AbbVie Just Filed the Most Important 340B Lawsuit Nobody Saw Coming

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Abstract

- AbbVie filed suit against HRSA on April 8, 2026 in D.C. federal court, challeng the agency's 30-year-old definition of "patient" under the 340B Drug Pricing Pr

- The lawsuit is the first time a drug manufacturer has gone to court to narrow t statutory meaning of "patient" in 340B, using the post-Chevron legal landscape doctrinal weapon

- AbbVie alleges that HRSA's 1996 guidance allows covered entities to claim 340 discounts on prescriptions for individuals with only cursory or outdated contact the entity, enabling systemic diversion

- The complaint details specific covered entities (Barrio Comprehensive Family H Care Center and Mount Sinai Hospital) whose purchasing patterns AbbVie characterizes as grossly anomalous

- 340B discounted purchases hit $81.4 billion in 2024, a 23% year-over-year incre and a compound annual growth rate of 23.5% from 2015 through 2024, now surpassing Medicaid drug spending

- AbbVie proposes a four-part patient definition requiring direct connection bet prescription and care, substantive medical encounter, 12-month recency, and dir provider oversight

- If the court sides with AbbVie, hospitals and health systems face tightened eligibility standards, increased audit exposure, and potential repayment obligati

on billions of dollars in annual 340B savings

- The case sits at the intersection of post-Loper Bright administrative law, healtl system economics, and pharma commercial strategy, with investment implicatio across digital health, health IT, compliance tech, and provider-side services

Table of Contents

The Setup: What Actually Happened

On April 8, 2026, AbbVie filed a 72-page complaint in the U.S. District Court fo District of Columbia against HRSA, HHS, Secretary Kennedy, and HRSA Administrator Thomas Engels. The filing is styled as a request for declaratory ar injunctive relief. In plain terms, AbbVie wants a federal judge to tell HRSA that three-decade-old definition of “patient” under the 340B Drug Pricing Program i wrong, and then order the agency to let AbbVie audit covered entities using a st definition. This is not a typical 340B dispute about contract pharmacies or dupli

discounting or reimbursement mechanics. This one goes to the core of how the e program defines eligibility, and if AbbVie wins, the ripple effects will be enorm

The immediate trigger was pretty simple. AbbVie submitted audit workplans to HRSA targeting two covered entities whose purchasing behavior looked, to put i mildly, weird. HRSA reviewed those workplans and basically said: your propose definition of "patient" goes beyond our 1996 guidance, and we will not enforce a findings that come from audits conducted under your definition. AbbVie argued that the 1996 guidance is not the best reading of the statute. HRSA did not budg AbbVie then did what large pharma companies do when the administrative proc fails them. They sued.

Why the Patient Definition Matters Mo Than You Think

Here is the foundational problem. The 340B statute says a covered entity cannot or transfer a 340B-discounted drug to "a person who is not a patient of the entit That phrase does a lot of heavy lifting. But Congress never actually defined "pati So in 1996, HRSA issued non-binding guidance laying out what the agency think "patient" means. That guidance says an individual is a patient if the covered ent "established a relationship" with the person such that the entity maintains recor their healthcare, the individual receives care from a professional employed by or contractually tied to the covered entity, and the service is consistent with the en grant funding. That is basically it.

The problem, from AbbVie's perspective (and honestly from the perspective of a who has spent time staring at 340B claims data), is that this definition is shockir permissive. Under HRSA's reading, a person who had one ten-minute phone call a covered entity provider two years ago, about an unrelated condition, and then a prescription written by a completely different doctor at a completely different facility, can still be classified as a "patient" of the covered entity. As long as the keeps some record of that original phone call and the prescriber has some contra or referral relationship with the entity, the prescription gets claimed at 340B pri

The covered entity pockets the spread between the deeply discounted 340B pric (sometimes pennies on the dollar) and whatever the insurer or the patient pays a commercial price. There is no requirement to pass the savings along to the patie And there is no time limit on how old the relationship can be, at least not one th HRSA has ever formally specified.

This is how a small federally qualified health center in San Antonio ends up witl nurse practitioners who are among the top prescribers in the entire country for specific AbbVie immunology drugs, and how 71% of that entity's 340B purchase up being dispensed through pharmacies outside of Texas. The math does not ma sense unless the patient definition is elastic enough to absorb essentially anyone has ever touched the entity's system.

