Chapter 4

Maintaining 340B compliance

How common are 340B health system audits?

Since 2015, HRSA has conducted roughly 200 340B audits annually. On June 17, 2025, HRSA reported that it had conducted 163 audits — which would equate to 356 audits for the full year.

Overview: The audit process

Selection for Audit

HRSA conducts both targeted and random audits of covered entities. Targeted audits generally occur when a manufacturer reports suspected diversion or duplicate discounts, the entity has had prior compliance issues, or there are unusual purchasing or prescribing patterns. Random audits are selected from the overall pool of covered entities, and entities typically receive notification letters several weeks in advance.

Audit Notification and Preparation

HRSA will notify the entity of the audit's scope (which outpatient sites, contract pharmacies, and time period), as well as the audit date(s) and format (on-site or virtual).

HRSA will also make a data request, for which the entity must submit:

- 340B policies and procedures.
- Lists of all 340B-eligible sites and contract pharmacies.
- Drug purchase and dispensing data.
- Patient encounter documentation.

The entity is then expected to conduct internal reviews and confirm its data accuracy before the audit begins.

Audit Fieldwork

Whether HRSA conducts its audit on-site or virtually, HRSA's auditors will:

- Review sampled drug transactions to ensure they meet 340B eligibility.
- Determine if any 340B drugs were diverted to ineligible patients or sites.
- Check for any duplicate discounts (IE: That Medicaid claims were properly flagged or not).
- Examine the entity's policies, systems, and oversight processes.
- Interview staff involved in pharmacy, compliance, and data management.

Post-Audit Process

After fieldwork, HRSA will issue a Draft Report, after which the covered entity will have the opportunity to respond to preliminary findings and provide clarifying documentation or corrective evidence.

Once HRSA finalizes its findings, a Final Audit Report is published on the HRSA website.

Possible outcomes include:

- No findings (fully compliant).
- Findings of non-compliance, typically involving:
- Diversion (340B drugs dispensed to ineligible patients or sites).
- Duplicate discounts (Medicaid rebate plus 340B discount).
- Database inaccuracies (IE: Outdated contract pharmacy listings).

Corrective Action and Repayment

If HRSA confirms non-compliance, the entity must submit a Corrective Action Plan (CAP) detailing how it will fix the issue(s), and how it will prevent recurrence. HRSA requires repayment to affected manufacturers for any ineligible discounts received. Finally, HRSA may re-auditto verify sustained compliance.

Additional factors impacting 340B compliance in 2025

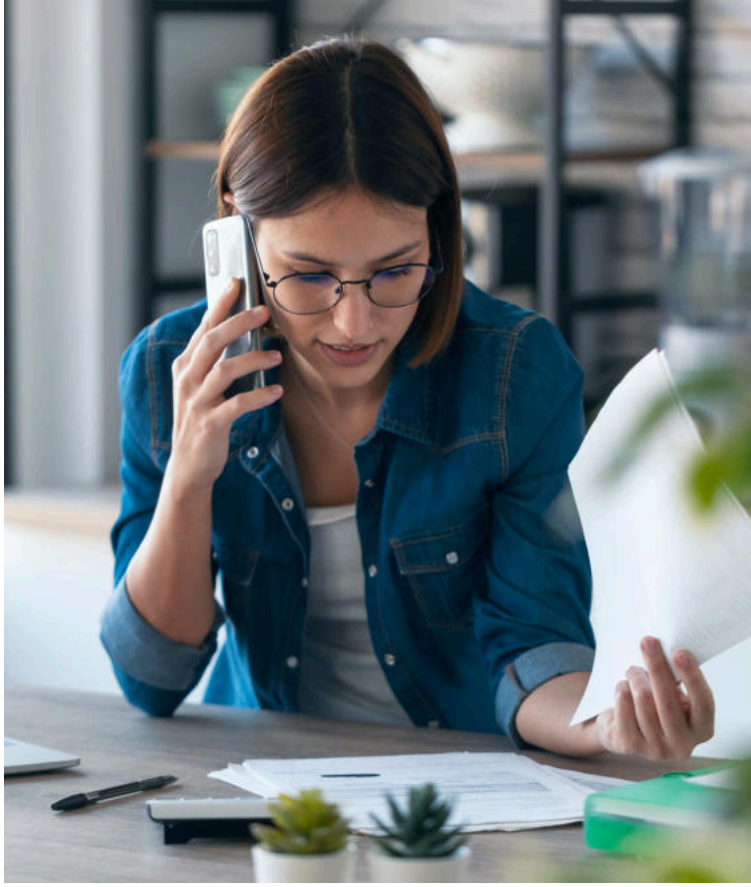
340B data transparency requirements

New scrutiny from lawmakers and regulatory agencies is prompting calls for better 340B program recording, tracking and reporting. Which is why the need for customized, analytics-driven technology has never been more critical to ensuring 340B compliance. At the same time, the need for proven experts to manage your 340B program has never been greater.

ADDITIONAL READING:

Empower Your Health System's 340B Program With Analytics
Specialized Software Can Only Do So Much For 340B Programs

A 340B Program Compliance Checklist



340B is complicated. That's why so many covered entities have full-time employees monitoring their 340B programs. At the same time, for the clients whose 340B programs we manage, VytlOne performs all the duties of a dedicated full-time staff — and more.

