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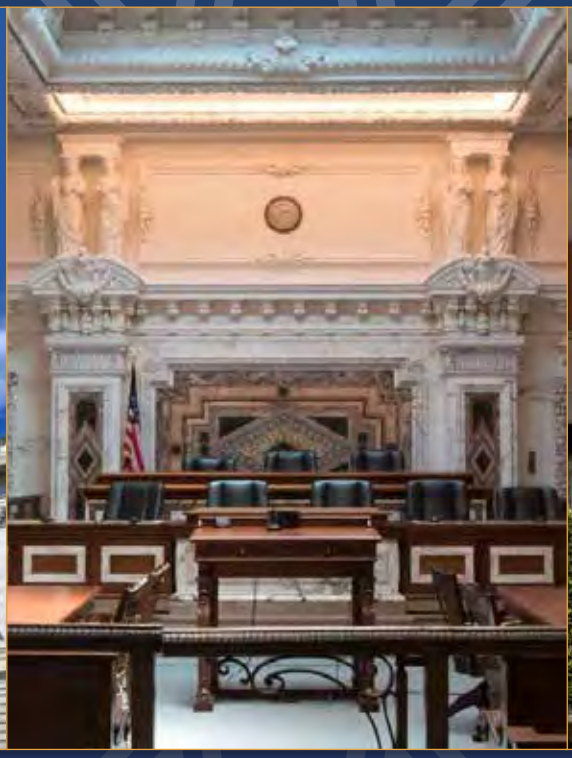

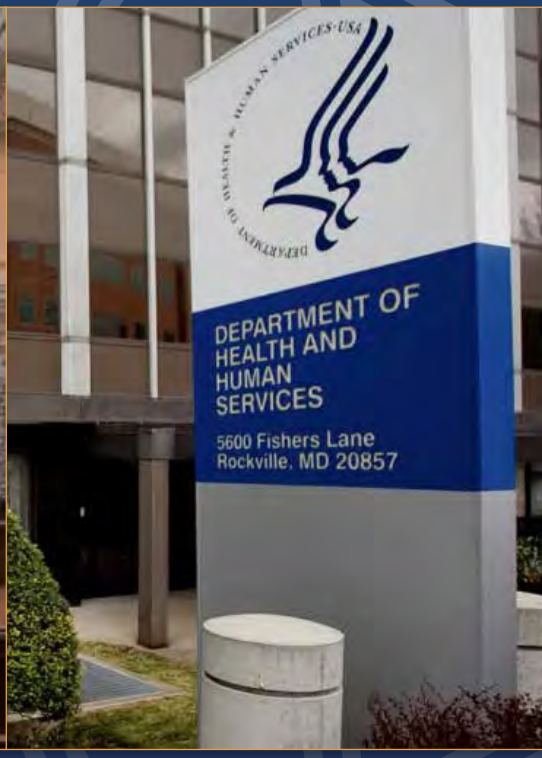

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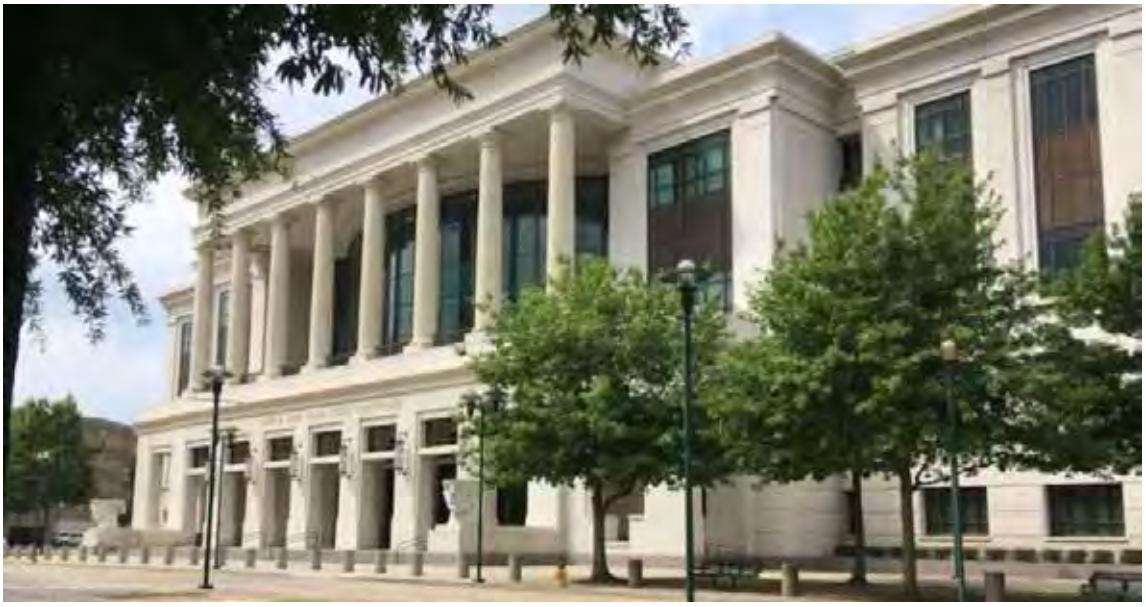

