

QUANTUM 5D CONSULTING — EXPERT ARTICLE

The Future of 340B: Trends and Predictions for Healthcare Organizations

By Dr. Adetoro Oriaifo, PharmD, MBA, FACHE, 340B ACE, CHCEF | 18-minute read | July 2026

Executive Summary

The 340B Drug Pricing Program stands at an inflection point. After three decades of steady expansion, the program now faces a convergence of forces—manufacturer restrictions, regulatory recalibration, technological disruption, and healthcare consolidation—that will fundamentally reshape how covered entities capture and deploy 340B savings. For safety-net providers that depend on these savings to fund patient care, the next three to five years will demand a level of strategic sophistication that most organizations have never needed before.

This article examines the major forces shaping the future of 340B, analyzes the trajectories most likely to play out, and provides a concrete strategic framework for healthcare organizations that intend to protect and grow their 340B programs in an increasingly adversarial environment.

50,000+

Covered Entity Sites

\$44B+

Est. Annual 340B Purchases

30+

Manufacturers with Restrictions

15+

States with 340B Legislation

1. The Current 340B Landscape

The 340B Drug Pricing Program, established under Section 340B of the Public Health Service Act in 1992, was designed with a straightforward premise: drug manufacturers participating in Medicaid must offer discounted prices to eligible safety-net providers so those providers can “stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” What began as a relatively modest program serving a few hundred hospitals and clinics has grown into one of the largest drug purchasing programs in the United States.

Today, the program encompasses more than 50,000 covered entity sites, including federally qualified health centers (FQHCs), disproportionate share hospitals (DSH), Ryan White HIV/AIDS clinics, children’s hospitals, and other safety-net providers. 340B-purchased drugs now account for an estimated 8–12% of all U.S. drug purchases by volume. The program generates billions of dollars in savings annually that covered entities reinvest in uncompensated care, sliding-fee-scale services, community health programs, and operational sustainability.

But the program’s growth has drawn intense scrutiny. The pharmaceutical industry argues that 340B has expanded far beyond its original intent and that savings are being captured by contract pharmacies and large health systems rather than flowing directly to low-income patients. Covered entities counter that the program is working exactly as designed

and that manufacturer restrictions are undermining their ability to serve vulnerable populations. This fundamental disagreement has produced the most turbulent period in the program’s history.

Key Stakeholders and Their Positions

Stakeholder	Core Position	Primary Lever
Drug Manufacturers (PhRMA)	Program has grown beyond intent; contract pharmacy use lacks oversight	Unilateral restrictions, lobbying for legislative reform
FQHCs / Safety-Net Providers	340B savings are essential to mission; restrictions threaten patient access	ADR filings, state legislation, coalition advocacy
Large Health Systems (DSH)	Contract pharmacy revenue supports charity care and community benefit	Litigation, lobbying, health system coalitions
HRSA / OPA	Statutory authority to administer and enforce program compliance	Rulemaking, audits, ADR process, enforcement letters
Congress	Divided; reform proposals range from expansion to significant curtailment	Legislation, oversight hearings, appropriations
Contract Pharmacies	Provide critical access points; administrative fees are fair compensation	Contractual relationships, pharmacy network coverage

2. The Contract Pharmacy Fight

The single most consequential issue facing 340B today is the ongoing battle over contract pharmacy access. Since 2020, more than 30 drug manufacturers have imposed unilateral restrictions on 340B pricing at contract pharmacies—some limiting covered entities to a single contract pharmacy, others requiring claims-level data submission through third-party platforms, and a few refusing to offer 340B pricing at contract pharmacies altogether unless specific conditions are met.

For many covered entities—particularly FQHCs that lack in-house pharmacies—contract pharmacies are the primary mechanism through which 340B savings are realized. When manufacturers restrict contract pharmacy access, those savings evaporate. Industry analyses estimate that manufacturer restrictions have collectively reduced 340B savings available through contract pharmacies by 20–40%, depending on the entity type and drug mix.

Administrative Dispute Resolution (ADR) Outcomes

HRSA's Administrative Dispute Resolution (ADR) process has become the central battlefield. After years of dormancy, the ADR panel has begun issuing decisions—and the early results have overwhelmingly favored covered entities. In multiple rulings, the ADR panel has found that manufacturers lack statutory authority to impose unilateral conditions on 340B pricing at contract pharmacies, reasoning that the statute requires manufacturers to offer the ceiling price on all covered outpatient drugs to covered entities without conditions beyond those specified in the statute.