Below is a condensed checklist of safeguards we implement to help ensure the success, and full compliance, of every 340B program we manage and support. Safeguards you can use for your own program:

- Develop written policies & procedures that detail all of your 340B-related decisions.
- Make sure your 340B policies are compatible with your hospital's existing policies and procedures.
- Double-check your provider files — as well as your National Drug Code crosswalks and the location maps for all of the contract pharmacies in your network — for accuracy.
- Utilize customized, analytics-driven software that's been specifically developed to ensure that your 340B information is always up-to-date.
- Maintain a constantly-updated database of strategies and tactics for dealing with 340B ESP and other manufacturer restrictions (See Chapter 5 below for a complete overview).
- Support your providers, by giving them complete information on 340B program regulations, and how those regulations work with your hospital's existing policies & procedures.
- Conduct regular inventory-management and tracking-procedure checks, to ensure that you're always in compliance.
- Establish a Governance Committee to meet regularly and review your health system's 340B program.
- Conduct regularly-scheduled internal audits of your health system's 340B program.

This final point is worth repeating: Routine self-audits are critical to ensuring your program's compliance.

Carve-in or Carve-out?

When you register your health system for the 340B program, you'll be asked to choose whether you'll Carve-In or Carve-Out Medicaid fee-for-service (FFS). This decision will apply to all of your Medicaid FFS patients. Choosing Carve-In means that you'll be using 340B-priced medications with your Medicaid FFS patients. Choosing Carve-Out means you will not use 340B-priced medications with your Medicaid FFS patients.

ADDITIONAL READING

The Definitive 340B Compliance Checklist For 2025

Avoid 340B Double-Dipping

The 340B program does not allow you to take advantage of 340B discounts and Medicaid drug rebates for the same drugs. That's the practice known as Double Dipping, and as a covered entity, you need to maintain compliance mechanisms that prevent duplicate discounts.

Preventing 340B double-dipping begins at enrollment

If you decide to Carve-In Medicaid fee-for-service, you'll be required to list each Medicaid state where plan to bill, as well as the corresponding billing number(s) you'll list on your bills to those states. It follows, then, that you shouldn't list any Medicaid states where you plan to carve-out.

Common 340B Errors to avoid in your program

Poor tracking. You must be able to prove that every drug purchased on your 340B account is administered to an eligible patient from an eligible point of service.

Lack of contract pharmacy oversight. As a covered entity, you're ultimately responsible for monitoring your contract pharmacies and ensuring that they maintain compliance with all 340B program requirements. If you identify any diversions or duplicate discounts, it's your responsibility to notify the Office of Population Affairs (OPA) of the violation — and offer a remedy.

Failing to register all of your Child sites. Even if you have child site inside your hospital, or another registered primary facility, you should register it. That way, if you ever need to move that child site, you won't have to go through the registration process — and that typically takes six to nine months, sometimes an entire year. And during that time, you will not be legally entitled to 340B savings.

Chapter 5

340B ESP & manufacturer restrictions, and how to overcome them

What is 340B ESP?

According to its website, "340B ESP allows 340B covered entities and pharmaceutical manufacturers to work collaboratively to resolve duplicate discounts." In truth, the "service" is a brazen, unlawful ploy by drug manufacturers to evade the prescription-replenishment discounts they are legally required to offer eligible entities — by placing extraordinary reporting burdens on hospitals submitting claims for 340B savings.

The real reasons behind 340B ESP?

We believe the key factor that led to 340B ESP is the extensive range of commercial rebates the manufacturers themselves have voluntarily extended to PBMs — rebates which, in total, far exceed the combined discounts extended to 340B-eligible hospitals and health systems. In short, it's a situation of their own making.

The reporting burdens 340B ESP place on covered entities

Under the requirements set down by Drug Manufacturers, 340B-eligible entities must report, twice monthly through the 340B ESP platform, their covered prescriptions from every TPA with whom they work.

Extracting covered prescription data from some TPAs is impossible, given the lack of available 340B pricing in the 340B wholesaler account. Moreover, it's pointless to assume that covered entities and their contract pharmacies will regain access to their 340B discounts — since some manufacturers have placed 45-day time-frame restrictions from the dispensing of the prescription to replenishment. Why? They know that covered entities won't be able to meet this requirement.

How effective has 340B ESP been in enabling drug manufacturers to evade their legal obligations? In the first year of its relationship with 340B ESP, Merck alone saved $2 billion.

How we help eligible entities deal with 340B ESP

If you choose to report claims data to 340B ESP, we'll report on your behalf. Then we'll track 340B price reinstatement — by manufacturer, and by contract pharmacy. We'll also verify 340B price availability for each manufacturer, in each wholesaler account, for each of your contract pharmacies. Once verified pricing has been restored along the entire chain, we'll work with your TPAs to "turn-on" replenishment — and ensure they replenish appropriately.