Attorneys representing the drug industry, the state of Louisiana, and Louisiana health centers presented oral arguments before a federal district court.

Federal Judge Presses Drug Industry on Preemption Arguments During Key Hearing on Louisiana 340B Law

July 11, 2024 William Newton, Washington Correspondent

A federal judge late last week pressed drug industry attorneys on their claims that Louisiana's 340B contract pharmacy law oversteps federal law, according to a transcript of oral arguments obtained by 340B Report.

U.S. District Judge Robert Summerhays for the Western District of Louisiana presided over July 6 combined oral arguments for three separate lawsuits challenging the constitutionality of Louisiana Act 358, which prohibits drugmaker 340B contract pharmacy restrictions in the state. Attorneys representing Pharmaceutical Research and Manufacturers of America (PhRMA), AbbVie, and AstraZeneca argued against Act 358, while attorneys representing the state of Louisiana and intervening health centers defended the law. *Continued on the next page…*

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Summerhays, who was appointed by former President Donald Trump (R) in 2018, focused the majority of his questioning on the drug industry's arguments that the federal 340B statute preempted Act 358. He also pressed the attorney representing intervening health centers on his defense that Act 358 only governs drug delivery, and not drug pricing.

Louisiana was the second state to enact a 340B contract pharmacy access law and is one of just seven states to do so. Act 358 took effect in August 2023, though the state apparently has not taken enforcement action amid the ongoing legal challenges.

A three-judge panel for the U.S. 8th Circuit Court of Appeals unanimously upheld Arkansas' similar 340B law on March 12, affirming a previous federal district court ruling. The 8th Circuit rejected PhRMA's request to have the case reheard by a full panel of judges. No other federal courts have weighed in on state 340B contract pharmacy access laws, and the 8th Circuit does not have jurisdiction over Louisiana.

PhRMA's Arguments

Philip Perry, a partner at Latham & Watkins, who represented PhRMA, argued that Congress "intended 340B to be exclusively federal." He cited the Supreme Court decision in Astra v. Santa Clara, which held that 340B should be administered "harmoniously on a uniform national basis," as evidence Congress intended to preempt laws like Act 358. Perry also represented PhRMA in the 8th Circuit case.

However, Summerhays repeatedly pressed Perry on whether Act 358 actually conflicted with the federal 340B enforcement scheme. He also told Perry that "most of my questions deal with preemption," and granted Perry more speaking time as the drug industry attorney tasked with that argument.

"Astra dealt with whether or not there was a private right of action to enforce anti-diversion, overcharges, double dipping, the types of things that are prescribed under 340B," Summerhays said to Perry. "If there's no…private right to enforce the statute, why can't the state step in under its traditional regulatory role and regulate some other aspect of the various relationships that comprise the 340B?"

Perry replied that Congress intended for federal regulators, and not states, to establish a "remedy for covered entities complaining of overcharges and other violations of discounted pricing requirements."

Nicole Longo, spokesperson for PhRMA, separately told 340B Report, "As noted in our arguments, Louisiana has no authority to place requirements on how manufacturers engage in the federal 340B program, let alone create new requirements that are not in the federal statute to begin with or that conflict with requirements in the statute."

