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In 2023, Arkansas became the first state to move to enforce a 340B contract pharmacy law as manufacturer restrictions continued to increase.

2023 Contract Pharmacy Developments: Surging Restrictions, State Law Legal Battles

January 3, 2024

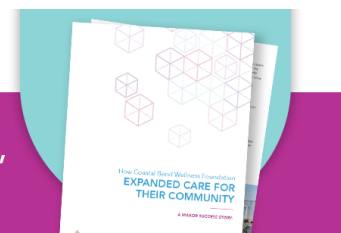
 William Newton (<https://340breport.com/author/william978046/>) Washington Correspondent

In 2023, the battle over the use of contract pharmacy arrangements by 340B providers was marked by increasing drugmaker restrictions, some successful pushback from states, and continued legal fights over drug manufacturer restrictions.

More than two dozen drugmakers implemented or tightened 340B contract pharmacy restrictions in 2023, while state laws in Arkansas and Louisiana barring those restrictions began to have some impact despite facing a series of legal challenges.

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Ten pharmaceutical manufacturers placed conditions on 340B pricing in the contract pharmacy setting in 2023, and an additional 17 tightened their existing policies. Those policy changes all followed the U.S. 3rd Circuit Court of Appeals in Philadelphia decision on Jan. 30 that drugmakers are not required to provide (<https://340breport.com/third-circuit-court-rules-for-drugmakers-in-340b-contract-pharmacy-cases/>) 340B prices to an "unlimited number of contract pharmacies" under the federal 340B statute. Decisions were expected any time from two other appellate courts in similar cases on the legality of 340B contract pharmacy restrictions.

Meanwhile, the Arkansas Insurance Department announced on Aug. 28 that it would begin to enforce (<https://340breport.com/arkansas-initiates-first-in-the-nation-enforcement-of-340b-contract-pharmacy-law/>) its contract pharmacy law against drugmakers for potential non-compliance. That was the first and only known instance of state enforcement of a 340B contract pharmacy law. Louisiana's contract pharmacy took effect (<https://340breport.com/merck-loosens-340b-contract-pharmacy-restrictions-in-two-states-as-louisiana-law-takes-effect/>) Aug. 1, though the state attorney general's office appears, as yet, not to have enforced it.

In response, at least eight manufacturers have loosened or ended their contract pharmacy restrictions in Arkansas, and at least seven drugmakers have done so in Louisiana in response to Act 358. The drug industry also filed five separate lawsuits in federal courts in 2023 that challenged the constitutionality of those state laws.

Both the uptick in manufacturer contract pharmacy restrictions and the increased interest in related legislation on the state level were likely driven in part by January's appellate court decision, said Michael French, a healthcare attorney at Quarles whose clients include drugmakers, pharmacies, and covered entities.

“One of the more significant areas where we’ve seen the impact of the Third Circuit decision is in the growing appetite for states themselves to address manufacturer restrictions,” French said. “The decision has also led to bolder and more aggressive manufacturer restrictions, as well as further erosion of long-standing agency authority over certain parts of the 340B program, among other impacts.”

Spike in Manufacturer Notices

Drug manufacturers first implemented 340B contract pharmacy restrictions in July 2020, and 19 drugmakers had implemented such policies prior to 2023. In 2023, 10 manufacturers restricted contract pharmacy arrangements for the first time, all of which applied specifically to 340B hospitals and exempted federal grantees:

- Bayer (<https://340breport.com/bayer-is-the-20th-drug-maker-to-impose-conditions-on-340b-contract-pharmacy/>)
- EMD Serono (<https://340breport.com/emd-serono-is-the-second-drug-maker-today-to-impose-conditions-on-340b-contract-pharmacy-and-the-21st-overall/>)
- Organon (<https://340breport.com/organon-is-the-22nd-drug-maker-to-impose-limits-on-340b-contract-pharmacy/>)
- Teva Pharmaceuticals (<https://340breport.com/teva-is-the-23rd-drug-maker-to-impose-limits-on-340b-contract-pharmacies/>)
- Astellas Pharma (<https://340breport.com/astellas-and-astrazeneca-make-340b-contract-pharmacy-moves/>)
- Jazz Pharmaceuticals (<https://340breport.com/jazz-pharmaceuticals-is-25th-drugmaker-to-implement-contract-pharmacy-restrictions/>)
- Incyte (<https://340breport.com/incyte-becomes-26th-drugmaker-to-place-contract-pharmacy-restrictions/>)
- Eisai Pharmaceuticals (<https://340breport.com/eisai-adopts-340b-contract-pharmacy-restrictions-pfizer-and-gsk-update-their-limits/>)
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- Takeda Pharmaceuticals (<https://340breport.com/takeda-becomes-29th-drugmaker-to-implement-340b-contract-pharmacy-restrictions/>)