Reporting to 340B ESP

- VytlOne tracks, on a per-manufacturer / per-pharmacy basis, 340B price eligibility according to what 340B ESP claims it is.
- We then verify in each 340B account — by Consumer Pricing and by manufacturer — if what 340B ESP claims is accurate.
- Once we've verified each data point, we'll notify your TPAs of newly restored pricing — then ensure that they request new price files from wholesalers.
- Once your TPAs have 340B prices, we'll order the 340B eligible drugs.

There are many places where communication-failure can and does occur — which is why we communicate with manufacturers, 340B ESP and wholesalers on your behalf. After that, we fight for reinstatement of the prices to which you're entitled under the 340B statute.

Six Common 340B ESP Reporting Errors

1. Uploading Excessive 340B Data

Never upload more data than is absolutely necessary, and required, by 340B ESP.

2. Trusting 340B ESP to Restore Prices On Its Promised Scheduling

Don't ever assume that 340B prices are restored in your contract pharmacies' 340B wholesaler accounts by the 10-day post-submission mark (the time frame 340B ESP says to allow).

3. Trusting 340B ESP Price Restoration, Period

If any manufacturer working with 340B ESP decides, unilaterally, that the purchases made for any of your contract pharmacies are more than the dispenses, they'll refuse to pay the wholesaler's chargeback. Which will result in a credit-rebill — which results in you, the covered entity, paying WAC — which is a much higher price.

4. Assuming submitted eligible dispenses result in 340B price access

Eligible 340B dispenses often do not occur in full-package-size increments. It may take months, and multiple claims, to equal a full reorderable package size — but some manufacturers won't reimburse 340B purchases past 45 or 60 days from dispense. Which means covered entities will likely never be able to get many of the 340B prices they are entitled to.

5. Counting-On 340B ESP-Compatibility In Your TPAs' Reports

When you submit your own reporting to 340B ESP, you can't simply pull reports, verbatim, from your TPAs and upload them. Your uploads must be submitted in a highly-specified format, and every upload is fraught with potential pitfalls that can cause failures.

6. Counting-On Support From 340B ESP

In our experience, nobody working with 340B ESP — or the manufacturers — will help you when you don't receive the 340B prices to which you're entitled, even if months have passed since your first data submission.

The good news about 340B ESP, for covered entities

Despite 340B ESP and manufacturer restrictions, VytlOne continues to produce results for health systems. Since late 2019, we've supported the 340B programs of 33 health systems and 38 health centers. Altogether, we've generated nearly $1 billion in pharmacy-related savings for our clients.

ADDITIONAL READING

340B ESP. Why it's Wrong, And How Hospitals Can Deal With It.

How VytlOne Maintains An Updated List Of 340B Covered Drugs

Describing just one aspect of his own experience with manufacturer restrictions, one VytlOne 340B Program Specialist notes, “Because they're so ambiguous, and changing so quickly, the restrictions force our team to review all of the restricted NDCs on a daily basis. Every pharmacy we serve has to be cognizant of all 1628 restricted NDCs when submitting prescriptions for 340B savings. And when a covered entity has multiple contract pharmacies, there's a multiplier in tracking NDC's and prescriptions.

“Each one of our team members is literally monitoring thousands of prescriptions on a daily basis. Which is one reason our team continues to grow. And why our clients have benefited so greatly from the 340B PRO software we developed, which has enabled us to grow and scale. Because you don't just have a single question needing answers on every prescription. It's not just about the NDC's. There are layers and layers of problem-solving involved.”

ADDITIONAL READING

Manufacturers Accelerate Pace And Severity Of 340B Drug Pricing Restrictions

Why specialized software is essential for successful 340B programs

Without specialized software solutions, the average 340B-eligible health system would likely need a dozen (or more) full-time employees, just to monitor their prescriptions to maximize savings and revenue. VytlOne rolled-out the first version of 340B Pro in 2021, and we are constantly updating and adjusting it to deal with the ever-evolving challenges manufacturers introduce in their 340B pricing restrictions.

340B programs need TPA support, but TPAs are far from perfect

TPAs' systems are not especially adept at monitoring and spotting provider / entity data mismatches — which are common occurrences in 340B programs. Nor do their fees generally incentivize them to improve their performance. That's meeting the challenge of minimizing data mismatches at the source is a core component of our 340B software and service package.

The critical role humans play in the 340B software equation

Over the years, VytlOne's software has identified untold millions of dollars' worth of 340B-eligible prescriptions missed by the TPAs working with hospitals we serve — as well as with their contract pharmacy networks. However, software solutions alone can't reliably requalify prescriptions for 340B drug pricing program savings — for the simple reason that there has to be a reason each prescription is requalified. And that reason has to be defensible, if it's challenged in audit.

All of that requires 340B program management experience and judgment on a prescription-by-prescription basis, and as anyone familiar with technology can tell you, Artificial Intelligence still has a long way to go in solving problems that require nuance and insight.

ADDITIONAL READING

Specialized Software Can Only Do So Much For 340B Programs

How VytlOne overcomes manufacturer restrictions on 340B pricing.

As much as we'd love to report that we've discovered the proverbial magic bullet for piercing manufacturer barriers to optimizing 340B cost savings and revenue, we can't. Our process starts with an in-depth assessment of a health system's current 340B-program status (assuming the health system has an active 340B program). Once we've conducted that analysis, we work with the health system's 340B professionals to develop strategies for improvement in every area of its program. VytlOne's 340B support team then implements software-supported processes for auditing missed opportunities.