AstraZeneca and AbbVie's Arguments

Allon Kedem, partner at Arnold & Porter, who represented AstraZeneca, argued that Act 358 regulates drug pricing, and therefore conflicts with the federal statute. He also cited recent unanimous decisions from three-judge panels of the U.S. 3rd Circuit Court of Appeals and the U.S. D.C. Circuit, both of which held that the 340B statute does not require drugmakers to ship 340B drugs to contract pharmacies without any restrictions. Kedem represented AstraZeneca in the 3rd Circuit case.

Summerhays, however, appeared skeptical that the two circuit decisions supported Kedem's arguments that states could not regulate contract pharmacy use.

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"Doesn't the 3rd Circuit case and the D.C. Circuit case treat those restrictions [on contract pharmacies] as a distribution issue?" Summerhays asked Kedem. "Because that's how they frame…the decision, that the [340B statute] is silent as to delivery."

In response to repeated questioning, Kedem said Act 358 governs drug pricing—not drug delivery—and therefore is preempted by the federal 340B statute.

"There is no difference, literally no difference between 340B drugs and drugs other than the price at which they're offered for sale," Kedem said. "Act [358] treats as a violation a manufacturer's failure to make reduced price drugs available for contract pharmacy sales. In other words, price is the only thing that distinguishes a sale that complies with the act from a sale that violates the act."

Matthew Owen, partner at Kirkland & Ellis, who represented AbbVie, said Act 358 violated drugmakers' 14th Amendment rights by taking private property, though he also spoke extensively about preemption. Summerhays then asked Owen questions about his arguments on the takings clause.

"It seems to me that one of the purposes of the [340B statute] was not only to benefit these community healthcare companies or organizations but also to provide lower cost drugs to patients," Summerhays said. "It almost seems like what you're arguing is the whole system is a violation of 340B."

Health Center Intervenor's Arguments

Ron Connelly, principal at Powers Pyles Sutter & Verville, argued in support of Act 358 on behalf of the Louisiana Primary Care Association (LPCA), which intervened on behalf of state community health care centers in all three cases. Connelly also represented Arkansas 340B covered entities defending the state's first-in-the-nation contract pharmacy access law that was upheld the by the 8th Circuit.

Connelly argued against the preemption arguments, stating that the federal 340B statute left the door open for states to regulate aspects of drug delivery. He also cited the 8th Circuit decision on Arkansas' law.

"The 8th Circuit in PhRMA v. McClain correctly held that Congress expressed no such clear and manifest purpose to preempt state law in governing distribution of 340B priced drugs," Connelly said. "Indeed, the court rejected many of the arguments that the plaintiffs present here."

Summerhays then asked Connelly whether Arkansas' law was distinguishable from Louisiana's.

"It's only distinguishable in one respect…in that Act 358 has a clause specifically stating that it must be construed consistent with federal law," Connelly replied. "Arkansas did not have that statute. Nonetheless, the 8th Circuit held it was not preempted, so we contend that Act 358 is even more clearly not preempted."

Summerhays also pressed Connelly on the drug industry's arguments that Act 358 regulated overcharges and therefore dealt with drug pricing.

"The plaintiffs at various points have made…the argument that [Act 358's]…purpose was to enforce or to prevent overcharges," Summerhays said to Connelly. "If that were the case, based on Astra, wouldn't that impinge on an exclusive federal enforcement scheme, duplicate the federal government's" enforcement?

Connelly responded, "We don't agree that the state statute regulates pricing…It addresses getting the drugs that are already priced under the federal 340B statute."

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Louisiana Attorney General's Arguments

The defendants' remaining time was divided between two attorneys representing the Louisiana attorney general, though Summerhays did not have any questions for either attorney.

Brent Hicks, shareholder at Baker Donelson, who represented Louisiana, argued against PhRMA and drugmakers' arguments that Act 358 violated conflict preemption, patent law, and the contracts clause of the U.S. Constitution. He said Act 358 did not preempt the federal 340B statute because both the 3rd Circuit and the D.C. Circuit, while deciding against the Health Resources and Services Administration (HRSA), "observed that the 340B statute is silent on delivery."

"Unlike HRSA, which is powerless to act unless authorized by Congress, Louisiana, as a sovereign state, retains the power to take all traditional state actions that Congress has not expressly prohibited," Hicks said. "The same statutory silence that prohibits HRSA from prohibiting manufacturers from imposing conditions on the distribution of 340B drugs permits states to enact legislation governing this distribution pursuant to their traditional power to regulate drug distribution."