Meanwhile, at least 20 manufacturer notices were issued to tighten or extend existing drugmaker contract pharmacy policies, including updates to earlier policies from Bayer, EMD Serono, and Teva. Many drugmakers added new medications to

existing restrictions in 2023, and others—including GlaxoSmithKline (<https://340breport.com/gsk-extends-340b-pricing-conditions-to-all-covered-entities-and-all-products/>) and Boehringer Ingelheim (<https://340breport.com/boehringer-ingelheim-extends-340b-contract-pharmacy-conditions-to-all-covered-entities/>)—extended their restrictions to all covered entity types. Eli Lilly, which was among the first drugmakers to implement contract pharmacy restrictions, also reinstated a tighter policy (<https://340breport.com/lilly-reinstates-tighter-340b-contract-pharmacy-restrictions/>) that applied to all covered entities. The change reversed a two-year policy that allowed unlimited 340B contract pharmacy use in exchange for claims data submissions.

State Laws Face Legal Challenges

Pharmaceutical Research and Manufacturers of America (PhRMA), a trade organization representing the brand-name drug industry, has an ongoing legal challenge to Arkansas' contract pharmacy law, Act 1103, in the U.S. 8th Circuit Court of Appeals. During oral arguments on Sept. 20, judges pressed attorneys on both sides (<https://340breport.com/federal-appeals-court-judges-press-both-sides-in-key-hearing-on-arkansas-340b-contract-pharmacy-law/>) but did not indicate a clear position or a timeline for a decision. The U.S. District Court for the Eastern District of Arkansas previously decided (<https://340breport.com/breaking-federal-law-doesnt-preempt-arkansas-novel-340b-contract-pharmacy-law-judge-rules/>) in favor of Arkansas and upheld the constitutionality of Act 1103 in December 2022.

There are four additional ongoing drug industry challenges to Arkansas Act 1103 and Louisiana's state law, Act 358, all of which are before federal district courts:

- PhRMA sued Louisiana (<https://340breport.com/louisianas-new-340b-contract-pharmacy-law-goes-into-effect-today-phrma-sues-and-teva-suspends-its-restrictions-in-the-state/>) over Act 358 on July 27 in the U.S. District Court for the Western District of Louisiana
- AstraZeneca sued Louisiana (<https://340breport.com/major-drug-company-sues-louisiana-over-340b-contract-pharmacy-law/>) over Act 358 on Aug. 4 in the District Court for the Western District of Louisiana
- AbbVie sued Louisiana (<https://340breport.com/abbvie-joins-legal-battle-over-louisianas-340b-contract-pharmacy-law/>) over Act 358 on Sept. 21 in the U.S. District Court for the Western District of Louisiana

- Novo Nordisk sued Arkansas (<https://340breport.com/novo-nordisk-files-suit-to-block-100000-arkansas-fine-for-340b-contract-pharmacy-violations/>) over Act 1103 on Oct. 12 in the U.S. District Court for the Eastern District of Arkansas

In legal filings, lawyers for PhRMA and other drugmakers argued that Act 1103 and Act 358 were preempted by the federal 340B statute and thus unconstitutional, contrary to the federal district court decision in Arkansas. The filings also cited the 3rd Circuit's decision that drugmakers are not obligated to provide 340B pricing to unlimited contract pharmacies.

Drugmakers React to State Laws

Novo Nordisk's lawsuit before a federal district court revealed for the first time Arkansas' planned mechanism of enforcement and proposed monetary penalties: a fine of \$50,000 for every six months of violations of Act 1103 up until the drugmaker ends its restrictions on 340B contract pharmacy arrangements in the state. It is unclear whether or how the Louisiana attorney general would enforce Act 358.

Meanwhile, drug industry-backed groups published studies in 2023 on 340B's growth in size (<https://340breport.com/340b-drug-purchases-reached-53-7-billion-in-2022-hrsa-data-show/>) and scope (<https://340breport.com/hospital-340b-sites-increased-by-400-over-11-years-analysis-finds/>) and questioned the expanding role (<https://340breport.com/share-of-retail-pharmacies-that-contract-with-core-340b-safety-net-facilities-fell-over-time-study-finds/>) of contract pharmacies in the program.