For most of the hospitals we serve, VytlOne's team also provides hands-on support in managing their 340B programs.

ADDITIONAL READING

Seven Steps For Overcoming 340B ESP and Other Manufacturer Restrictions on 340B Pricing

Chapter 6

Using specialty pharmacy to optimize 340B revenue and patient outcomes

Why 340B Hospitals Should Build Their Own Specialty Pharmacies

The ultimate Win-Win scenario for any health system is increasing the quality of patient care, and getting paid to do it.

Chronic illnesses have become increasingly common in the United States. According to a report by The American Hospital Association, the number of Americans with chronic medical conditions will grow by a projected 14 million people between 2020 and 2030. According to some online reports, nearly 80% of new drug introductions are now specialty medications.

Moreover, an in-house specialty pharmacy offers enormous savings and revenue potential. Some covered entities generate as much as 600% in specialty pharmacy revenue from 340B drugs as they do in traditional retail / outpatient pharmacy 340B revenue.

Better patient outcomes. Better health system incomes.

In short, the reason 340B hospitals should build onsite specialty pharmacies is the significantly increased potential for generating 340B savings — and for passing-along those savings to patients in need. Today, hospitals and other 340B covered entities can acquire many specialty drugs for as little as 1¢ — which happens when a drug has hit its 100% Medicaid rebate cap.

In 2016, Humira, the top-selling drug in the U.S., hit the rebate cap. Since that time, 340B hospitals have been able to buy Humira, and many other specialty drugs — including Epclusa, Harvoni, Imbruvica, Iressa, Gilenya, Revlimid and Stelara — at significantly-reduced prices.

Nearly 90% of all large, for-profit hospitals are already operating their own specialty pharmacies. Ultimately, it stands to reason, every 340B health system looking to increase pharmacy revenue will need to consider building their own.

Streamlining 340B patient care

Onsite specialty pharmacies in 340B hospitals offer a seamless approach to caring for the "sickest of the sick" patients they serve. With their expertise, pharmacists at your onsite specialty pharmacy can collaborate closely with your health system's providers, effectively managing complex medication regimens — while minimizing the risk of medication errors.

Enhancing 340B-patient medication adherence

Onsite pharmacies can play a pivotal role in improving medication adherence among patients likeliest to burden hospitals with costly, compliance-related readmissions. Onsite specialty pharmacists can engage patients in one-on-one counseling, providing them with essential information about their medications' purposes, potential side effects, and proper administration.

Expanding 340B-patient access to specialty medications

The top two reasons for patient noncompliance with medication protocols are **1)** the prohibitive cost of their prescriptions, and **2)** the limited availability of those prescriptions. Onsite specialty pharmacies in 340B hospitals can overcome those problems by procuring 340B specialty drugs at discounted prices.

340B specialty-medication cost savings

With your own onsite specialty pharmacy, your hospital can capture a greater percentage of the 340B revenue that would otherwise go to outside pharmacies — supporting your financial stability, while enabling you to expand healthcare services and make infrastructure improvements in serving your community.

Improving overall patient satisfaction

Onsite 340B specialty pharmacies can contribute to higher satisfaction levels in several ways:

- Reducing patient wait times
- Offering patients greater access to tailored medication services.
- Improving patients' confidence in their treatment plans.
- Increasing overall trust in the healthcare system.
- Ensuring greater levels of medication compliance.

Facilitating clinical research and innovation

Onsite specialty pharmacies can serve as valuable resources for 340B hospitals conducting clinical research — promoting medical innovation and, ultimately, benefiting patient care for everyone.

Leveraging 340B Data Analytics

The integration of onsite specialty pharmacies within 340B hospitals enables the collection and analysis of comprehensive patient data. With enhanced data-driven insights, 340B hospitals can continually improve their patient care protocols and optimize treatment outcomes.

Overcoming 340B ESP And Drug Manufacturer Restrictions

The majority of 340B-eligible medications under access-restrictions are the most expensive and profitable drugs — which often means specialty drugs. This includes the aforementioned 40-mile-radius restriction and the Single Contract Pharmacy restriction.

Fortunately, there is a workaround for 340B hospitals forced to select a single pharmacy for certain manufacturers' 340B pricing — and it's legal in many states. Hospitals can operate specialty pharmacies alongside their retail pharmacies IF the two operations are in separate spaces (with separate Pharmacists-In-Charge), and there is no procedural, functional or personnel overlap between the two.

ADDITIONAL READING

Enhancing Patient Care and System Revenue: The Case for Onsite Specialty Pharmacies in 340B Hospitals.

Specialty Pharmacy Best Practices For 340B Hospitals

Meeting specialty pharmacy accreditation standards & policies

Accreditation can take 6 months to a year, depending on the health system and the process of integrating a specialty pharmacy into its resources.

You have to have reporting in place when you begin filling prescriptions. And while you're filling those prescriptions without accreditation, you're getting in the networks with your PBMs. And then, as you get your pharmacy and process stood up — and its procedures and policies in place — you're able to become accredited.

