



U.S. Supreme Court Will Not Review Drug Manufacturer Lobbyist's Challenge to Arkansas' Recent Law Implementing 340B Contract Pharmacy Protections

On December 9, 2024, the U.S. Supreme Court declined to take up a petition by a powerful pharmaceutical industry lobbyist urging the Court to review a U.S. Court of Appeals for the Eighth Circuit decision after they lost at the District Court, lost on appeal to a three-judge panel of the Eighth Circuit, and were denied in their request for rehearing by the full court. The Arkansas law at issue protects access to drugs discounted under the federal 340B program through contract pharmacies. Arkansas is one of eight states (KS, LA, MD, MS, MO, MN, and WV) with laws in place that prohibit drug manufacturers from imposing restrictions or limitations on the use of 340B contract pharmacies. Minnesota and Missouri, like Arkansas, are in the Eighth Circuit.

At issue are arrangements entered by 340B covered entities, which include a variety of non-profit safety-net providers, with third-party pharmacies (called contract pharmacies) to expand the locations where patients of the 340B covered entity can fill their prescriptions with products purchased at the discounted 340B price. The availability of discounted 340B medications at contract pharmacies in patients' communities or through mail order facilitates these patients' access to their medications, can improve their health, and ensures the 340B covered entities can continue to use revenue from the discounts to improve patient services and access to care.

However, since 2020, many drug manufacturers have been imposing restrictions on access to 340B pricing when drugs are dispensed at contract pharmacies. These restrictions typically limit the number of contract pharmacies a covered entity may

have, restrict the distance of the pharmacies from the covered entity, and/or require an exchange of data for the manufacturer's product to receive the 340B price at a contract pharmacy. Some manufacturer policies go as far as prohibiting the use of any contract pharmacies under any circumstances.

After the federal government tried and failed to stop the manufacturers from imposing these kinds of restrictions on contract pharmacy use, states started stepping into the gap and passing their own laws. Arkansas was the first in the nation both to pass a law protecting contract pharmacy access and to initiate enforcement against manufacturers who violate the law.

The Arkansas law, like the laws in the seven other states, prohibits drug manufacturers from imposing these kinds of restrictions on 340B contract pharmacies. In 2021, Pharmaceutical Research and Manufacturers of America (PhRMA) sued the State of Arkansas in *PhRMA v. McLain* alleging that the Arkansas contract pharmacy law improperly regulated the federal 340B program, violating the Supremacy and Commerce clauses of the U.S. Constitution, and was preempted by federal law. The U.S. District Court for the Eastern District of Arkansas ruled in December 2022 that the Arkansas law was not preempted by federal 340B law and that the 340B program was not immune from state regulation. PhRMA appealed this ruling to the Eighth Circuit, which affirmed the district court's decision in March 2024.

In its decision, the Eighth Circuit indicated that, in implementing and regulating the 340B program, Congress must have been aware of the role of pharmacies – including contract pharmacies – in the context of a drug pricing and acquisition regime such as 340B. Congress's silence on the role of pharmacies in the 340B context, the Eighth Circuit determined, therefore meant that Congress did not intend to preempt states' regulation of contract pharmacies and 340B drug distribution. PhRMA appealed this ruling to the U.S. Supreme Court, which declined to hear PhRMA's petition. This means that the Eighth Circuit's decision upholding the constitutionality of the Arkansas contract pharmacy law stands.

In the states with contract pharmacy protections in place, major drug manufacturers have begun partially or completely lifted their contract pharmacy restrictions, with Arkansas having the most success at being exempted from manufacturer policies, likely thanks to its diligence in enforcing its law. Only

AstraZeneca remains among manufacturers subject to a complaint under the Arkansas law that has refused to comply. Arkansas initiated enforcement proceedings against AstraZeneca in early October 2024; those proceedings remain ongoing.

Many other drug manufacturers and drug industry lobbyists are currently challenging other states' contract pharmacy protections. However, none of these challenges have proved successful for the pharmaceutical industry to date. The restrictions they continue to impose, however, are continuing to be costly for safety-net healthcare. We can expect that manufacturers will continue to find ways to try minimize utilization of 340B discounts: it is no secret that these discounts don't help their bottom line.

But, so far, the state-level pushback on those manufacturer efforts by 340B covered entities and contract pharmacies, through legislation coupled with enforcement, has been the most successful at protecting access to the discounts. Arkansas responded the fastest of all the states and has been the most assertive with enforcement, which has led to fewer restrictions and shorter-lived restrictions. States that want to protect the revenue of their safety-net providers should take note.

We will continue to monitor developments in this space.

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