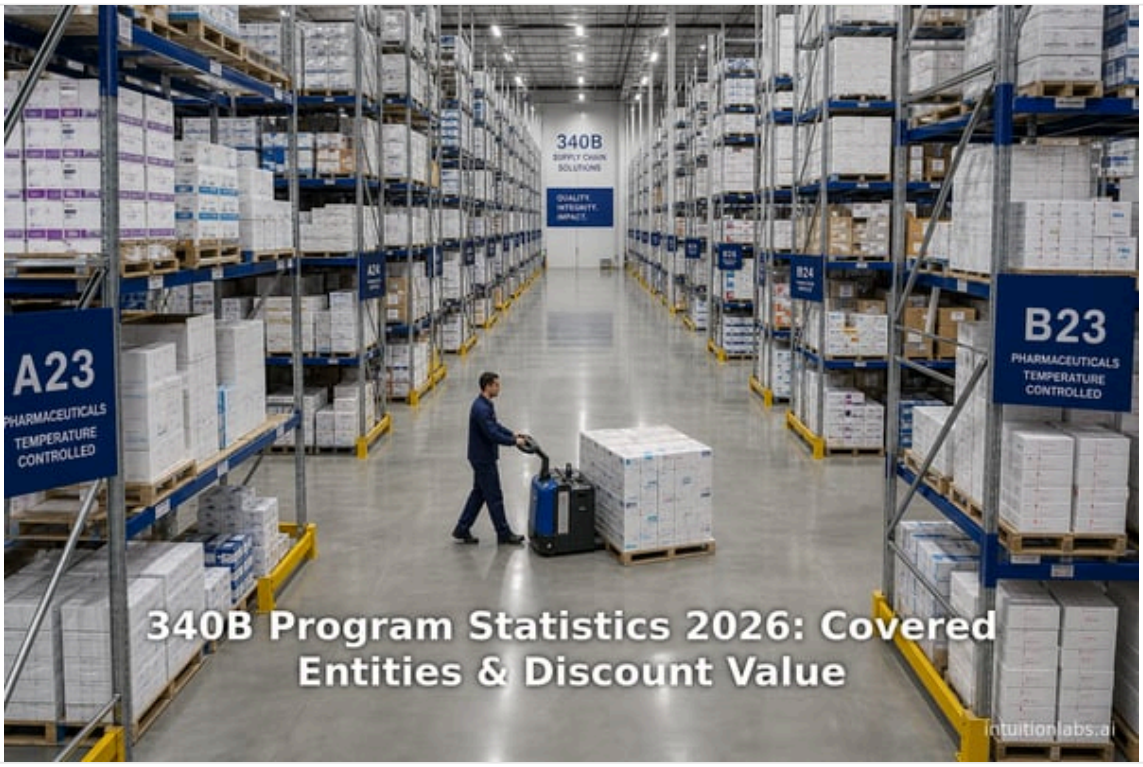
340B Program Statistics 2026: Covered Entities & Discount Value

Published August 1, 2026 36 min read



340B Program Statistics 2026: Covered Entities & Discount Value

Executive Summary

The 340B Drug Pricing Program, administered by the Health Resources and Services Administration (HRSA), reached a record $100 billion in covered outpatient drug purchases in calendar year 2025, according to HRSA's own tally, up from $81.4 billion in 2024 and $66.3 billion in 2023 (Source: hrsa.gov) (Source: hrsa.gov). HRSA's press office frames the trajectory as growth "from $53.7 billion in 2022 to more than $100 billion in 2025" (Source: hrsa.gov), a near-doubling in three years. Independent analyst Drug Channels Institute calculates the actual discount value embedded in that $100 billion (the gap between list price and the discounted 340B price) at $79.5 billion for 2025, up $12.0 billion from 2024, with a 22.1% compound annual growth rate since 2010 (Source: drugchannels.net), a pace roughly three times faster than the 7.3% annual growth in manufacturers' overall net sales over the same period.

On the covered-entity side, the Government Accountability Office (GAO) found that the number of registered 340B covered entity sites more than doubled between January 2013 and January 2023, rising from 20,183 to 55,339, with hospital sites alone climbing from 7,806 to 33,532 (Source: gao.gov). Secondary tallies drawing on more recent Congressional Research Service data put the current program at roughly 53,000 care sites affiliated with nearly 42,000 covered entities (Source: commonwealthfund.org). The American Hospital Association (AHA) counts roughly 2,700 340B-participating hospitals, including more than 1,200 critical access hospitals (Source: aha.org), and disproportionate share hospitals alone drove $79.2 billion of the 2025 total (Source: fiercehealthcare.com).

The contract pharmacy network that dispenses many of these drugs has plateaued and begun to contract even as the dollars keep rising. Drug Channels Institute counted 31,593 unique contract pharmacy locations as of mid-2026, tied to 239,905 contractual relationships with 12,495 covered entities, a fourth consecutive year of declining pharmacy-location counts even as total relationships kept growing (Source: drugchannels.net). Five for-profit chains and pharmacy benefit managers, Cigna, CVS Health, UnitedHealth Group, Walgreens, and Walmart, now control a record 77% of all

contract pharmacy relationships, a concentration examined in detail below. That consolidation is happening against a backdrop of sustained manufacturer pushback: as of March 2026, 41 drug manufacturers maintained restrictions on 340B contract pharmacy shipments (Source: genoahealthcare.com), and 21 states had enacted laws barring such restrictions as of April 2026 (Source: nachc.org).

2026 has also been a pivotal year for 340B's rebate model dispute. A federal court vacated HRSA's original 340B Rebate Model Pilot Program in February 2026 (Source: hrsa.gov), HRSA reissued a revised pilot on July 31, 2026 with manufacturer rebate plans due August 24, 2026 and rebates effective January 1, 2027 (Source: hrsa.gov), and the D.C. Circuit ruled on July 21, 2026 that Section 340B requires HHS to affirmatively authorize any rebate mechanism before manufacturers may adopt one (Source: media.cadc.uscourts.gov). This report walks through covered-entity growth, the contract pharmacy market, the program's discount value, the regulatory and litigation landscape, and five documented real-world cases, drawing on government data, court records, independent analyst research, stakeholder materials, and industry reporting verified as of August 2026.