Specialty pharmacy accreditation metrics

When you become accredited, you have to keep certain metrics for patient phone calls. That means there must be someone in the pharmacy every hour it's open. Someone who can answer phone calls promptly, so your patients have easy access to a pharmacy professional, who can answer their questions — and make sure they're getting the appropriate care. For accreditation, this confirms that you're a qualified specialty pharmacy, and that you're taking care of your patients in the possible best way.

Specialty pharmacy service-data reporting

There are patient monitoring and clinical assessments that have to be tracked and measured. Every specialty pharmacy patient should be monitored by a clinic pharmacist.

Clinical assessment for specialty pharmacy patients

In initial assessments, specialty pharmacists should ask patients what other medications they're on, and what side effects they've experienced. Specialty pharmacy pharmacists should also work hand-in-hand with patients' providers, to make sure that medication regimens are appropriate, up to date, and the most accurate regimens for patients and their disease states.

Continuous monitoring & reporting

In addition to ongoing monitoring, most patients should be monitored yearly by pharmacists — to review any side effects they may be having, or any other issues they have taking their medication.

Pharmacists should ask patients if they've skipped any medications, and if it's affected their disease state. Moreover, all of that data should be reported back to the accrediting bodies.

Ensuring patient satisfaction with their specialty pharmacy's support

Patient satisfaction surveys, conducted by independent third parties, are required — to ensure that you're upholding high standards.

To ensure that you're meeting or exceeding those standards, you should make sure your providers know what it takes to ensure that patients know you care about their outcomes, and that they have the access to the appropriate medication.

Specialty pharmacy shipping & packaging protocols

Most specialty medications are delivered to patients at home. A lot of them require refrigeration, and some have to be frozen. Some need to stay at room temperature, and can't get too hot or too cold.

All of which is why it’s so important that your specialty pharmacy follows shipping and packaging protocols required by the accrediting bodies.

Integrating your specialty pharmacy’s technology with your health system’s technology

VytlOne has its own technology platform in place that pulls all the data, so we can create the necessary outlooks and outputs from our analytical tools. Data we then report back, not only to the accrediting bodies, but also to the payers — the PBMs. That way, when we're getting a specialty pharmacy in-network for a patient’s PBM, we can bill for the patient’s care.

Integrating Specialty Pharmacy With 340B

VytlOne's unique approach to specialty pharmacy provides health systems with a financial "glide path" to help fund their specialty pharmacies. One that starts with optimizing their 340B network. We've proven that VytlOne can help health systems improve revenues — often by millions of dollars annually — while their specialty pharmacies are being built. More importantly, we do it while helping hospitals improve the quality of patient care.

There are so many ways to optimize a 340B program, while making it more compliant, including:

Avoiding negative specialty pharmacy 340B reimbursements

What causes negative reimbursement? Several factors, including:

- #1 Overlooking 340B dispense status
- Purchasing drugs at WAC instead of on a 340B account
- Receiving 340B specialty pharmacy drugs without PBM access

Overcoming 340B PBM / payor hurdles

Many PBMs will not pay for prescriptions right out of the gate, so there are a lot of hurdles you have to jump with payors to get drugs covered. Even after 340B specialty drugs are covered, copays can be very high — sometimes thousands of dollars. Most patients can't afford copays that high, so you need to know how to get copay assistance. There are a number manufacturer programs, and other assistance programs — including charity care.

Performing prior authorizations for specialty drugs

Another benefit of having a pharmacist embedded in the clinic where your patients are is: They're able to look for financial assistance, and perform those prior authorizations — making sure that prescriptions are going to be paid for, and that patients can afford them.

340B specialty pharmacy accreditation: A VERY brief overview

Our Specialty Pharmacy team follows a comprehensive To Do list it manages — and personally undertakes — in guiding 340B health systems through the process of earning specialty pharmacy accreditation. Below is you'll find just six of the twelve steps we take in the first of nine separate stages to earn specialty pharmacy accreditation:

- Create a call center function. (Customized according to your specific goals).
- Develop Key Performance Indicators and reporting metrics for all relevant stakeholders. These services may be performed either virtually or in-person at your facilities and/or clinics.
- Establish call center services for managing your prescription orders, refill requests, medication related questions, and other calls.
- Evaluate your PBM for available Specialty Pharmacy benefits.
- Obtain prior authorizations under your health insurance benefit plans, or other Specialty Pharmacy plans.
- Implement and manage financial assistance programs for your indigent or uninsured patients.

Stage Two of our Nine Stage process involves no less than 12 primary steps, with 39 separate "sub-steps" spread-out across those 12 primary steps. And it goes without saying, every stage in process requires highly-specialized expertise; the kind of expertise that only comes from highly-specialized training, and hands-on experience.

Why VytlOne For Your 340B Hospital's Specialty Pharmacy?

We guide the health systems we serve through the process steps that they're required to participate in. Fortunately, those steps tend to be the least burdensome in the process. We handle the rest of the process — painstakingly documenting everything we do, and reporting back to the health systems at every critical step.

Helping fund your 340B specialty pharmacy

As we mentioned earlier, VytlOne helps health systems create a financial glide path to build their specialty pharmacies. A path that ensures the burden of financing their specialty pharmacy is of little to no risk to the health system.