However, several manufacturers have refused to comply with adverse ADR decisions and have instead filed federal lawsuits challenging HRSA's authority to adjudicate these disputes. The legal outcomes remain uncertain, and the resulting patchwork—some manufacturers complying, others litigating, and others operating under different restriction models—has created an extraordinarily complex operating environment for covered entities.

Key Takeaway: Covered entities should not wait for a definitive legal resolution. Instead, they should build compliance infrastructure that can adapt to multiple outcomes—full contract pharmacy restoration, partial restrictions, or a claims-data-submission model that becomes the industry standard.

Legislative Trends

Congressional action on 340B remains deeply divided. On one side, proposals seek to codify contract pharmacy protections into statute and clarify that manufacturers cannot impose unilateral restrictions. On the other, reform bills would impose new transparency requirements on covered entities, limit contract pharmacy arrangements, or require covered entities to demonstrate that 340B savings are being passed through to patients in the form of lower prices or expanded services.

The most likely legislative scenario in the near term is not a comprehensive 340B reform bill but rather incremental measures attached to must-pass legislation—such as transparency reporting requirements included in appropriations bills or drug pricing packages. Covered entities should prepare for a future in which some form of enhanced reporting is required, even if the broader program structure remains intact.

3. Regulatory Trajectory: What HRSA Is Building

HRSA's Office of Pharmacy Affairs (OPA) has spent the past several years building the regulatory infrastructure that the 340B program has historically lacked. After decades of operating with minimal rulemaking authority exercised, HRSA is now actively constructing a more robust oversight framework. Understanding where this is headed is critical for covered entities planning their compliance strategies.

Enforcement Trends

The volume and rigor of 340B audits have increased substantially. HRSA's audit findings now carry real consequences: entities found to have diverted 340B drugs to ineligible patients or generated duplicate discounts face repayment obligations, corrective action plans, and in severe cases, removal from the program. The days of audit findings resulting in gentle corrective suggestions are over.

Several enforcement patterns have emerged that signal HRSA's future direction:

- **Patient eligibility verification** is receiving heightened scrutiny, with HRSA expecting covered entities to demonstrate robust processes for ensuring that 340B drugs are dispensed only to patients who meet the statutory definition.
- **Contract pharmacy oversight** requirements are expanding, with HRSA expecting covered entities to maintain meaningful oversight of their contract pharmacy arrangements rather than delegating compliance entirely to third-party administrators.
- **Duplicate discount prevention** remains a top priority, and entities that cannot demonstrate reliable processes for preventing 340B/Medicaid duplicate discounts face significant audit risk.
- **Mixed-use pharmacy compliance**—the split-billing processes used by entities with both 340B and non-340B inventory—continues to be one of the most common audit finding areas.

What to Watch: HRSA Rulemaking Pipeline

HRSA has signaled interest in rulemaking across several areas: formal patient definition, standards for contract pharmacy arrangements, civil monetary penalty authority, and enhanced reporting requirements. While the timeline for any final rule remains uncertain given the broader political environment, covered entities should treat these as eventual realities and begin building compliance systems that meet the likely standard.

The Patient Definition Question

Perhaps no single regulatory question has greater operational significance than how HRSA ultimately defines a “patient” for 340B purposes. The current guidance—which relies on the concept of a provider-patient relationship and a healthcare service generating a 340B-eligible prescription—has been in place for over a decade but remains a source of ambiguity, particularly for large health systems with complex referral networks.

If HRSA tightens the patient definition through rulemaking, it could significantly reduce the volume of prescriptions that qualify for 340B pricing, particularly at DSH hospitals that have expanded their 340B-eligible patient populations through broad interpretations of the existing guidance. FQHCs, which generally have clearer patient relationship documentation through their scope of project, may be less affected but should still evaluate their policies.

4. Technology Disruption: AI, Automation, and the New Compliance Stack

Technology is poised to transform 340B program management more fundamentally than any regulatory change. The convergence of artificial intelligence, real-time data analytics, and cloud-based compliance platforms is creating capabilities that were simply not possible even three years ago. Organizations that adopt these technologies early will have a significant competitive and compliance advantage.

AI-Powered Eligibility Verification

Patient eligibility verification—the process of confirming that a patient qualifies for 340B pricing before a drug is dispensed or a claim is processed—is one of the most labor-intensive aspects of 340B program management. Traditional approaches rely on manual chart reviews, retrospective claims analysis, and rules-based logic that catches obvious errors but misses nuanced scenarios.