Finally, Carey Jones, an attorney for the Louisiana office of the attorney general, used the defendant's remaining time to address two "incidental arguments that weren't prominently featured" during oral arguments but were mentioned in prior briefs.

Jones said Act 358 did not violate the due process clause of the U.S. Constitution because the term "interference," as used in Act 358, is "a term that can be commonly understood by the ordinary person." Additionally, he said Act 358 did not violate the takings clause.

"Here we're not talking about a taking in any respect, regulatory or otherwise," Jones said. "What the Louisiana statute is about is honoring a contract that exists."

The Louisiana attorney general's office declined to comment on the oral arguments.

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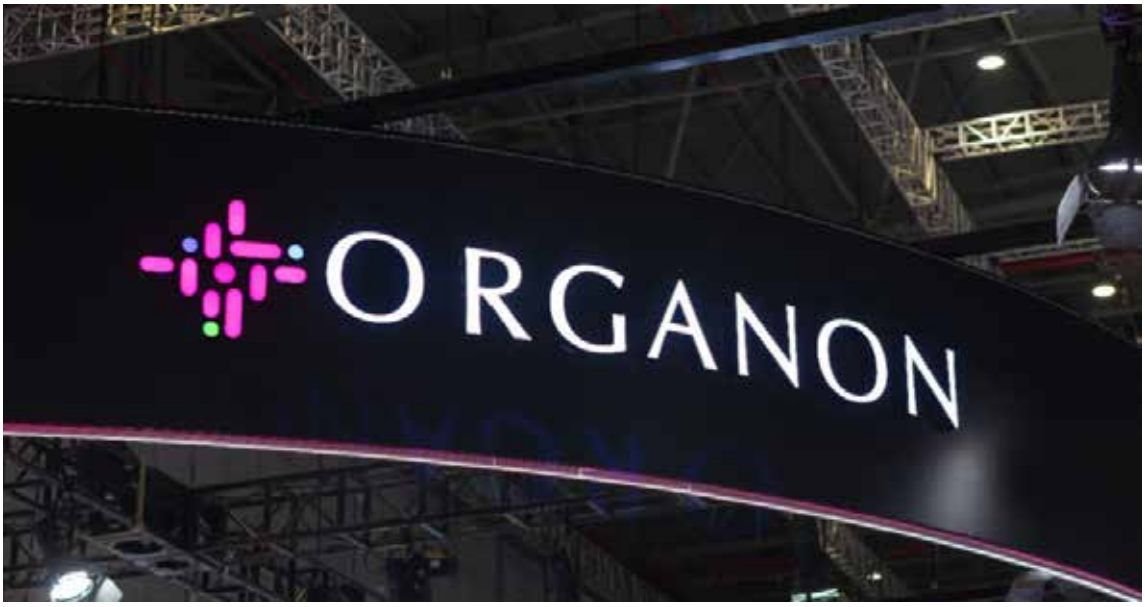

Drugmaker Organon fully exempted West Virginia providers from its contract pharmacy policy and loosened its restrictions in three additional states.

Organon Ends or Loosens 340B Contract Pharmacy Restrictions in Four More States

July 11, 2024 William Newton, Washington Correspondent

Organon, a spinoff of pharmaceutical giant Merck with a focus on women's health, is now fully exempting West Virginia covered entities from its 340B contract pharmacy restrictions.

The drugmaker also is now shipping 340B priced drugs to providers in Kansas, Maryland, and Mississippi at an unlimited number of contract pharmacies—but unlike West Virginia, it will still require claims data submissions in those states.

Organon's contract pharmacy policy change for all four states took effect on July 6, the same day that West Virginia's 340B contract pharmacy access law took effect. Similar laws enacted in Maryland, Mississippi and Kansas will all take effect on July 1.

Organon previously loosened its contract pharmacy restrictions for providers in Arkansas and Louisiana, where 340B contract pharmacy access laws have been in effect since 2021 and 2023, respectively. That policy change, which took effect in December 2023, allowed Arkansas and Louisiana providers to access Organon products at their 340B price at an unlimited number of contract pharmacies provided they submit claims data to drug industry vendor 340B ESP.

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Organon's policy did not specify any exemptions for providers in Minnesota, which is the only other state to enact a 340B contract pharmacy access law. Minnesota's law takes effect Aug. 1.