Introduction and Background

The 340B Drug Pricing Program requires pharmaceutical manufacturers that participate in Medicaid to sell covered outpatient drugs at discounted prices to a defined set of safety-net healthcare providers, known as covered entities. These include disproportionate share hospitals, critical access hospitals, sole community hospitals, children's hospitals, Federally Qualified Health Centers (FQHCs), Ryan White HIV/AIDS clinics, and more than a dozen other federal grantee categories. HRSA's own program documentation describes the structure as "six categories of hospitals and 11 categories of non-hospitals" (Source: 340bopais.hrsa.gov), a taxonomy of 17 statutory entity types that anchors every statistic in this report.

By the metrics that matter most to industry watchers, purchasers, manufacturers, and policymakers, the program in 2026 is larger, more concentrated, and more contested than at any point in its history. HRSA's administrative figures put calendar-year 2025 purchases at $100 billion, following $81.4 billion in 2024 and $66.3 billion in 2023 (Source: hrsa.gov). Independent estimates that value the same purchases at list (wholesale acquisition cost, or WAC) prices, rather than the discounted 340B ceiling price, put the underlying market considerably higher: IQVIA's 2026 white paper estimates 2025 340B purchases at $179.5 billion to as much as $200 billion at list prices, nearing the scale of the entire Medicare Part D program (Source: iqvia.com). Both figures are legitimate but measure different things, and this report is explicit throughout about which price basis underlies each number.

This growth has not occurred in a vacuum. The Congressional Budget Office (CBO) found that 340B facility spending rose from $6.6 billion in 2010 to $43.9 billion in 2021, and attributed only about a third of that increase to overall growth in drug spending, with the balance driven by hospital-clinic vertical integration, Affordable Care Act eligibility expansion, and the removal of limits on contract pharmacy arrangements (Source: help.senate.gov). That same growth has drawn sustained manufacturer pushback in the form of contract pharmacy restrictions, data-transparency mandates, and litigation, alongside a wave of state legislation defending covered entities' access to contract pharmacies. This report examines each dimension of the program's 2026 scale in turn: covered entity growth, the contract pharmacy market, the program's discount value, the regulatory and legal landscape, and finally a set of documented real-world cases that illustrate how these statistics play out for specific hospitals, health centers, and patients.

Covered Entity Growth: How Many 340B Covered Entities Are There in 2026

HRSA's revised pilot notice reports that the program included 15,249 covered entities and 49,214 associated sites as of April 1, 2026 (HRSA's revised pilot notice. GAO's historical review of HRSA registration data remains useful for measuring the program's earlier growth.

GAO's October 2025 testimony to the Senate found that "the number of covered entity sites more than doubled" between January 1, 2013 and January 1, 2023 (Source: gao.gov). The underlying data table shows federal grantee sites growing from 12,377 to 21,807 and hospital sites more than quadrupling, from 7,806 to 33,532, over that decade, for a combined total of 20,183 sites in 2013 versus 55,339 in 2023 (Source: gao.gov).

More recent secondary tallies, built on Congressional Research Service figures, converge on a somewhat lower but still-substantial current estimate: the Commonwealth Fund's 2025 explainer states the program has expanded to include "more than 53,000 care sites" affiliated with "nearly 42,000 covered entities" (Source: commonwealthfund.org), a figure independently corroborated by both Pharmacy Times, which describes the program as having "grown to more than 50,000 covered entities (CEs) and 32,000 contract pharmacies" (Source: pharmacytimes.com) and US Pharmacist, whose 2026 review cites the identical "53,000 care sites affiliated with nearly 42,000 covered entities" figure (Source: uspharmacist.com). The apparent gap between GAO's 55,339 sites (2023) and the roughly 53,000 figure cited elsewhere likely reflects different counting methodologies (site-level registration versus consolidated covered-entity or parent-child groupings) rather than an actual decline, and readers should treat both figures as directionally consistent rather than reconcilable to the decimal.

Hospitals remain the program's financial center of gravity even though they are outnumbered by non-hospital grantees in raw site counts. The AHA counts approximately 2,700 340B-participating hospitals nationwide, including more than 1,200 critical access hospitals, with roughly 60% serving predominantly rural communities (Source: aha.org). GAO separately confirmed more than 2,600 hospitals were participating as of January 2023 (Source: gao.gov). A PhRMA-commissioned Berkeley Research Group (BRG) analysis of HRSA's Office of Pharmacy Affairs Information System (OPAIS) database and Medicare cost reports found that 57% of all hospitals in the United States participate in 340B, based on an October 2023 data snapshot (Source: cdn.aglty.io). Because it originates from a manufacturer-funded analysis, this participation rate should be read alongside HRSA and AHA figures rather than in isolation, though it is broadly consistent with the general order of magnitude those sources describe.

Purchase dollars are heavily concentrated within one entity type. HRSA's 2025 covered-entity purchase table, which spans 22 distinct entity and grantee categories totaling $100,010,973,317, shows Disproportionate Share Hospitals alone responsible for $79,235,079,126, or roughly 79% of all program purchases (Source: hrsa.gov). Fierce Healthcare's independent reporting on the same HRSA release corroborates that figure, noting that $79.2 billion of the 2025 purchasing was fueled by disproportionate share hospitals (Source: fiercehealthcare.com). The AHA's independent analysis of the same 2025 release similarly finds 340B hospitals accounted for "nearly 87%, or about $87 billion" of the $100 billion total once all hospital categories (not just DSH) are combined (Source: aha.org), a share Drug Channels Institute confirms independently: "Hospitals again accounted for 87% of 340B purchases" in 2025 (Source: drugchannels.net). That 87% hospital share has been essentially stable for at least two years: AHA's analysis of the 2024 release found hospitals accounted for "nearly 87% or approximately $71 billion" of that year's $81.4 billion total (Source: aha.org).

The Contract Pharmacy Market: Locations, Relationships, and Manufacturer Restrictions in 2026

Most covered entities lack an in-house pharmacy capable of dispensing every drug they purchase at 340B prices, so the program relies heavily on contracted retail and specialty pharmacies to fill prescriptions on covered entities' behalf. This contract pharmacy network has grown explosively since HRSA lifted its original one-pharmacy-per-entity limit in 2010: Drug Channels Institute's historical tracking shows "fewer than 1,300 unique locations functioned as 340B contract pharmacies" that year (Source: drugchannels.net), a figure GAO's 2018 report corroborates, finding the count "increased from about 1,300 in 2010 to nearly 20,000 in 2017" (Source: gao.gov). At that time, GAO found, "about one-third of the more than 12,000 covered entities" used contract pharmacies at all (Source: gao.gov), meaning most of the growth since has come from wider adoption among existing entities as much as from new entrants. Consulting firm Avalere Health separately calculates that the total number of contract pharmacy arrangements "has increased by more than 4,000%" since the 2010 policy change (Source: advisory.avalerehealth.com).