The Numbers Behind the 340B Explosic

The growth trajectory of 340B is genuinely staggering and worth spending a mir on, because it is the backdrop against which this lawsuit makes strategic sense. I 2010, spending on drugs purchased through the program was about $6.6 billion. 2021 it was $43.9 billion. By 2023 it was $66.3 billion. By 2024 it hit $81.4 billio 23% year-over-year increase. The compound annual growth rate from 2015 throu 2024 was 23.5%. For context, manufacturers' net drug sales over the same period at roughly 5% annually. The program is now the second-largest federal prescript drug program in the country, behind only Medicare Part D, and it is larger than Medicaid drug spending.

When the program launched in 1992, there were about 1,000 covered entities. By there were over 50,000. The number of contract pharmacies went from about 1,3 2010 to nearly 20,000 by 2017, and by mid-2023 there were more than 33,000 pharmacies with over 194,000 individual contracts. That is a 2,400% increase in contract pharmacy arrangements in 13 years. CBO attributed roughly one-third spending growth between 2010 and 2021 to marketwide drug price trends, and t remaining two-thirds to hospital-clinic integration, ACA-driven expansion of eli entities, and that 2010 HRSA guidance change that let covered entities use unlin

contract pharmacies. A PMC-published study from 2025 decomposed 340B grov from 2018 through 2024 and found that utilization accounted for roughly 80% o growth on a list-price basis, with price increases accounting for only about 17%. other words, this is not just drug prices going up. It is the program getting bigg because more prescriptions are being funneled through 340B-eligible channels.

The financial incentives are pretty transparent. A covered entity buys a drug at t 340B ceiling price, which can be a 99%+ discount off wholesale acquisition cost some products. The entity then dispenses or has a contract pharmacy dispense t drug to an insured patient at full commercial price. Nobody is required to share discount with the patient. GAO survey data from 2018 showed that 45% of cover entities using contract pharmacies admitted they do not pass along any 340B dis to any patient at any of their contract pharmacy locations. The HHS OIG found 2014 that some contract pharmacies charge uninsured customers the full non-34 price. The entire economic structure of the program has shifted from "help poo people afford drugs" to "generate arbitrage revenue for entities and their pharm partners."

Post-Chevron: Why Now and Why This Matters Legally

The timing of this lawsuit is not a coincidence. In June 2024, the Supreme Court decided Loper Bright Enterprises v. Raimondo, which overturned the Chevron doctrine after 40 years. Under Chevron, courts were supposed to defer to a feder agency's "reasonable" interpretation of an ambiguous statute that the agency administered. Post-Loper Bright, courts must exercise their own independent judgment about what a statute means. Agency interpretations can still inform th analysis under the surviving Skidmore standard, but they no longer get automati deference just because the statute is ambiguous and the agency has spoken.

This matters enormously for 340B because the entire patient definition framewo rests on HRSA guidance, not on statutory text. Congress did not define "patient. HRSA filled the gap through non-binding guidance in 1996. That guidance was

promulgated as a formal rule. Under the old Chevron framework, a court might said: the statute is ambiguous, HRSA's reading is reasonable, case closed. Post-L Bright, the question becomes: what is the best reading of the statutory text? Anc AbbVie's argument is that a court doing that analysis from scratch, without defe to HRSA, should land on a much tighter definition.

The complaint leans into this explicitly. AbbVie cites Loper Bright repeatedly ar frames its entire case around the proposition that the court should identify the "single, best meaning" of the statutory term. AbbVie argues that HRSA's 1996 guidance does not reflect the best reading and instead enables exactly the kind o program abuse that Congress built safeguards against. It is a clean post-Chevror the statute is silent, the agency filled the gap, the agency's gap-filling is no longe entitled to deference, and a court should now determine the correct interpretati independently.

Whether it works is another question. But the legal environment is undeniably r favorable for this kind of challenge than it was two years ago. And AbbVie surel knows that even if this particular case takes years to resolve, the filing itself puts pressure on HRSA to revisit its guidance and signals to other manufacturers tha patient definition is now a live legal issue.

Barrio and Mount Sinai: The Case Stud That Made AbbVie Move

The complaint's factual allegations are, frankly, a good read if you enjoy stories a regulatory arbitrage and creative interpretations of who qualifies as your patient AbbVie details two covered entities whose purchasing patterns triggered the auc requests that HRSA eventually rejected.