Organon became the 22nd drugmaker to implement 340B contract pharmacy restrictions in July 2023. Under that policy, which still applies to all other states, Organon only ships 340B priced drugs to a single pharmacy location for 340B hospitals, regardless of whether they have an in-house pharmacy. Organon's restrictions exempt 340B grantee covered entities.

Karissa Peer, spokesperson for Organon, said the policy change "is due to recently enacted state laws that prohibit manufacturers from restricting the use of contract pharmacies by covered entities. Covered entities in states not exempted by the policy are still subject to our policy that allows one contract pharmacy with the submission of 340B claims data."

Full Exemption in West Virginia

Organon will allow West Virginia providers to access Organon products at their 340B price at "an unlimited number of contract pharmacies with no claims submission requirements," the notice said. As a result, it said "there is no action required by covered entities in the state."

West Virginia's law, which Gov. Jim Justice (R) signed on March 27, specifically prohibits drugmakers from requiring "a 340B entity to submit any claims or utilization data as a condition for allowing the acquisition of a 340B drug." The bill received near unanimous support in the Republican-controlled state legislature, and state provider groups have praised the legislation.

Organon is the sixth drugmaker to fully or partially exempt West Virginia providers from its 340B contract pharmacy restrictions, joining Sanofi, Vertex, GlaxoSmithKline, Alkermes, and Merck. Pharmaceutical Research and Manufacturers of America (PhRMA) and Novartis also each filed May 31 lawsuits asking a federal district court to declare unconstitutional West Virginia's law.

Partial Exemption in Five States

Organon's latest policy change will allow providers in Kansas, Maryland, and Mississippi to access 340B discounts at an unlimited number of contract pharmacies if they submit claims data to 340B ESP within 45 days of date of dispense. The notice said providers that do not meet the claims submission requirements "will be considered out of compliance and the 340B discount for Organon products will no longer be permitted."

Organon is only the second drugmaker to partially exempt these three states from its 340B contract pharmacy restrictions, joining Vertex. The laws in Maryland and Mississippi are also subject to multiple drug industry legal challenges in federal district courts.

The July 6 policy change for Kansas, Maryland, and Mississippi has the same conditions as Organon's December 2023 policy change in Arkansas and Louisiana. Organon is one of more than two dozen drugmakers to fully or partially exempt Arkansas providers from 340B contract pharmacy restrictions, and one of 10 to do so in Louisiana.

A three-panel for the U.S. 8th Circuit Court of Appeals unanimously upheld the constitutionality of Arkansas' law on March 12 in a suit brought by PhRMA, and Arkansas is the only known state that has begun pursuing enforcement. Meanwhile, combined oral arguments for three drug industry lawsuits challenging Louisiana's law in a federal district court took place on July 6.

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INDUSTRY insights

Are You Prepared for an Office of Pharmacy Affairs (OPA) Audit?

July 4, 2024 Sponsored Content

Essential Current Audit Trends, Risks and Preparation Steps

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All entities who participate in the 340B program are subject to an Office of Pharmacy Affairs (OPA) audit regardless of entity type, size or volume of transactions. For the last five years, HRSA's OPA has been completing approximately 200 audits a year and as of May, 2024, 19 audits have been completed. Historically, the entity types at highest risk for audit were disproportionate share hospitals and critical access hospitals, but in the past few years there has been a shift to audit more non-hospital grantees such as Federally Qualified Health Centers, STD clinics, and even specialty clinics. No entity should consider themselves "safe" and all entities should be prepared to receive the dreaded OPA audit notice.

An OPA audit can last anywhere from 2 to 6 months and can include up to five separate phases. The burden is unwieldy – how do you prepare for every aspect of an OPA audit? We believe the answer is through building an educated team who designs and implements an environment which prioritizes compliance and integrity of the 340B program.

In our years of performing 340B audits, we have identified the minimum key behaviors and priorities of entities who receive a clean audit report (documented as "No Adverse Findings"):

- Annual staff trainings on the 340B program and compliance requirements (this includes pharmacy, program and finance staff).
- At minimum, quarterly reviews of published OPA audit results to summarize and address key areas of focus.
- Detailed policies and procedures updated regularly for changes in the entity, the 340B program, billing practices or the pharmacy structure.
- Minimum quarterly internal audits including detailed testing and documentation of results.
- An annual external audit from an independent source and the prioritization of follow-up on any findings.
- Constant monitoring and updating of the Office of Pharmacy Affairs Information System (OPAIS) for changes in the pharmacy structure, billing and program.
- Building a support network of similar organizations to share trends and best practices.