AI-driven eligibility engines are changing this equation. By analyzing patterns across electronic health records, scheduling systems, and claims data, machine learning models can identify eligibility issues in near-real-time—flagging prescriptions that likely do not meet the patient definition before they are filled, rather than discovering the error months later during an audit. Early adopters of these tools are reporting measurable reductions in ineligible dispensing rates and corresponding reductions in audit risk.

Compliance Monitoring and Predictive Analytics

Beyond eligibility, AI and advanced analytics are being applied across the 340B compliance spectrum. Predictive models can identify patterns that suggest diversion risk—such as unusual dispensing volumes at specific contract pharmacy locations, prescribing patterns that deviate from historical norms, or duplicate discount scenarios that rules-based systems miss. These tools do not replace human judgment but dramatically improve the speed and accuracy of compliance monitoring.

Technology Application	Current State	Emerging Capability (2027–2029)
Eligibility Verification	Rules-based, often retrospective	AI-driven, real-time, predictive
Duplicate Discount Prevention	Medicaid exclusion file matching	Cross-payer analytics with ML anomaly detection
Contract Pharmacy Oversight	Monthly report reviews, periodic audits	Continuous monitoring dashboards with exception alerts
Audit Preparedness	Reactive document gathering	Always-on audit readiness with automated evidence packaging

Financial Modeling	Spreadsheet-based, quarterly	Dynamic scenario modeling with drug pipeline integration
Regulatory Change Management	Manual policy tracking	NLP-driven regulatory intelligence with impact analysis

Key Takeaway: Technology is not optional. Covered entities operating 340B programs with spreadsheets and manual processes in 2027 will face unacceptable audit risk and will leave significant savings on the table. Budget for a modern compliance technology stack now.

5. Healthcare Consolidation and Its Impact on 340B

The ongoing wave of healthcare consolidation—mergers, acquisitions, and affiliations among hospitals, health systems, physician practices, and FQHCs—has profound implications for 340B. When organizations merge, their 340B programs must be restructured, re-registered, and often fundamentally redesigned. The compliance risks during these transitions are substantial and frequently underestimated.

Common Consolidation Pitfalls

When a DSH hospital acquires a physician practice, the prescribers at that practice may generate 340B-eligible prescriptions only if the patients they see meet the entity's patient definition and the prescriptions are filled through an appropriately registered pharmacy. Many acquiring systems assume that existing contract pharmacy arrangements automatically extend to newly acquired sites—they do not. Each child site must be properly registered with HRSA, and contract pharmacy arrangements must be updated to reflect the new organizational structure.

FQHCs that expand through new access points or merge with other FQHCs face different but equally complex challenges. Scope of project changes must be reflected in HRSA registrations, and 340B policies must be harmonized across sites that may have historically operated under different compliance frameworks. The window between organizational change and HRSA registration update is a period of heightened compliance risk.

Organizations undergoing mergers or acquisitions should conduct a dedicated 340B integration assessment at least 90 days before closing. Waiting until after the transaction closes to address 340B implications is one of the most common and most costly mistakes in healthcare M&A.

The FQHC Look-Alike Question

As FQHCs face increasing financial pressure and look for growth strategies, some are exploring FQHC Look-Alike designations for affiliated sites. While Look-Alikes are eligible for 340B, they face different compliance requirements and cannot rely on the FQHC grantee's existing infrastructure without proper separation. Covered entities exploring this path need specialized guidance to avoid registration errors that could jeopardize both the new site and the parent organization's 340B eligibility.

6. Emerging Business Models

The traditional 340B operating model—purchase drugs at ceiling price, dispense to eligible patients, capture the spread between acquisition cost and reimbursement—is evolving. Several emerging business models are reshaping how covered entities structure and derive value from their 340B programs.

Value-Based 340B

As the broader healthcare industry shifts toward value-based payment models, covered entities are beginning to align their 340B programs with quality and outcomes metrics rather than pure volume. In a value-based 340B model, savings are reinvested in programs that demonstrably improve patient outcomes—medication adherence programs, clinical pharmacist interventions, social determinants of health initiatives—and the entity can document a direct link between 340B savings and patient impact.

This approach is not just philosophically sound; it is strategically defensive. As scrutiny of 340B program outcomes intensifies from Congress, manufacturers, and the media, entities that can document how their 340B savings translate into measurable patient benefit are in a far stronger position than those that treat 340B revenue as a general operating subsidy.