Amid the series of manufacturer notices that exempt covered entities in Arkansas and Louisiana from contract pharmacy restrictions, 340B Report has compiled a tracker of the publication's most recent coverage.

340B Report Tracker of Manufacturer Notices for Arkansas and Louisiana

Drugmakers that loosened or ended 340B contract pharmacy restrictions in response to Arkansas and Louisiana laws

Drug manufacturer	Date manufacturer notice issued	Read more on 340B Report:
Merck *	Arkansas and Louisiana on July 31	Merck Loosens 340B Contract Pharmacy Restrictions in Two States as Louisiana Law Takes Effect
Teva Pharmaceuticals	Louisiana on July 31; Arkansas on Sept. 20	Teva Ends 340B Contract Pharmacy Restrictions in Arkansas in Response to State Law
Eisai *	Arkansas and Louisiana on Oct. 2	Eisai's New 340B Contract Pharmacy Restrictions to Exclude Arkansas and Louisiana
Astellas Pharma *	Arkansas and Louisiana on Oct. 10	Astellas Ends 340B Contract Pharmacy Restrictions in Arkansas and Louisiana
GlaxoSmithKline (GSK) *	Arkansas and Louisiana on Oct. 31	GSK Loosens 340B Contract Pharmacy Restrictions in Arkansas and Louisiana
Organon	Arkansas and Louisiana on Nov. 1	Sixth Drugmaker Loosens 340B Contract Pharmacy Restrictions in Arkansas and Louisiana
Eli Lilly *	Arkansas on Nov. 14	Lilly to Exempt Arkansas from New Tighter 340B Contract Pharmacy Restrictions

Providers Grapple with Restrictions

Hospitals advocates said contract pharmacy restrictions had financial consequences for safety net providers. A July 2023 study from hospital advocacy group 340B Health found that contract pharmacy restrictions cost hospitals \$1.5 billion in 340B revenue (<https://340breport.com/contract-pharmacy-restrictions-cut-1-5-billion-in-340b-hospital-revenue-8-4-billion-more-endangered-report-says/>) in 2021 and that a further \$8.4 billion was at risk from drugmaker restrictions in place as of June 1, 2023.

For community health centers, the effects of contract pharmacy restrictions on 340B savings are “no longer a theoretical possibility,” said Colleen Meiman, national policy advisor for State & Regional Associations of Community Health Centers. “I talk to a

health center probably every week that has downsized some program, failed to backfill some position, or even laid off staff, and the number one reason they point to is [restrictions on] 340B," she said.

Mainline Health Systems, a federally qualified health center with 33 locations throughout rural Arkansas, uses 340B savings to provide dental care, open school-based clinics, and give patients discounted medications, said Allan Nichols, CEO of Mainline. Over the past 12 months, Mainline provided \$3.5 million in drug discounts to patients, he said.

However, contract pharmacy restrictions have cost Mainline around \$2.1 million in annual 340B savings, Nichols said. After some manufacturers exempted Arkansas providers in response to Act 1103, Mainline is on track to recoup around \$1 million of lost savings, he said.

"The hope is that we come to a resolution with contract pharmacy restrictions because the last step is going to be shutting down the practices in towns of 400 or 500 [residents] that are not financially viable," Nichols said. "Those are the communities that need us the most."

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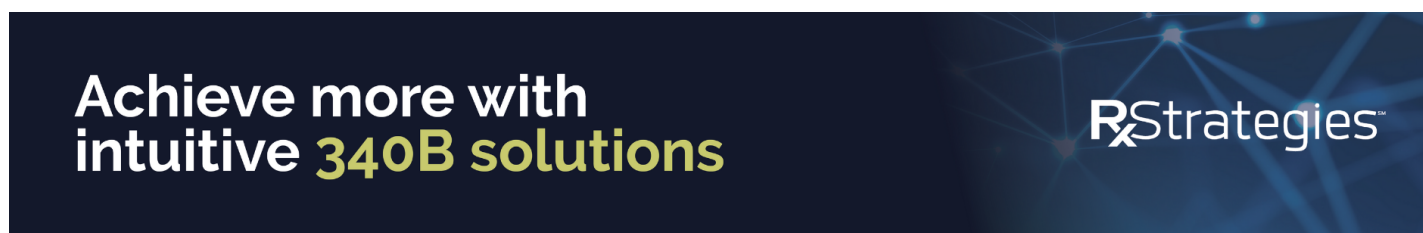


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