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In Stinging Op-Ed, West Virginia Senate Leader Bashes Drug Industry and Rejects Efforts to Politicize 340B Program
Verity Panel Discussion: 340B Outlook from Washington, D.C. & the States
Super PAC with Dark Money Ties Launches New Anti-340B Ad
Range of Motives Likely Behind Surge in Drugmaker Contract Pharmacy Changes, Say Provider Advisers

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- Regular executive level review of key risk areas such as:
  - » Medicaid billing policies
  - » Physician administered drugs (inventory, tracking and dispensing)
  - » Materiality threshold for self-reporting
  - » Patient and provider definition changes
  - » Documentation of savings, and reasonableness of third-party fees (if applicable)

Don't wait until a OPA audit notice is received to get prepared! At AAFCPAs, we work with you to collaborate on the implementation of processes to minimize risks and inefficiencies, and maximize integrity and savings, all with a focus on technology and reducing burden on your team. Learn more here.

Courtney McFarland, Partner at AAFCPAs, can be reached at cmcfarland@aafcpa.com.

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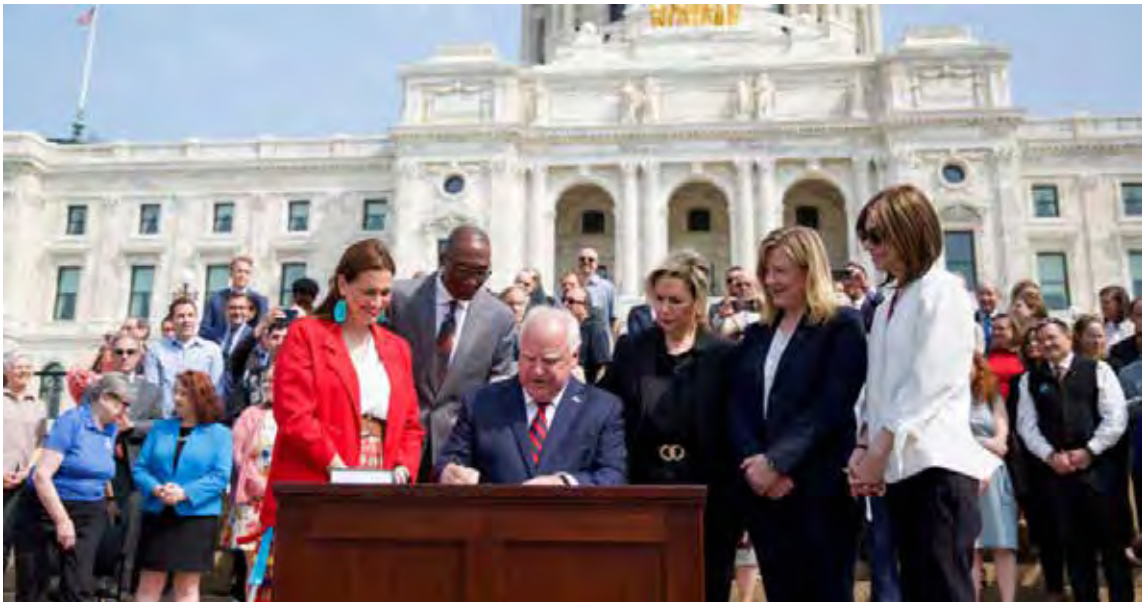

Minnesota Gov. Tim Walz (D) signed a law to prohibit drugmaker 340B contract pharmacy restrictions in the state.

Minnesota Is Seventh State to Enact 340B Contract Pharmacy Law, State Also Expands Covered Entity Reporting

July 6, 2024 Editor in Chief

Minnesota became the 7th state to enact a law to protect distribution of 340B drugs through contract pharmacies when the governor recently signed it. The state separately enacted a law to expand reporting by covered entities.

On May 24, Gov. Tim Walz (D) signed a measure to bar 340B contract pharmacy access restrictions by manufacturers. Language from the contract pharmacy bill (H.F.4991), sponsored by state Rep. Dave Lislegard (D), was included in a Commerce Budget Bill which was approved by the state house on May 18, shortly before the legislature adjourned.