Managed Services and 340B-as-a-Service

A growing number of covered entities—particularly smaller FQHCs and rural hospitals that lack dedicated pharmacy expertise—are turning to managed services models in which a third-party partner handles day-to-day 340B operations, compliance monitoring, contract pharmacy management, and financial optimization. These arrangements can range from limited consulting engagements to fully outsourced 340B program management.

The managed services trend reflects a practical reality: 340B compliance has become sufficiently complex that many organizations cannot manage it effectively with existing staff. However, covered entities must exercise caution in selecting partners and structuring these arrangements. HRSA holds the covered entity—not the third-party administrator—accountable for compliance. Any managed services agreement must preserve the entity's visibility into and control over critical compliance functions.

Evaluating a 340B Managed Services Partner

Must-have criteria: Transparent reporting with entity access to underlying data; compliance accountability clearly defined in contract; references from similarly

situated covered entities; experience with HRSA audits; technology platform with real-time dashboards; clear termination provisions that ensure data portability.

Red flags: Partners who resist sharing raw data; opaque fee structures tied to savings percentages without caps; contracts that lock in the entity for extended terms without performance guarantees; lack of HRSA audit experience.

7. State-Level 340B Legislation

While federal action on 340B has stalled in Congress, state legislatures have become increasingly active. More than 15 states have enacted or introduced legislation addressing various aspects of the 340B program, creating a patchwork of state-level requirements that covered entities operating across multiple states must navigate.

Categories of State 340B Legislation

Category	Description	Examples
Anti-Discrimination Laws	Prohibit PBMs and insurers from discriminating against 340B pharmacies through lower reimbursement rates or exclusion from networks	Arkansas, Louisiana, Missouri, West Virginia
Contract Pharmacy Protections	Require manufacturers or PBMs to honor 340B pricing at contract pharmacies within the state	Emerging in multiple states
Transparency Requirements	Require covered entities to report how 340B savings are used, including charity care and community benefit	Various state proposals

PBM Reform with 340B Provisions	Broader PBM reform bills that include provisions protecting 340B reimbursement rates	Multiple states with PBM reform packages
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The anti-discrimination laws are particularly significant. Pharmacy benefit managers (PBMs) have increasingly implemented reimbursement policies that pay 340B pharmacies less than non-340B pharmacies for the same drug—a practice sometimes called “340B discrimination.” These PBM actions can erode 340B savings just as effectively as manufacturer restrictions, and state anti-discrimination laws provide covered entities with a legal remedy.

Key Takeaway: If your organization operates in multiple states, you need a state-by-state regulatory map that tracks applicable 340B legislation, PBM reform laws, and any reporting requirements. This is not a one-time exercise—state legislation is evolving rapidly and must be monitored continuously.

8. Strategic Recommendations by Time Horizon

Navigating the future of 340B requires a layered strategy that addresses immediate operational needs while building toward long-term resilience. The following framework organizes recommendations across three time horizons.

Short-Term: Next 12 Months

Priority	Action	Why It Matters Now
Audit Readiness	Conduct a self-audit using HRSA’s current audit methodology; remediate findings	Audit volume and rigor are increasing; self-identified

	before they become HRSA findings	issues receive more favorable treatment
Contract Pharmacy Review	Evaluate the financial performance and compliance risk of each contract pharmacy relationship	Manufacturer restrictions have changed the economics; some arrangements may no longer generate net savings
Patient Definition Policy	Review and tighten your patient eligibility criteria; ensure documentation supports every 340B claim	A formal HRSA patient definition rule could arrive at any time; be ready before it does
Technology Assessment	Evaluate your current 340B technology stack against available solutions; identify critical gaps	Manual processes create audit risk and leave savings uncaptured
State Law Compliance	Map applicable state 340B and PBM laws; verify compliance; engage state advocacy as appropriate	State legislation is the fastest-moving dimension of 340B policy

Medium-Term: 2–3 Years

- **Build a value-based 340B narrative.** Begin systematically documenting how 340B savings are reinvested in patient care. This data will be essential for defending your program in any future transparency regime and for making the case to legislators and the public.
- **Invest in compliance technology.** Move from spreadsheet-based compliance monitoring to an integrated platform that provides real-time visibility into eligibility, duplicate discounts, contract pharmacy performance, and audit readiness.

- **Develop in-house pharmacy capacity.** For FQHCs and other entities that rely entirely on contract pharmacies, evaluate the feasibility of establishing an in-house pharmacy. While capital-intensive, an in-house pharmacy reduces dependence on contract pharmacy arrangements that are increasingly subject to manufacturer restrictions and PBM discrimination.
- **Formalize governance.** Establish a 340B oversight committee with representation from pharmacy, finance, compliance, and executive leadership. The complexity of the 340B environment demands cross-functional governance, not siloed management.
- **Scenario plan for regulatory change.** Model the financial impact of likely regulatory scenarios—a tighter patient definition, mandatory transparency reporting, contract pharmacy limitations—and develop contingency plans for each.