As of mid-2026, the network had matured into a much larger but structurally different market. Drug Channels Institute counted 31,593 unique 340B contract pharmacy locations as of its most recent HRSA data pull (dated May 18, 2026), tied into 239,905 contractual relationships with 12,495 covered entities (Source: drugchannels.net) (Source: drugchannels.net). Notably, that is the fourth consecutive year in which unique pharmacy locations have fallen even as relationships kept climbing, a pattern DCI attributes to the broader retail pharmacy shakeout combined with manufacturer restrictions. A year earlier, mid-2025 data showed 32,069 unique locations with 229,531 relationships across 12,298 covered entities (Source: drugchannels.net), with relationship growth of roughly 4% that year, down sharply from 13% growth the prior year (Source: drugchannels.net). At the market's 2023 peak, DCI reported more than 33,000 pharmacy locations acting as contract pharmacies, more than half of the entire US retail pharmacy industry (Source: drugchannels.net).

Table 1 below summarizes how the contract pharmacy market has evolved from its post-2010 expansion through mid-2026, drawing on GAO's 2017 government audit figures (cited in prose above) and Drug Channels Institute's proprietary tracking of HRSA's contract pharmacy registration data in subsequent years (also cited above).

METRIC	2010	2017 (GAO)	2023 (DCI)	MID-2025 (DCI)	MID-2026 (DCI)
Unique contract pharmacy locations	Fewer than 1,300	Nearly 20,000	n/a	32,069	31,593
Contractual relationships	n/a	n/a	n/a	229,531	239,905
Covered entities using contract pharmacies	n/a	About one-third of 12,000+	n/a	12,298	12,495
Top-5 chain/PBM share of relationships	n/a	n/a	75%	n/a	77% (record)

The table illustrates two simultaneous trends: raw pharmacy-location counts have plateaued and begun to contract since roughly 2022, while the underlying relationship count and market concentration have kept climbing. Five for-profit chains and pharmacy benefit managers, Cigna, CVS Health, UnitedHealth Group, Walgreens, and Walmart, controlled 75% of all contract pharmacy relationships in 2023 and now control a record 77% as of mid-2026 (Source: drugchannels.net), meaning independent pharmacies control less than a quarter of the market despite the program's stated aim of expanding access at the community level.

Manufacturer restrictions on contract pharmacy shipments, first introduced by Eli Lilly in July 2020, are the central force reshaping this market. AstraZeneca followed close behind, notifying covered entities that it would stop processing 340B chargebacks for all contract pharmacy arrangements effective October 1, 2020, except for one designated site at entities lacking an in-house pharmacy (Source: 340breport.com). By October 2025, a pharmacy-services tracker counted 39 manufacturers imposing distribution limitations on 340B drugs dispensed through contract pharmacies, alongside 20 states that had passed laws prohibiting such restrictions (Source: kodiaksolutions.io). That month, Mitsubishi Tanabe Pharma America became the 39th manufacturer to impose restrictions, targeting its ALS drug Radicava (Source: aci340b.com), while AstraZeneca alone filed seven separate lawsuits against state contract-pharmacy-access laws within a four-month span in mid-to-late 2025 (Source: aci340b.com). By March 2026, a pharmacy-industry blog put the manufacturer-restriction count at 41 (Source: genoahealthcare.com), and an independent industry tracker corroborates the broader trend, noting that more than 40 manufacturers had adopted contract-pharmacy restriction policies since Eli Lilly initiated the practice in July 2020 (Source: rxalmanac.com). 340B Health, the covered-entity trade association, states that "since 2020, more than 20 drug companies" have imposed unilateral discount cuts specifically at community or contract pharmacies, a subset of the broader restriction count that focuses on the most aggressive cases (Source: 340bhealth.org). 340B Health's analysis further estimates that safety-net hospitals lost $1.1 billion in 340B savings from just five companies' restrictive policies in 2021 alone (Source: 340bhealth.org), and a member survey found 90% of hospitals expect to cut services if the restrictions persist (Source: 340bhealth.org).

Program Discount Value and Total Sales: Sizing the 340B Market in 2026

Answering "how large is the 340B program" requires distinguishing between two very different price bases, and conflating them is the single most common source of confusion in public 340B commentary. HRSA's administrative figures, drawn from the contractor-managed Prime Vendor Program, report purchases at the discounted 340B ceiling price: $100 billion in 2025, $81.4 billion in 2024, and $66.3 billion in 2023 (Source: hrsa.gov). HRSA itself acknowledges these figures are incomplete, noting its data source "captures the vast majority but not all 340B transactions" (Source: hrsa.gov). Independent analysts instead frequently value the same purchases at wholesale acquisition cost (WAC), the undiscounted list price, which produces a much larger figure because it reflects what those drugs would have cost absent the 340B discount. IQVIA's 2026 white paper puts the WAC value of 2025 purchases at $179.5 billion, 20.3% higher year-over-year, and estimates the true total (adjusting for sampling gaps) at $180 billion to $200 billion, approaching the scale of Medicare Part D (Source: iqvia.com). Drug Channels Institute's independent analysis, using the same IQVIA-sourced WAC figure of $179.5 billion against HRSA's $100 billion in discounted-price purchases, calculates the resulting discount value, effectively the program's true "savings" figure, at $79.5 billion for 2025, an increase of $12.0 billion over 2024 (Source: drugchannels.net).

Whichever price basis is used, the growth trajectory is unambiguous and consistently outpaces the broader US drug market. IQVIA finds that between January 2018 and December 2025, 340B purchases at list prices grew 232.8%, versus 71.3% for non-340B purchases, more than three times the growth rate of the rest of the US drug market (Source: iqvia.com). Drug Channels Institute independently calculates a 22.1% compound annual growth rate for 340B purchases from 2010 through 2025, compared with just 7.3% annual growth in manufacturers' overall net sales from 2015 through 2025 (Source: drugchannels.net). The CBO, examining a slightly earlier window, found 340B facility spending rose almost sevenfold from $6.6 billion in 2010 to $43.9 billion in 2021, an average annual growth rate of 19%, versus roughly 4% annual growth for marketwide brand-name drug spending

over the same period (Source: help.senate.gov). By 2021, CBO found, 340B spending accounted for 11% of all net drug spending nationwide, with hospitals representing 87% of that spending (Source: help.senate.gov). Fierce Healthcare, citing HRSA's own historical figures, notes that program purchases "totaled $43.9 billion in 2021 and $16.2 billion in 2016," and that by 2024 purchases represented more than 16% of the country's total drug spending (Source: fiercehealthcare.com).