Barrio Comprehensive Family Health Care Center is a HRSA-funded health cent San Antonio. It is not a large hospital. It is a comparatively small entity. Yet Abb data showed that Barrio's 340B purchases of Humira, Skyrizi, and Rinvoq increa over 119% from 2021 to 2022 and over 53% from 2022 to 2023. Barrio was the to purchaser of AbbVie immunology products among all health centers and FQHC

nationwide. And here is the part that really caught AbbVie's attention: while 80
340B purchases by Texas covered entities were dispensed through Texas pharma
71% of Barrio's purchases went through out-of-state pharmacies. When AbbVie
in, Barrio explained that it does not require in-person visits. A short phone or vi
call is enough. An individual is considered a "patient" for 24 months after any m
encounter, and the prescription does not need to be related to whatever happene
during that encounter. In Q1 2025, a single nurse practitioner at Barrio wrote
approximately 225 prescriptions for Skyrizi 150MG that were claimed as 340B
eligible, putting that individual at the very top of all 22,000 prescribers for that
nationwide.

Mount Sinai Hospital, a DSH in New York City, presented a different flavor of tl
same problem. AbbVie found that Mount Sinai's purchasing volume in the first
quarters of 2024 was 35% higher than all of 2023 combined. Claims data showed
multiple instances where three separate Mount Sinai-affiliated covered entities
submitted the exact same claim for the exact same drug for the exact same patie
with the same date of service, same provider ID, same prescription number, sam
NDC, and same quantity. The only difference was which Mount Sinai entity was
claiming the discount. Mount Sinai told AbbVie it follows HRSA's patient defini
that prescriptions written within 18 months of an eligible encounter are treated
340B eligible, and that it does not require a minimum amount of time for a prov
to practice at Mount Sinai to be considered a Mount Sinai provider.

What AbbVie Actually Wants the Definition to Be

AbbVie proposed a four-part definition of patient that is considerably narrower
HRSA's 1996 guidance. Under AbbVie's reading, someone is a "patient of the en
only if the prescription was a direct result of a healthcare encounter with a
professional who provides services at the covered entity (not a referral from an
unrelated provider), the healthcare encounter involved substantive medical care
sufficient to meet clinical practice standards for diagnosing and treating the con
for which the drug was prescribed (not a perfunctory ten-minute telehealth chec

the encounter occurred within 12 months of when the drug was dispensed (not s open-ended lookback window), and the prescribing professional has direct overs of the patient's care for the condition being treated, with the covered entity maintaining primary responsibility for managing that care.

AbbVie builds this interpretation from dictionary definitions of "patient" (some actively receiving medical care from a specific professional), the present tense of statutory language (indicating a current active relationship), the highly detailed structure of the 340B statute itself (which Congress designed with precision and narrow eligibility categories), and the legislative history showing Congress inten the program to help a narrow set of safety-net providers serve indigent and unin populations.

The argument is textually coherent and structurally well-built. Whether a court buy it is uncertain, but AbbVie clearly did its homework. The complaint is dens statutory construction analysis and cites the AMA Code of Medical Ethics, mult dictionary definitions, and a long trail of legislative history to support the propo that Congress meant something narrower and more rigorous than what HRSA's guidance allows.

The Genesis Precedent: A Complicatior

There is at least one prior case that dealt with the 340B patient definition, thoug came from the opposite direction. In 2017, a federally qualified health center cal Genesis Health Care sued HRSA because the agency's audit had found that Gene improperly diverted 340B drugs by filling prescriptions that did not originate w Genesis providers. Genesis argued the opposite of what AbbVie is arguing: that definition should be broader, that covered entities should be able to claim 340B discounts even when the prescription came from a different provider, as long as patient had received services from the covered entity.

Genesis won. In 2023, the U.S. District Court for South Carolina ruled that the s does not require the covered entity to have initiated the healthcare service result the prescription. The court did say an "ongoing patient relationship" is required

it did not attach a specific time frame to that requirement. The ruling applied o
Genesis (not nationwide), and it remains to be seen whether the AbbVie court w
find that reasoning persuasive or distinguishable. Interestingly, AbbVie did not
reference the Genesis case anywhere in its complaint, which is either a deliberat
strategic choice or an unusual omission.