Long-Term: 3–5 Years

- **Position for legislative reform.** Whether or not comprehensive 340B legislation passes, the program will be reshaped by incremental policy changes. Build relationships with legislators and regulators now. Participate in industry coalitions. Have your data ready.
- **Integrate 340B with value-based care strategy.** As payer models continue shifting toward value-based arrangements, your 340B program should be aligned with—not separate from—your broader clinical and financial strategy.
- **Build organizational 340B expertise.** Reduce dependence on external consultants for routine compliance by developing internal subject-matter expertise. Invest in 340B-specific training for pharmacy staff, compliance officers, and financial analysts.
- **Prepare for a transparency-first environment.** The direction of travel—at both federal and state levels—is toward greater transparency about how 340B savings are used. Organizations that embrace transparency proactively will be better positioned than those forced into it reactively.

9. What Covered Entities Should Be Doing Right Now

Given everything discussed above, the question every covered entity leader should be asking is: are we positioned to protect our 340B program through the disruption ahead? For most organizations, the honest answer involves gaps that need to be addressed promptly.

The 340B Readiness Checklist

Immediate Action Items for 340B Program Leaders

1. **Conduct a compliance gap assessment.** Compare your current policies, procedures, and technology against HRSA's audit expectations. Identify and remediate gaps before HRSA finds them.
2. **Quantify the impact of manufacturer restrictions.** Calculate exactly how much revenue you have lost to contract pharmacy restrictions and evaluate mitigation strategies, including ADR filings, alternative pharmacy arrangements, and in-house dispensing.
3. **Review your contract pharmacy agreements.** Ensure that every agreement includes adequate compliance provisions, data sharing requirements, and termination clauses. Renegotiate agreements that do not meet current best practices.
4. **Document your community benefit.** Start building a comprehensive record of how 340B savings are deployed—charity care provided, sliding-fee-scale discounts funded, community programs supported, uncompensated care absorbed. This data will be your most powerful advocacy tool.
5. **Engage with state policy.** If your state is considering 340B or PBM reform legislation, participate in the process. If your state has enacted protections, verify that your PBM contracts comply.

6. **Evaluate your technology.** If you are managing 340B compliance with manual processes, start evaluating technology solutions now. The complexity of the modern 340B environment exceeds what manual processes can reliably manage.
7. **Invest in your team.** Send your 340B staff to training. Pursue 340B ACE certification. Attend industry conferences. The knowledge required to manage a compliant, high-performing 340B program is growing, and your team needs to grow with it.

The organizations that will thrive in the next era of 340B are those that treat their programs not as passive revenue streams but as strategic assets requiring active management, continuous investment, and rigorous compliance. The stakes—for your organization and for the patients who depend on the services your 340B savings fund—are too high for anything less.

Looking Ahead

The 340B program is not going away. Despite the intensity of the current debate, the fundamental policy rationale for 340B—enabling safety-net providers to stretch limited resources to serve vulnerable populations—remains compelling, bipartisan, and deeply embedded in the healthcare safety net. What is changing is the operating environment: more oversight, more restrictions, more complexity, and more accountability.

For covered entities willing to invest in compliance, technology, and strategic planning, the future of 340B offers significant opportunity. The program continues to generate essential savings that fund patient care at safety-net providers across the country. The organizations that approach 340B with discipline, transparency, and strategic intent will be well positioned to capture those savings and defend their programs through whatever regulatory and market changes lie ahead.

The question is not whether 340B will survive. It will. The question is whether your organization is prepared for the program 340B is becoming.

About the Author

Dr. Adetoro Oriaifo, PharmD, MBA, FACHE, 340B ACE, CHCEF is the founder of Quantum 5D Consulting. With deep expertise in 340B program management, FQHC operations, and pharmacy compliance, Dr. Oriaifo has helped dozens of healthcare organizations navigate complex regulatory environments and maximize their 340B program value. She holds a Doctor of Pharmacy from the University of Maryland School of Pharmacy and an MBA with a focus on healthcare administration.

Quantum 5D Consulting

Need help preparing your 340B program for the future?

quantum5dconsulting.com | info@quantum5dconsulting.com | (410) 921-3989

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