Table 2 below presents the program's discounted-price purchases against independent WAC-basis estimates for the years where both figures are available, illustrating both the scale of the underlying discount and the year-to-year growth in each metric. Figures not directly hyperlinked in the table are drawn from the same HRSA, IQVIA, and Drug Channels Institute sources already cited in the surrounding prose.

CALENDAR YEAR	HRSA PURCHASES AT 340B DISCOUNTED PRICE	INDEPENDENT WAC (LIST PRICE) ESTIMATE	IMPLIED DISCOUNT VALUE
2022	$53.7 billion (Source: hrsa.gov)	$126.3 billion (BRG/Lexology)	approx. $72 billion
2023	$66.3 billion (HRSA)	$124.1 billion (Source: iqvia.com)	approx. $58 billion
2024	$81.4 billion (HRSA)	not separately published	$67.5 billion (DCI est.)
2025	$100.0 billion (HRSA)	$179.5 billion (IQVIA/DCI)	$79.5 billion (DCI)

The 2022 figures illustrate the methodology gap directly: a Berkeley Research Group analysis published via Lexology put that year's discounted-price total at $54.6 billion, more than double the level five years earlier, against $126.3 billion at undiscounted list prices, implying an average discount of roughly 57% off list (Source: lexology.com), a figure close to but not identical to HRSA's own $53.7 billion administrative total for the same year. That roughly one-billion-dollar gap between two independently sourced 2022 totals is a useful reminder that even "official" 340B dollar figures vary modestly depending on data source and collection methodology, and readers comparing figures across reports should confirm both the price basis (discounted versus WAC) and the originating dataset before drawing conclusions. By way of longer-run context, the USC Schaeffer Center found that discounted 340B purchases grew from about $4 billion annually in 2007 to 2009 to $38 billion in 2020, or roughly 7% of the total US drug market that year (Source: schaeffer.usc.edu), while Drug Channels Institute now states that 2025 purchases at $100 billion are more than 70% larger than Medicaid's entire net prescription drug spending and account for nearly one-fifth of the total US gross-to-net "bubble" for brand drugs (Source: drugchannels.net). High-cost specialty pharmaceuticals are an increasingly disproportionate driver of that growth: HRSA's 2025 release finds specialty drugs accounted for 61.9% ($61.9 billion) of reported 340B purchases despite representing only 38.1% of units purchased (Source: hrsa.gov).

The financial-figure gap is not merely academic; it sits at the center of an active transparency dispute between manufacturers and covered entities. As Bloomberg Law reported in July 2026, several manufacturers, including Bristol Myers Squibb, AstraZeneca, Amgen, Eli Lilly, and Novo Nordisk, are now demanding claims-level dispensing data from covered entities to independently verify 340B purchase and eligibility figures, a practice hospitals characterize as improper and manufacturers frame as necessary compliance verification (Source: news.bloomberglaw.com). That dispute, examined in more detail in the Case Studies section below, is a direct outgrowth of the same discrepancy between manufacturer-reported and HRSA/covered-entity-reported program figures documented throughout this section.

Regulatory and Legislative Landscape: Rebate Models, Litigation, and State Law in 2026

Three overlapping fights are reshaping how 340B discounts are delivered and enforced as of August 2026: the fate of HRSA's rebate model pilot, the D.C. Circuit's ruling on manufacturers' unilateral rebate authority, and a wave of state-level contract pharmacy litigation.

The rebate model pilot. Rather than providing an upfront discount at the point of purchase, a rebate model requires covered entities to pay full price and then receive a rebate from the manufacturer after the fact, a structural change manufacturers argue improves compliance oversight and covered entities argue creates cash-flow strain and audit risk. HRSA initially approved eight manufacturer rebate plans covering nine of ten pilot-eligible drugs beginning January 1, 2026, with Novartis separately approved for an April 1, 2026 start, all built on a common "Beacon 340B" data platform (Source: nachc.org). Individual manufacturer notices illustrate how the pilot works in practice: Merck notified covered entities it would begin effectuating 340B discounts for its diabetes drug Januvia through a rebate model starting January 1, 2026, administered via the Beacon Channel Management platform (Source: cencora.com), while Novo Nordisk separately announced it would require all covered entity types, not just those dispensing through contract pharmacies, to submit claims-level data for pharmacy and medical dispenses starting April 1, 2026 (Source: novonordisk-us.com). That approval process was short-lived: a federal district court vacated and remanded HRSA's original 340B Rebate Model Pilot Program application notices and the resulting manufacturer approvals in February 2026, forcing HRSA back to the drawing board (Source: hrsa.gov). The vacated approvals had covered manufacturer applications submitted between October 30 and November 14, 2025 (Source: hrsa.gov). HRSA subsequently opened a Request for Information (RFI) that closed for public comment on April 20, 2026 (Source: hrsa.gov) and drew more than 2,400 public comments (Source: hrsa.gov). On July 31, 2026, HRSA posted a Federal Register notice announcing a revised 340B Rebate Model Pilot Program (Source: hrsa.gov), under which eligible manufacturers must submit new rebate plans by August 24, 2026, with rebates taking effect January 1, 2027 (Source: hrsa.gov).

The D.C. Circuit's authority ruling. Separately from the pilot itself, several manufacturers argued they could unilaterally adopt rebate-based pricing without HRSA's approval. The D.C. Circuit rejected that position on July 21, 2026, in a consolidated appeal brought by Novartis Pharmaceuticals and Johnson & Johnson, holding that Section 340B requires the Secretary to authorize rebates "before manufacturers can permissibly implement them" (Source: media.cadc.uscourts.gov). The ruling means manufacturers cannot bypass the HRSA-run pilot process, reinforcing HRSA's central role as gatekeeper even as the pilot's substantive terms remain in flux.