Minimizing the burden of opening a 340B specialty pharmacy

We take the burden of opening a specialty pharmacy off your health system. We navigate you through the process of getting your specialty pharmacy running and successful. We handle the accreditation requirements. We get you access to the medications you need. We get you access to the payors.

Clinically integrating your 340B specialty pharmacy

We also take responsibility for integrating your specialty pharmacy with your clinic teams. Then we take-on everything that's required to grow your specialty pharmacy. We get to know your doctors, your clinicians, and your patients — so that we can tailor your specialty pharmacy's services and medications to the needs of your patients, and the difficult disease states that your health system needs to manage.

Ensuring your specialty pharmacy's success

Internal operations are only part of the formula for a specialty pharmacy's success. Which is why we go in-network, securing cooperation and approval from all the major local insurers, for the PBMs that their patients are covered by. What's more, we seek access from the drug manufacturers for what they're prescribing — even the most restrictive manufacturers

A proven track record

In 2024, we helped build, fund and open a specialty pharmacy for a large regional 340B hospital located in the Southeast; within six months of its launch, the pharmacy began generating a monthly income of $1 million net. More important is the fact that the pharmacy began positively impacting the quality and scope of the health system's patient care months in advance of its official opening date, and that impact has increased significantly since then.

When VytlOne supports you in building and owning a specialty pharmacy, we'll get you in-network with payers long before the physical space opens — which will enable you to generate additional 340B revenue to pay for your investment during the process. We can even help you secure a contract to dispense what's known as "soft" specialty drugs — which you can legally prescribe through your retail pharmacy.

All of which is why, by Q2 2025, we were in the development process for specialty pharmacies with seven health systems and several FQHCs.

ADDITIONAL READING

Best Practices For A 340B Hospital Looking To Build An Onsite Specialty Pharmacy

So You Want To Build A 340B Specialty Pharmacy. How Hard Can It Be?

How Recent 340B Changes Impact Specialty Pharmacies In 2025

The evolving legal and legislative landscape surrounding the 340B Drug Pricing Program has significant implications for hospitals' specialty pharmacies. Here's a breakdown of the new developments and their likely impacts:

1. 340B contract pharmacy restrictions

Drug manufacturers have increasingly restricted the use of contract pharmacies, especially specialty pharmacies, arguing that the 340B statute does not require them to deliver drugs to multiple contract pharmacies.

2. Court decisions and legal precedents

Litigation over HRSA's authority to enforce contract pharmacy arrangements is central to the current landscape.

Two Key 340B legal cases:

1) Sanofi v. HHS (2023)

In this case, the court ruled in favor of Sanofi and the drug manufacturers, finding that the 340B statute is silent on the use of contract pharmacies.

2) AstraZeneca v. HHS (D. Del. and 3rd Cir.)

AstraZeneca similarly challenged HHS's interpretation of the 340B statute in this case. The District of Delaware sided with HHS, but was reversed on appeal.

Potential Impact on 340B Entities

These two rulings have already had significant consequences for many 340B-covered entities:

- Reduced Access to 340B Savings
- Increased Administrative Burden
- Service Reductions
- Lower 340B savings could force hospitals and clinics to scale back charity care, outreach programs or specialty services.
- Legal Uncertainty
- Increased Scrutiny
- Regardless of court rulings, the spotlight on 340B program integrity means hospitals must tighten eligibility and documentation controls.

3. HRSA 340B enforcement shifts

HRSA has taken varying stances on 340B enforcement due to the legal challenges and changes in administration policy.

Impact on 340B hospitals:

- **Compliance Burden:** 340B entities must navigate a shifting regulatory environment, including stricter audits and data tracking.
- **Uncertainty in Planning:** Legal ambiguity forces hospital systems to be overly cautious in optimizing their 340B programs.

4. State-level 340B legal actions

Numerous states have passed laws to protect 340B-covered entities and their contract pharmacies, leading to further legal conflicts with drug manufacturers. Altogether, eleven states have either enacted 340B protection laws or passed legislation protecting 340B health systems in at least one chamber of their state legislatures, while 15 more states have introduced similar bills.

Impact on 340B hospitals:

- **Patchwork Compliance:** Hospitals operating across multiple states must navigate differing rules regarding specialty pharmacy operations and 340B usage.
- **Potential Relief:** In supportive states, hospitals should be able to maintain access to 340B pricing through specialty pharmacies.

5. Direct manufacturer distribution models

Under this model, drug manufacturers ship medications directly to the covered entities (or their contract pharmacies) rather than through traditional wholesalers. The problem, of course, is that this places distribution in the hands of the very entities seeking to undermine the 340B program wherever possible.

6. Technology and 340b data transparency demands

Legal and regulatory scrutiny is prompting demands for better tracking of 340B drug use and patient eligibility. Given the ever-increasing complexity involved in dealing with manufacturer restrictions, and the 340B program itself, the need for customized, analytics-driven technology has never been more critical to optimizing prescription savings opportunities.

For Further Reading:

Empower Your Health System's 340B Program With Analytics
Specialized Software Can Only Do So Much For 340B Programs

Chapter 7

340B's Outlook Moving Forward, And How To Prepare Your Program

What the changing 340B landscape means for your health system.