Minnesota joins Arkansas, Louisiana, West Virginia, Maryland, Mississippi and Kansas as the only states to enact 340B contract pharmacy access laws.

The language included in the larger budget bill dropped references from Lislegard's bill on enforcement and adds a sunset for the law on July 1, 2027. The law goes into effect Aug. 1, according to the sponsor's office.

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The measure will prohibit drug manufacturers from interfering with the acquisition or delivery of 340B drugs to covered entities and their contract pharmacies in the state.

"Health Centers in Minnesota are happy to see the passage of this important legislation," Rochelle Westlund, a spokesperson for the Minnesota Association of Community Health Centers (MNACHC), previously told 340B Report. "Our patients already face significant barriers to care. Contract pharmacy restrictions contribute to noncompliance with needed medication, and our patients experience adverse outcomes impacted for manageable diseases like diabetes and hypertension. This bill creates better access and outcomes for vulnerable populations."

Liselgard introduced his bill—back by the MNACHC—on March 18. A Senate companion bill (S.F.5159) was approved in April by the Senate Health and Human Services Committee, shortly after state Sen. Allice Mann (D) replaced state Sen. Grant Hauschild (D) as the bill's chief author. On April 9, it was approved by the Rules and Administration Committee.

Reporting Expansion

Separately, Walz signed on May 23 legislation that contained language from companion bills, S.F.4861 and H.F.4755, to expand on the state's existing 340B covered entity reporting requirements. Minnesota enacted one of the first state 340B reporting laws in May 2023 and all 340B covered entities were required to start submitting data by April 1.

The measure will require all state 340B providers to additionally report aggregated expenses for 340B program administration and payments made to any non-pharmacy entity. They also will, for the first time, require $500 daily fines for 340B providers non-compliant with data submission requirements.

The updated reporting requirements were passed May 19, as part of large tax package.

"After the session ended last year, we learned that there needed to be modifications based on input from the Department of Health and an expert who is at the [University of Minnesota]," state Sen. Melissa Wiklund, the bill's sponsor and chair of the Health and Human Services Committee, told 340B Report. "I'm really looking forward to the first report which is due in November. There is a lot of interest in understanding how the 340B program is working in Minnesota. Many feel that it is very important that the covered entities have the ability to utilize the program, but there are others who feel that it isn't being used properly. The lack of transparency has made it difficult for policymakers to decide on health care reforms that might have an impact on the covered entities use of the program in an inadvertent way."

The April reporting to the Minnesota Department of Health (MDH) will be compiled into a comprehensive report due to the legislature by Nov. 1. Some of that data will be publicly released on Nov. 15 on an MDH website and yearly reporting of data and reports are required going forward.

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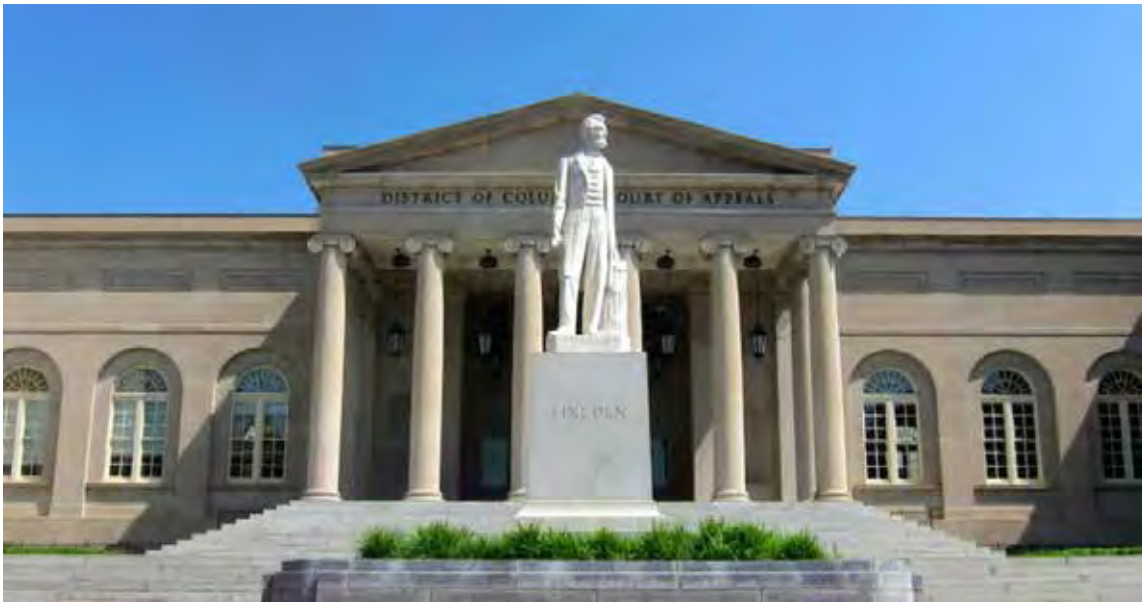