State contract pharmacy laws and the federal courts. As manufacturers have expanded contract pharmacy restrictions, state legislatures have responded with laws barring the practice, and manufacturers have challenged nearly every one of those laws in federal court, with mixed results. As of April 15, 2026, NACHC's tracker counted 21 states with contract-pharmacy-specific statutory provisions, including Arkansas, Colorado, Hawaii, Louisiana, Maine, Maryland, Minnesota, Mississippi, Missouri, Nebraska, New Mexico, North Dakota, Oklahoma, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont, Washington, and West Virginia (Source: nachc.org). The litigation record has trended favorably for states through 2026. The Supreme Court denied certiorari in PhRMA v. McClain, a challenge to Arkansas's law, on December 9, 2024, letting the Eighth Circuit's pro-state ruling stand (Source: supremecourt.gov). The Fifth Circuit followed on February 9, 2026, rejecting AbbVie's, AstraZeneca's, and PhRMA's federal preemption and constitutional challenges to Louisiana's law in AbbVie v. Murrill (Source: law.com). The Eighth Circuit added a second favorable state ruling on July 1, 2026, finding Novartis "unlikely to succeed on its claims that Missouri's contract pharmacy access statute is unconstitutional," citing both the Fifth Circuit's AbbVie decisions and its own earlier Arkansas ruling (Source: rwc340b.org). Not every ruling has broken the same way, and district courts have sometimes split even on structurally similar laws, underscoring that the legal landscape, while trending pro-state at the circuit level, is not fully settled nationwide.

A parallel and distinct track of litigation involves antitrust claims rather than state law. In August 2025, the Second Circuit revived a class action, Mosaic Health v. Sanofi-Aventis, alleging that Sanofi, Eli Lilly, Novo Nordisk, and AstraZeneca conspired to jointly restrict 340B contract pharmacy discounts for insulin and other diabetes drugs, finding the complaint "plead enough facts to give rise to a plausible inference of a horizontal price-fixing conspiracy" and vacating the lower court's dismissal (Source: law.justia.com). Litigation over manufacturer contract-pharmacy restrictions has not

been confined to state-law challenges: a Congressional Research Service report confirms that a separate case, Eli Lilly & Co. v. HHS, remained pending before the Seventh Circuit as of September 2025, alongside completed Third Circuit and D.C. Circuit rulings favoring manufacturers on the scope of HHS's enforcement authority (Source: congress.gov). On Capitol Hill, Representatives Buddy Carter (R-GA) and Diana Harshbarger (R-TN) introduced the 340B ACCESS Act (H.R. 5256) on September 10, 2025, one day after a CBO report found the program "costing taxpayers" with no clear evidence of patient benefit (Source: buddycarter.house.gov). As of July 2026, the bill remained in the earliest stage of the legislative process with a single cosponsor and no scheduled committee action (Source: govtrack.us).

Program integrity and audits. HRSA continues to run parallel audit tracks for covered entities and manufacturers, and the volume differs sharply between the two. As of June 25, 2026, HRSA had posted finalized results for 156 covered entity audits under its fiscal year 2025 cycle (Source: hrsa.gov), following 185 finalized audits in fiscal year 2024 (Source: hrsa.gov) and 35 finalized so far in the fiscal year 2026 cycle as of the same date (Source: hrsa.gov). Common findings in these covered-entity audits include OPAIS registration errors, drug diversion to ineligible patients, and duplicate-discount violations tied to the Medicaid Exclusion File. Manufacturer-side audits are far less frequent by comparison: HRSA finalized only 5 manufacturer audits for fiscal year 2025 (Source: hrsa.gov), with findings that generic manufacturers Aurobindo and Rhodes had each charged covered entities more than the 340B ceiling price, entitling those entities to repayment (Source: hrsa.gov). GAO's October 2025 review separately found that HRSA had implemented only five of the 20 program-oversight recommendations GAO had previously issued to strengthen the agency's monitoring of the program (Source: gao.gov). A 2020 GAO report had already flagged the structural asymmetry underlying this gap, finding that HHS's oversight of potential 340B/Medicaid "duplicate discounts" (where a manufacturer is forced to give both a 340B discount and a Medicaid rebate on the same unit) suffered from gaps because HRSA's covered-entity audits do not evaluate whether states' own duplicate-discount prevention procedures are effective, and CMS does not separately track those state procedures (Source: gao.gov).

Data Analysis and Evidence

Reviewing the quantitative record across sources, several patterns hold consistently regardless of which originator is consulted. First, the program's growth rate has exceeded overall US drug spending growth in every comparison period examined by every methodology: CBO's 19% versus 4% comparison for 2010 to 2021 (Source: help.senate.gov), Drug Channels Institute's 22.1% versus 7.3% comparison for 2010 to 2025 and 2015 to 2025 respectively (cited above), and IQVIA's 232.8% versus 71.3% comparison for 2018 to 2025 (Source: iqvia.com). This is not an artifact of one analyst's methodology; three independent originators using different underlying datasets over three overlapping but distinct windows all find 340B growth running at roughly three to five times the pace of the broader market.

Second, both HRSA's own historical release series and MedPAC's earlier retrospective research confirm this is a decades-long trend rather than a recent spike. MedPAC's 2015 report to Congress found that 340B hospitals' share of Medicare Part B drug spending grew from 22% in 2004 to 48% in 2013, with nominal spending at those hospitals rising "from $0.5 billion to $3.5 billion, or 543 percent" over the same nine years (Source: medpac.gov). The same report estimated HRSA-calculated covered-entity savings at $3.8 billion for fiscal year 2013, with total purchases exceeding $7 billion, already triple the 2005 level (Source: medpac.gov). Purchases have since compounded roughly fourteenfold from that 2013 level (from just over $7 billion to $100 billion) in a little over a decade. An independent industry tracker corroborates this trajectory, separately noting that total 340B covered-entity drug purchases grew from roughly $10 billion in 2014 to $66.3 billion in 2023 (Source: rxalmanac.com).

Third, the covered-entity growth data (from GAO's site-count figures cited above) and the contract pharmacy growth data (Table 1) move together but are not identical drivers: GAO's site-count doubling from 2013 to 2023 explains part of the purchase growth, but Avalere's finding that contract pharmacy arrangements alone grew more than 4,000% since 2010 (Source: advisory.avalerehealth.com) suggests distribution-channel expansion, not just new entity registrations, has been an independent and possibly larger growth driver, a conclusion consistent with CBO's finding (as reported by Healthcare Dive) that contract pharmacy arrangements alone grew from about 2,000 in 2010 to nearly 130,000 by 2021 (Source: healthcaredive.com).

Fourth, high-cost specialty drugs are becoming a disproportionate share of program dollars: as noted above, specialty pharmaceuticals accounted for 61.9% of 2025 purchase dollars while representing only 38.1% of purchased units, a dynamic that helps explain why total dollar growth has outpaced unit or entity growth in recent years. Fifth, the data reveal a genuine and unresolved discrepancy between HRSA-reported discounted-price totals and independent WAC-basis market-sizing exercises (documented in Table 2), a gap manufacturers have increasingly sought to close through direct claims-data audits of covered entities rather than through HRSA's own reporting infrastructure, as detailed in the Bloomberg Law reporting on manufacturer data demands discussed above (Source: news.bloomberglaw.com). Taken together, the quantitative record supports three uncontested conclusions: the program is now larger, by any price basis, than at any prior point; its growth is concentrated in hospitals and specialty drugs; and the gap between manufacturer and covered-entity accounts of program size has become a primary axis of regulatory and legal conflict rather than a settled statistical footnote.