Downstream Consequences for Health Systems

If AbbVie wins, even partially, the consequences cascade quickly. Start with
compliance risk. Hospitals and health centers that have been operating under H
1996 guidance, which is basically everyone, would potentially face retroactive au
exposure under a tighter definition. The complaint specifically seeks to enable
AbbVie to audit using its proposed definition, and a court order directing HRSA
authorize and enforce such audits would be precedent-setting.

Then there is the revenue impact. DSH hospitals accounted for roughly $64 billi
the $81.4 billion in 340B purchases in 2024. Much of that spend generates arbit
revenue. A narrower patient definition shrinks the eligible prescription pool. Fe
eligible prescriptions means fewer 340B purchases means less spread. For large
systems that have built contract pharmacy networks and telehealth referral pipe
to maximize 340B capture, this is a direct hit to operating margins.

Contract pharmacy arrangements get squeezed too. The replenishment model, w
a pharmacy dispenses at full price and retroactively claims 340B eligibility, depe
on a loose patient definition. Tighten the definition and a meaningful percentag
those retroactive claims fail. The pharmacy still dispensed the drug at full price,
nobody gets to claim the 340B discount on the replenishment purchase.

Telehealth prescribing for 340B purposes also comes under threat. AbbVie's pro
definition requires "substantive medical care" sufficient for proper diagnosis an
treatment. A ten-minute video consult that functions primarily as a patient-capt
mechanism for 340B eligibility probably does not meet that standard. This matt
because telehealth-driven 340B enrollment has been a growth vector for covered

entities, especially FQHCs, since COVID-era flexibilities made virtual visits mainstream.

Investment Implications for Health Tec

For angel investors and entrepreneurs in health tech, this case creates both risk opportunity across several vectors.

On the risk side, any portfolio company whose revenue model depends materiall 340B economics should be stress-tested against a world where the patient defini narrows. That includes specialty pharmacy platforms, contract pharmacy administrators, 340B third-party administrators, and health systems that use 34(arbitrage to fund uncompensated care or subsidize operating budgets. If the elig patient pool contracts, volumes drop, and the unit economics of 340B-dependen business models deteriorate. Companies in the 340B TPA space, which includes players that help covered entities identify and claim 340B-eligible prescriptions, would see reduced addressable market. Contract pharmacy networks that have expanded aggressively on the assumption of continued growth may find themsel overbuilt.

On the opportunity side, tighter standards create demand for better compliance infrastructure. If covered entities need to demonstrate that every 340B-eligible prescription meets a four-part test including substantive medical encounter, 12-month recency, direct prescriber oversight, and care management responsibility, is a data problem. You need systems that can track patient encounters, link prescriptions to specific clinical relationships, verify provider employment or contractual status, and timestamp everything within a defined lookback window sounds a lot like a software problem. Health IT companies and compliance-tech startups that can build tooling to help covered entities audit-proof their 340B programs under a stricter standard will find demand. Same for analytics compan that can help health systems model the financial impact of different patient defi scenarios on their 340B revenue.

There is also a secondary effect on value-based care and care management infrastructure. AbbVie's proposed definition effectively requires that the covere entity maintain ongoing oversight of the patient's care. That is not just a 340B compliance requirement; it maps to care coordination infrastructure that health systems need for value-based contracts anyway. Companies building longitudina management platforms, provider attribution models, and referral management systems might find their products suddenly relevant to a 340B compliance use ca they had not been targeting.

The broader strategic question for investors is whether this lawsuit, regardless o outcome, signals a structural shift in how pharma approaches 340B. If AbbVie is willing to spend the money and political capital to sue HRSA over the patient definition, other manufacturers are watching. The 340B program represents tens billions in foregone pharma revenue. Any judicial precedent that gives manufact a tighter audit framework is going to get used. And every time a manufacturer successfully narrows the scope of 340B, the economics of contract pharmacy arrangements, 340B TPA services, and covered entity operating models shift.

The case is also a reminder that post-Loper Bright, the regulatory floor in health is less stable than it used to be. Agency guidance that has functioned as settled l decades can now be challenged on first principles. That creates uncertainty, whi creates risk, but it also creates arbitrage for teams that can move faster than the regulatory environment. For early-stage health tech companies, the question is whether you are building for the regulatory regime that exists today or the one t might exist in 18 months. The smart money, as always, is on building for both.

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