The 340B landscape continues to evolve rapidly, and most 340B hospitals continue losing substantial amounts of money to drug manufacturer restrictions. These losses have forced many safety-net hospitals to cut back on services, making it even harder for underserved patients and communities to access affordable medications and critical healthcare programs.

HRSA's Rebate Model Pilot Program

As we mentioned in the introduction of this document, HRSA's 2026 Rebate Model Pilot Program, first introduced publicly July 31, is a program which — if expanded to include all 340B-eligible prescriptions — could literally have a catastrophic impact on every participating 340B health system's finances, moving forward. Here's why:

Section 340B of the Public Health Service Act requires manufacturers to "offer" covered entities a price no higher than the 340B ceiling price at the time of purchase.

HRSA's rebate model flips the order on its head: Under the Pilot Program, 340B hospitals will be forced pay, up front, Wholesale Acquisition Cost (WAC) — which is often double or triple the 340B ceiling — and only later (if all documentation and claims are accepted) will they receive their lawfully-entitled 340B-replenishment rebates.

Although the 2026 Pilot Program covers only 10 drugs, it's been estimated that the annual 340B reimbursements for those drugs alone ranges from $6.3 billion to $12.5 billion. With some 2700 hospitals participating in 340B, that averages-out to an annual cash-flow burden of more than $2.340B million to nearly $4.67 million per hospital.

Which means, strictly calculating on the average numbers, in any given month, your health system's cash flow could be down by as much as $388,888 — while you wait for replenishment from drug manufacturers you hope will honor the program's 30-day reimbursement period.

What VytlOne is doing to prepare the 340B health systems we serve

340B health systems with on-campus pharmacies should expect a preliminary financial impact assessment for those pharmacies. Which is why we've taken the following preparatory steps:

- Assembled cross-functional team of experts across operations, 340B, finance, and technology.
- Assessing financial and operational impacts for each pharmacy.

We'll also be offering a new financial-support service.

VytlOne's 340Bridge is a market-competitive, short-term loan designed to meet this moment by reducing health systems' working capital exposure due to the 340B discount-to-rebate changes.

Additional support we'll be offering

- Assessing pharmacy workflow and dispense platforms (e.g., GuardianRx) to support updated workflows and reporting requirements.
- Coordinating with the 340B program's many stakeholders — including wholesalers, 340B TPAs and Beacon — to streamline communications and processes.
- Determining the best approach to register, submit data, and reconcile payments for 340B Rebate (i.e., Beacon) and Medicare's Maximum Fair Price (MFP) Rebate.

FOR FURTHER READING:

How HRSA's Rebate Model Pilot Program Could Destroy 340B

Bausch Pulls Its Drug Catalog From The 340B Program.

NOTE: *The following is a highly-condensed version of our in-depth article / editorial exploring the Bausch issue.*

Bausch Health shocked many healthcare industry observers when it publicly declared its intention to cease participation in the Medicaid Drug Rebate Program and the 340B Drug Pricing Program effective October 1, 2025.

In a statement published on its own website, the company claims, Bausch Health remains committed to Medicaid patients who have been prescribed our products and maintaining patient care and ensuring continuity of treatment is important.

How about Bausch's commitment to 340B hospitals & patients?

By withdrawing its drugs from the 340B program, BHC is reducing access to a critical source of support for financially-struggling 340B hospitals, and for the patients they serve.

Is Bausch surrendering its Medicare Part B reimbursements?

Legally, participating in the 340B program is optional only insofar as the company not participating forfeits the right to have its drugs covered by Medicare Part B — which represents an estimated 27% of all Medicare reimbursements.

We have to wonder if BHS's legal team has devised what they believe is a strategy for eliminating 340B obligations while still qualifying for Medicare Part B reimbursements. That said, there seems to be some uncertainty about BHC's intentions in withdrawing from the 340B program. Company verbiage indicates BHC does not intend to withdraw every single product from 340B pricing. However, the 340B law as written is clear: You're either all-in, or all-out.

The PPA and Medicaid Program participation

The Pharmaceutical Pricing Agreement (PPA) is a contract between drug manufacturers and Health and Human Services (HHS), and is a prerequisite for participation in the Medicaid Program and the 340B Drug Discount Program. BHS never signed the PPA.

What does this mean for 340B hospitals & patients?

Presumably, it means many patients will be forced to buy prescriptions direct from Bausch without insurance. What about hospitals who count-on 340B savings to help them stay afloat? Those hospitals will now be required to pay either Wholesale Acquisition Costs or Group Purchasing Organization prices — both which are significantly higher than 340B costs.

Will other manufacturers follow Bausch's lead?

This, of course, is the most far-reaching question for, and threat to, the future of the 340B program and the health systems who depend on it.

The good news for 340B entities

Despite the hundreds, if not thousands, of individual 340B manufacturer restrictions thrown our way, VytlOne continues to generate substantial savings and revenues for the health systems we serve. Which is why we remain optimistic that the 340B program will survive this latest attack.

Navigating 340B Program Changes

Maximizing pharmacy's role in your hospital's revenue cycle

The sad truth is that most 340B hospitals are struggling to protect their programs from further prescription-savings erosion — which is particularly unfortunate, given the fact that the hospitals we serve are often asking themselves how they can further optimize their 340B savings. All of which is why the ultimate question for a 340B-eligible entity might be: Which group is your hospital in: The former, or the latter?