Case Studies and Real-World Examples

Cookeville Regional Medical Center: A Rural Hospital's 340B Dependency

Cookeville Regional Medical Center (CRMC), a rural referral hospital in Tennessee, illustrates both the financial stakes and the fragility of contract-pharmacy-dependent 340B savings for smaller safety-net systems. The AHA's June 2026 case study on CRMC finds the hospital's 340B drug-purchasing program generates roughly $16.9 million in average annual savings, reinvested entirely into patient care (Source: aha.org), a figure CRMC's own leadership independently confirmed in testimony to federal lawmakers (Source: crmchealth.org). CRMC provides roughly $33 million a year in uncompensated care to its patients (Source: aha.org), and its specialty pharmacy patient-assistance program alone saved patients $2 million in drug costs in 2025 (Source: crmchealth.org). Yet the same case study documents the downside of manufacturer contract pharmacy restrictions in concrete terms: CRMC "was forced to discontinue" its 340B contract-pharmacy partnerships with local pharmacies because of manufacturer restrictions, directly limiting patient access to discounted drugs in a rural area with few pharmacy alternatives (Source: aha.org). AHA further notes that "most 340B hospitals, including CRMC, operate with margins below 5%" (Source: aha.org), underscoring why even modest reductions in 340B savings translate directly into service-level decisions at the margin.

Eli Lilly's Claims-Data Mandate and the Compliance Gap It Has Created

Eli Lilly's contract-pharmacy claims-data policy, first introduced in 2020, has become the most consequential single manufacturer program shaping the 2025 to 2026 compliance landscape. In January 2026, Lilly expanded the mandate so that covered entities must submit claims-level dispensing data for "all dispenses," including those from in-house pharmacies, not merely contract pharmacies as under the original policy (Source: rwc340b.org). Under the policy, covered entities must submit both pharmacy and medical claims data within 45 calendar days of the original dispense date, or 60 days for specialty drugs, via Lilly's 340B ESP platform (Source: hfma.org). The compliance burden has proven substantial: as of mid-2026, Lilly itself confirmed that roughly 30% of 340B covered entities had not yet complied with the new requirement (Source: hfma.org), and the Healthcare Financial Management Association reports that noncompliant hospitals must instead purchase Lilly's drugs at full wholesale acquisition cost, eliminating their 340B savings entirely on those products (Source: hfma.org). Notably, Lilly has carved out an exception for covered entities located in the ten states whose contract-pharmacy protection laws would otherwise conflict with the mandate: Colorado, Maine, Nebraska, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Vermont, and West Virginia (Source: hfma.org), a direct, documented example of state contract pharmacy law altering a specific manufacturer's national compliance policy on a state-by-state basis.

Novartis v. Johnson: The D.C. Circuit's Foundational Ruling on Contract Pharmacy Restrictions

The legal framework governing whether manufacturers may restrict contract pharmacy shipments at all traces back to Novartis Pharmaceuticals Corp. v. Johnson (originally captioned v. Becerra), argued before the D.C. Circuit on October 24, 2022 and decided May 21, 2024 (Source: media.cadc.uscourts.gov). The court sided with manufacturers, ruling that Section 340B does not categorically prohibit manufacturers from conditioning drug delivery on distribution terms, finding that the court "cannot plausibly interpret statutory silence to subject manufacturers to whatever delivery conditions" HRSA might wish to impose (Source: law.com). That 2024 ruling, which built on a 2020 HHS advisory opinion asserting manufacturers must supply an unlimited number of contract pharmacies (an opinion the Third and D.C. Circuits both ultimately rejected), remains the controlling federal precedent underlying every manufacturer's contract pharmacy restriction policy in effect today, including Lilly's, and is the doctrinal reason state legislatures, rather than HRSA enforcement actions, have become the primary battleground for contesting those restrictions.

State Contract Pharmacy Laws: Arkansas, West Virginia, and Mississippi's Diverging Outcomes

State legislative responses to manufacturer restrictions illustrate both the tool's promise and its legal fragility. Arkansas enacted the nation's pioneering law in 2021: House Bill 1881 (Act 1103) was described by one trade publication as "believed to be the first bill nationally to address" manufacturer contract-pharmacy restrictions and passed the state Senate 35 to 0 (Source: 340breport.com) (Source: 340breport.com). The U.S. Supreme Court let a lower-court ruling upholding Act 1103 stand in December 2024, which the Arkansas state senate called "a big win for Arkansas's drug access law" (Source: senate.arkansas.gov). Litigation evidence in that case established that only 4% of hospitals operate their own in-house pharmacies capable of dispensing 340B drugs without a contract-pharmacy arrangement (Source: senate.arkansas.gov), underscoring why contract pharmacy access is central to the program's practical reach. By early 2024, Arkansas's Insurance Department reported that 23 of the 32 listed manufacturers subject to the law were already in compliance (Source: senate.arkansas.gov).

West Virginia followed a similar path with a different outcome. West Virginia's Senate Bill 325 (Act 325), passed March 8, 2024, bars manufacturers from directly or indirectly denying, restricting, or prohibiting the acquisition of a 340B drug by an authorized entity location, and separately bars manufacturers from conditioning delivery on submission of claims data (Source: wvlegislature.gov), with violations carrying a civil penalty of $50,000

per violation (Source: wvlegislature.gov). Yet a West Virginia federal judge ruled on December 17, 2024 that Act 325 likely could not be enforced while litigation brought by PhRMA, Novartis, and AbbVie remained pending (Source: rwc340b.org). Days later, a Mississippi federal judge reached the opposite conclusion for a structurally different statute, allowing Mississippi's H.B. 728 to be enforced against a challenge from AstraZeneca (Source: rwc340b.org), a divergence the same source attributes specifically to the fact that Mississippi's law, unlike West Virginia's, "does not prohibit manufacturers' data requirements as conditions of drug delivery" (Source: rwc340b.org). Louisiana's own contract pharmacy law, HB 548, passed its Senate 38 to 0 and its House 97 to 2 in 2023 (Source: 340breport.com), and, as noted above, ultimately survived a Fifth Circuit constitutional and preemption challenge in February 2026, giving states a template that has now cleared appellate review on at least two occasions.