A federal appeals court decided that the 340B statute does not prohibit all types of restrictions on 340B contract pharmacy use.

BREAKING NEWS

Appeals Court Approves Drugmakers' Federal 340B Contract Pharmacy Restrictions But Leaves Open Possibility of Enforcement Against Stricter Policies

May 21, 2024 William Newton, Associate Editor/Senior Writer

A federal appeals court today decided that the 340B statute does not prohibit drugmakers from placing conditions on the distribution of 340B drugs to covered entities—though it left open the possibility that more stringent conditions could be illegal.

Three judges for the U.S. Court of Appeals for the District of Columbia decided unanimously on May 21 that the 340B statute "does not categorically prohibit manufacturers from imposing conditions on the distribution of covered drugs to covered entities" in the case Novartis v. Johnson, which combined a similar lawsuit by United Therapeutics. The decision affirmed a November 2021 ruling from U.S. District Court for the District of Columbia.

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The appeals court said the specific contract pharmacy restrictions placed by drugmakers Novartis and United Therapeutics "do not violate section 340B on their face." However, the court also left open the possibility that more stringent restrictions could violate the statute, including terms that cause the price of a 340B drug to rise above the statutorily required 340B ceiling price.

"We do not foreclose the possibility that other, more onerous conditions might violate the statute," wrote U.S. Circuit Judge Gregory Katsas in the decision. "Likewise, we do not foreclose the possibility that these conditions may violate section 340B as applied in particular circumstances—if, for example, HRSA could show that a specific covered entity for some reason could not supply the claims information demanded by United Therapeutics."

The court declined to decide on the legality of restricting contract pharmacy use to within a 40 mile radius, as it said Novartis had abandoned that condition since it first brought suit.

Victory for Drugmakers

The D.C. appeals court is the second major federal appeals court to side mostly in favor of drugmakers on the legality of 340B contract pharmacy restrictions.

In January 2023, the U.S. 3rd Circuit Court of Appeals in Philadelphia decided in favor of drug manufacturers AstraZeneca, Sanofi, and Novo Nordisk in a related 340B contract pharmacy dispute with the Department of Health and Human Services (HHS). The three-judge panel held, 3-0, in Sanofi v. HHS that drug manufacturers are not required to provide 340B prices to an "unlimited number of contract pharmacies" under the federal 340B program statute.

Another related 340B contract pharmacy case, Lilly v. Becerra, is before the U.S. 7th Circuit Court of Appeals in Chicago. A decision is expected soon.

Background on Novartis v. Johnson

Both Novartis and United Therapeutics separately sued the federal government after the Health Resources and Services Administration (HRSA) sent them letters on May 17, 2021, that said their restrictions on 340B contract pharmacy use were illegal and resulted in overcharges to providers.

In a November 2021 ruling, U.S. District Judge Dabney Friedrich of the District of Columbia held that the 340B program statute does not prohibit drug makers from attaching any conditions to 340B sales and that HRSA's letters to Novartis and United Therapeutics "rest on an erroneous reading of Section 340B."

However, Friedrich said the 340B statute did not permit all conditions on contract pharmacy use. The ruling said any future federal enforcement action "must rest on a new statutory provision, a new legislative rule, or a well-developed legal theory that Section 340B precludes the specific conditions at issue."

"The district court held that section 340B does not prohibit manufacturers from limiting the distribution of discounted drugs by contract," Katsas wrote in the appeals court decision. "We agree."

340B Report will provide more in-depth coverage of the decision, including stakeholder reactions, in our next issue.

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~ Ryan Stice, Chief Pharmacy Officer,
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