Breakthrough: A PBM just for 340B hospitals

With VytlOne's PBM, health system pharmacies (retail and specialty) get prescription drugs on a pricing basis that's similar to the cost-plus model.

The hospitals we serve have the ability to design their own formularies and networks. They determine the margins their pharmacies generate on prescriptions, ensuring they operate on a positive-revenue basis — while enabling them to **1)** drive the lowest possible costs for patient prescriptions, and **2)** pass-along lower prescription costs to their employees.

Full transparency plus pricing and patient-care control for your hospital.

When VytlOne also manages your 340B program, your providers can choose — on a per-prescription basis — whether to take the associated rebate price of a drug or the discounted 340B price on each 340B-eligible prescription. Not only does your hospital benefit from lower pricing, you benefit from the full transparency we offer you on every prescription.

By having full access to pricing information, your pharmacists and providers can select the best prescription for each patient individually. In short, you ensure maximum clinical benefit for your patients and the highest possible revenue benefit for your 340B health system.

You can even extend savings to your employees.

With your prescription drug savings, you could easily cover the copay of every employee prescription filled in your pharmacies, and still increase your margins. Using the additional remaining margins, you can invest even further in caring for the community's most vulnerable patients.

Think of the positive impact you could have on employees' sense of well-being, their job satisfaction and their motivation to perform, by covering 100% of their prescription copays. Think of the positive impact that could have on your patients.

Understanding the current 340B landscape

Key changes either anticipated or already implemented include:

Heightened 340B audits and oversight

The Health Resources and Services Administration (HRSA) has signaled its intention to increase the number and complexity of 340B program audits it conducts.

Dirty tricks from who knows where

Someone is authoring false reports and smear campaigns to undermine the 340B program in the court of public opinion. The Kentucky Lantern, an independent news service, reported that a 'dark money' group has claimed the 340B program is being used to subsidize health care for illegal immigrants and pay for gender transition for kids. Another myth being spread is that the money supporting the 340B program comes out of taxpayers' pockets.

340B legislative updates: States opposing manufacturer restrictions

More states are enacting 340B protection bills. As we mentioned in a previous chapter, eleven states have either enacted 340B protection laws or passed legislation protecting 340B health systems in at least one chamber of their state legislatures, while 15 more states have introduced similar bills.

Few manufacturers have officially abandoned their restrictive practices completely, but now the states have firepower to answer them. "In states where the laws have been in place the longest," says VytlOne VP Heather Brooks, "we're seeing significantly more savings generated for their programs. For one of our clients, we were able to increase one pharmacy chain's monthly 340B reimbursements from less than $10,000 to more than $100,000 a month."

MAY, 2025 UPDATE: Executive Order 14297

On May 12, President Trump signed Executive Order 14297 — which could significantly impact the 340B Drug Pricing Program.

Key Implications for 340B Reimbursements

1. Potential Reinstatement of Medicare Reimbursement Cuts

2. Introduction of 'Site Neutrality' Payment Models

This approach could lower reimbursements for hospital outpatient departments to match those of non-hospital facilities, potentially diminishing the 340B program's financial benefits for hospitals.

3. Emphasis on Transparency and Direct Patient Discounts

This includes proposals requiring PBMs and pharmacies to pass drug discounts directly to patients at the point of sale. Such measures could transform the 340B program into a patient entitlement system, potentially impacting the financial viability of safety-net providers.

4. Implementation of 'Most Favored Nation' Pricing

The goal here is to align U.S. drug prices with those in other developed countries. This could lead to significant reductions in drug prices, and decrease 340B margins.

Qualities Common To Successful 340B Programs

A solid understanding of 340B program benefits

Launching and maintaining a successful 340B program starts with your health system truly understanding 340B's savings and revenue potential — and, in turn, the potential of your 340B income to positively impact patient outcomes, not to mention your system's overall mission in the community you serve.

A system-wide culture of 340B program support

"The hospitals who benefit the most from working with us," says Brooks, "are the ones who are willing to collaborate with us, and recognize that they can trust us. We do the vast majority of the work, but we still need their support — particularly in responding to our team's data requests."

A commitment to optimizing 340B clinical opportunities

"It's no secret that some covered entities have more existing 340B opportunities than others," Brooks continues, "because they have more 340B-compatible clinical programs. We've helped a number of health systems add clinical programs that can serve new 340B-eligible patients."

"Ultimately," Brooks concludes, "what gives me the greatest job satisfaction from serving health systems' 340B programs is my ability to positively impact their missions. I consider myself to be more than just a partner of those hospitals. In a very real sense, I'm an extension of their missions."

FOR FURTHER READING:

Overcome 340B Restrictions With Software And Human Insight

Optimize 340B Program Savings & Compliance With Data Mining

VytlOne is here to help.

There are so many ways to optimize your 340B drug program savings and benefits — overcoming manufacturer restrictions while maintaining compliance at all times. For more information on any aspect of developing and managing a successful 340B program, contact Howard Hall: howard.hall@vytlone.com | **214.808.2700**