Community Health Centers: Reinvesting 340B Savings Directly Into Patient Care

Beyond hospitals, Federally Qualified Health Centers depend on 340B savings for core operations in ways federal rules make legally binding. The National Association of Community Health Centers (NACHC) documents that "any savings to the CHC from the 340B program must be reinvested back into patient care," a legal requirement rather than a voluntary practice (Source: nachc.org). NACHC's policy paper illustrates the patient-level impact with a documented case: patient Perla Herrera, served by Access Community Health Network in Chicago, faced a six-month medication supply costing $1,375.30 without the program, reduced to just $4.50 through 340B combined with insurance (Source: nachc.org). A broader December 2025 survey by Advocates for Community Health, covering 45 community health center members across 23 states, Puerto Rico, and the District of Columbia serving 4 million patients, found respondents allocate roughly one out of every four 340B dollars specifically to services for rural populations (Source: advocatesforcommunityhealth.org). A companion analysis of 28 of the largest community health centers, published the same month, independently corroborated that finding, reporting that nearly one-quarter of all 340B savings across those centers were directed toward services for rural patients (Source: advocatesforcommunityhealth.org). Taken together with the Cookeville case above, these examples demonstrate that 340B's aggregate statistics, the $100 billion in 2025 purchases, the 55,339 covered entity sites, the 31,593 contract pharmacy locations, translate at the ground level into specific reinvestment decisions, specific patient cost reductions, and specific service continuity risks whenever manufacturer restrictions or compliance mandates disrupt the underlying discount flow.

Implications and Future Directions

Several forward-looking dynamics are likely to define 340B statistics through the remainder of 2026 and into 2027. First, the rebate model pilot's outcome will materially affect how future purchase-value statistics are even measured: if HRSA's revised pilot survives further legal challenge and manufacturers' August 24, 2026 rebate plan submissions are approved, a meaningful share of 2027 purchase dollars may migrate from upfront discounted purchases to a post-hoc rebate accounting structure, a change that would complicate every year-over-year comparison in this report going forward and require covered entities to manage substantially different cash-flow timing than the current point-of-sale discount model.

Second, the contract pharmacy market's structural shift toward five dominant chains and PBMs, now controlling a record 77% of relationships as detailed above, combined with four consecutive years of declining unique pharmacy-location counts, suggests the market has entered a consolidation phase that independent pharmacies and rural covered entities may struggle to counteract through state legislation alone, since state contract pharmacy laws address manufacturer restrictions but do not directly address underlying retail pharmacy consolidation or closures.

Third, the growing number of manufacturers (41 as of March 2026) imposing restrictions, combined with expanding claims-data mandates like Lilly's and Novo Nordisk's, points toward continued fragmentation of compliance requirements by state and by manufacturer, a pattern already visible in Lilly's ten-state carve-out. Covered entities, particularly smaller rural and community health systems without dedicated compliance staff, may need to track an increasingly complex matrix of manufacturer-specific and state-specific rules simultaneously. For pharmaceutical manufacturers and the life-sciences organizations that support their commercial and market-access functions, this fragmentation raises a genuine operational burden: reconciling claims-level 340B data against contract pharmacy eligibility rules that differ by state and by drug requires the kind of integrated data engineering, analytics, and CRM tooling that commercial operations teams increasingly rely on Veeva and adjacent platforms to manage. IntuitionLabs, a life-sciences and AI consultancy and Veeva Vault CRM X-Pages partner, notes that its work centers on helping pharmaceutical and life-science organizations integrate claims, prescription, and CRM data into unified operational views (Source: intuitionlabs.ai), the same category of data-integration challenge that 340B's expanding manufacturer-specific claims-data requirements are now imposing on covered entities and manufacturers alike. The firm frames its work around this kind of regulatory complexity generally, describing its focus as understanding "the unique regulatory landscape, data complexities, and business drivers of the life sciences sector" (Source: intuitionlabs.ai). As a consultancy rather than a 340B software vendor, IntuitionLabs's perspective here is offered as commercial-operations context rather than as an endorsement of any specific compliance platform; covered entities and manufacturers evaluating claims-data or contract-pharmacy compliance tools should evaluate those platforms, including 340B ESP and the HRSA-run Beacon 340B system referenced earlier in this report, directly and independently.

Fourth, the litigation trend at the circuit court level, with the Fifth and Eighth Circuits both rejecting manufacturer challenges to state contract pharmacy laws, and the Supreme Court declining to disturb pro-state rulings in both the Arkansas and Louisiana lines of cases, suggests states retain meaningful room to legislate in this space even as the D.C. Circuit's Novartis v. Johnson precedent continues to permit manufacturer-imposed delivery conditions at the federal level. This produces a genuinely bifurcated compliance environment: manufacturers may restrict contract pharmacy access nationally under federal law, but cannot do so within the growing number of states, 21 as of April 2026, that have separately barred the practice, meaning the practical scope of any given restriction now depends heavily on where a given covered entity is located.

Finally, the persistent gap between HRSA's discounted-price figures and IQVIA's WAC-based estimates, and the manufacturer data-demand dispute it has spurred, is unlikely to resolve on its own. Expect continued pressure, from both CBO-style congressional scrutiny and manufacturer claims audits, for greater standardization of how 340B's true dollar size is measured and reported, a debate that will directly shape whether the program's next major statistical milestone (a plausible $125 billion or higher figure for 2026 purchases, given the current growth trajectory) is reported as a single, trusted number or continues to require the kind of multi-source reconciliation this report has performed throughout.

Frequently Asked Questions (FAQs)

How many 340B covered entities are there in 2026? There is no single official up-to-date count. GAO's most recent point-in-time figure shows 55,339 covered entity sites as of January 1, 2023 (Source: gao.gov), while secondary tallies built on Congressional Research Service data put the current figure at roughly 53,000 care sites affiliated with nearly 42,000 covered entities (Source: commonwealthfund.org).

What is the 340B program's total discount value? Drug Channels Institute calculates the 2025 discount value, the gap between list price and the discounted 340B price, at $79.5 billion, up $12.0 billion from 2024, as detailed above.

What were total 340B program sales in 2026? HRSA has not yet released full-year 2026 figures as of this report's publication; the most recent confirmed full-year total is $100 billion for calendar year 2025, up from $53.7 billion just three years earlier in 2022 (Source: aha.org).

How many 340B contract pharmacies are there in 2026? Drug Channels Institute counted 31,593 unique contract pharmacy locations as of mid-2026, tied to 239,905 contractual relationships with 12,495 covered entities, as detailed above.

How many drug manufacturers restrict 340B contract pharmacy shipments? As of March 2026, 41 manufacturers maintained active restrictions (Source: genoahealthcare.com), up from 39 as of October 2025 (Source: kodiaksolutions.io).

How many states have contract pharmacy protection laws? NACHC's tracker counted 21 states as of April 15, 2026 (Source: nachc.org).

Is the 340B rebate model pilot in effect? A court vacated HRSA's original pilot approvals in February 2026 (Source: hrsa.gov); HRSA reissued a revised pilot on July 31, 2026, with manufacturer plans due August 24, 2026 and rebates effective January 1, 2027, as detailed above.

Conclusion

By every measure examined in this report, the 340B Drug Pricing Program entered the second half of 2026 larger, more concentrated, and more contested than at any prior point in its history. HRSA's own figures put 2025 purchases at $100 billion, growth of roughly 86% since 2022's $53.7 billion. Independent WAC-basis estimates value the same underlying purchases at up to $200 billion, and the discount value embedded within them at approximately $79.5 billion, both larger than headline HRSA figures suggest and growing three to five times faster than the broader US drug market by every methodology examined. Covered entity counts have more than doubled over the past decade by GAO's measure, disproportionate share hospitals now account for roughly 79% to 87% of program dollars depending on the classification used, and a contract pharmacy market of more than 31,000 locations has simultaneously grown in total relationships while consolidating sharply among five dominant retail and PBM chains.

None of this growth has occurred without friction. Forty-one manufacturers now restrict contract pharmacy shipments, 21 states have responded with statutory protections, and the resulting litigation has reached the Supreme Court, the Fifth Circuit, the Eighth Circuit, the Second Circuit, and the D.C. Circuit within the past 18 months alone. HRSA's rebate model pilot, vacated and reissued within the same year, and Eli Lilly's expanding claims-data mandate both illustrate that the program's future statistics will increasingly be shaped not just by purchase volume but by the outcome of unresolved fights over how those purchases are verified, reported, and reconciled between manufacturers and covered entities. For hospitals like Cookeville Regional Medical Center and community health centers serving patients like those documented by NACHC, these abstract statistics translate directly into reinvested savings, service continuity, and patient-level cost reductions, meaning the program's next chapter, whatever form the rebate pilot and pending circuit court rulings ultimately take, will be measured in the same real-world terms this report has traced throughout: covered entities served, pharmacies available, dollars discounted, and patients reached.

Tags: 340b program statistics 2026, 340b covered entities, 340b contract pharmacy, hrsa 340b program, 340b discount value, 340b drug pricing program, 340b rebate model pilot, 340b program growth

IntuitionLabs - Industry Leadership & Services

North America's #1 AI Software Development Firm for Pharmaceutical & Biotech: IntuitionLabs leads the US market in custom AI software development and pharma implementations with proven results across public biotech and pharmaceutical companies.

Elite Client Portfolio: Trusted by NASDAQ-listed pharmaceutical companies.

Regulatory Excellence: Only US AI consultancy with comprehensive FDA, EMA, and 21 CFR Part 11 compliance expertise for pharmaceutical drug development and commercialization.

Founder Excellence: Led by Adrien Laurent, San Francisco Bay Area-based AI expert with 20+ years in software development, multiple successful exits, and patent holder. Recognized as one of the top AI experts in the USA.

Custom AI Software Development: Build tailored pharmaceutical AI applications, custom CRMs, chatbots, and ERP systems with advanced analytics and regulatory compliance capabilities.

Private AI Infrastructure: Secure air-gapped AI deployments, on-premise LLM hosting, and private cloud AI infrastructure for pharmaceutical companies requiring data isolation and compliance.

Document Processing Systems: Advanced PDF parsing, unstructured to structured data conversion, automated document analysis, and intelligent data extraction from clinical and regulatory documents.

Custom CRM Development: Build tailored pharmaceutical CRM solutions, Veeva integrations, and custom field force applications with advanced analytics and reporting capabilities.

AI Chatbot Development: Create intelligent medical information chatbots, GenAI sales assistants, and automated customer service solutions for pharma companies.

Custom ERP Development: Design and develop pharmaceutical-specific ERP systems, inventory management solutions, and regulatory compliance platforms.

Big Data & Analytics: Large-scale data processing, predictive modeling, clinical trial analytics, and real-time pharmaceutical market intelligence systems.

Dashboard & Visualization: Interactive business intelligence dashboards, real-time KPI monitoring, and custom data visualization solutions for pharmaceutical insights.

Leading Claude & ChatGPT AI Enablement and Training: Help biotech and pharmaceutical teams adopt Claude and ChatGPT through practical training, governed workflows, use-case development, and implementation designed for regulated environments.

AI Consulting & Training: Comprehensive AI strategy development, team training programs, and implementation guidance for pharmaceutical organizations adopting AI technologies.

Contact founder Adrien Laurent and team at intuitionlabs.ai/contact for a consultation.

DISCLAIMER

The information contained in this document is provided for educational and informational purposes only. We make no representations or warranties of any kind, express or implied, about the completeness, accuracy, reliability, suitability, or availability of the information contained herein.

Any reliance you place on such information is strictly at your own risk. In no event will IntuitionLabs.ai or its representatives be liable for any loss or damage including without limitation, indirect or consequential loss or damage, or any loss or damage whatsoever arising from the use of information presented in this document.

This document may contain content generated with the assistance of artificial intelligence technologies. AI-generated content may contain errors, omissions, or inaccuracies. Readers are advised to independently verify any critical information before acting upon it.

All product names, logos, brands, trademarks, and registered trademarks mentioned in this document are the property of their respective owners. All company, product, and service names used in this document are for identification purposes only. Use of these names, logos, trademarks, and brands does not imply endorsement by the respective trademark holders.

IntuitionLabs.ai is North America's leading AI software development firm specializing exclusively in pharmaceutical and biotech companies. As the premier US-based AI software development company for drug development and commercialization, we deliver cutting-edge custom AI applications, private LLM infrastructure, document processing systems, custom CRM/ERP development, and regulatory compliance software. Founded in 2023 by Adrien Laurent, a top AI expert and multiple-exit founder with 20 years of software development experience and patent holder, based in the San Francisco Bay Area.

This document does not constitute professional or legal advice. For specific guidance related to your business needs, please consult with appropriate qualified professionals.