

# Summary: PhRMA Litigation Challenging Constitutionality of Provisions in Arkansas Act 1103

## Background

PhRMA's complaint challenges provisions of Arkansas Act 1103, enacted by the Arkansas legislature in May 2021, that purport to mandate federal 340B program pricing for certain Arkansas pharmacies. These provisions of Arkansas Act 1103 seek to regulate manufacturers' participation in the federal 340B Drug Pricing Program. Specifically, they require manufacturers to provide 340B pricing not just to the 15 types of "covered entities" that Congress specified in the federal 340B statute, but also to certain pharmacies with whom the covered entities may choose to enter into contract arrangements.

Whether the federal 340B statute requires manufacturers to ship 340B medicines to an unlimited number of contract pharmacies is the subject of numerous lawsuits in federal district courts across the country and is actively being debated. Contract pharmacies were never authorized by the U.S. Congress in the federal 340B statute, and the 340B statute does not explicitly require manufacturers to ship 340B medicines to contract pharmacies. Despite this, there are nearly 30,000 contract pharmacies participating in 340B today and government watchdog reports have found that uninsured patients who show up at 340B hospital's contract pharmacies generally do not benefit from the discounted price.

## Legal Claims

PhRMA's complaint asserts that the 340B pricing mandate provisions (and other related provisions) in Act 1103 are invalid for two principal reasons.

First, the provisions are preempted by federal law because they directly conflict with explicit requirements in the federal 340B statute in at least three respects.

1. While federal law requires manufacturers to provide 340B pricing to 15 types of "covered entities," like certain hospitals and clinics, Act 1103 impermissibly seeks to add a 16th entity—contract pharmacies.
2. While Congress established a process for policing 340B compliance and resolving disputes between manufacturers and covered entities via audit procedures and administrative dispute resolution, and imposed careful limits on monetary penalties, Act 1103 imposes additional and conflicting requirements related to 340B program dispute resolution.
3. The provisions also interfere with a comprehensive and carefully designed federal framework of regulation.

Second, the 340B pricing mandate provisions of Act 1103 are invalid because they violate the Commerce Clause of the U.S. Constitution, which protects against the projection of one State's regulatory regime into the jurisdiction of another State and prohibits any State from regulating the price to be paid in another State for goods acquired there. The provisions violate this fundamental limitation on state power because they would apply extraterritorially to most PhRMA members and regulate manufacturers' out-of-state sales to out-of-state wholesalers.

Accordingly, PhRMA has asked the U.S. District Court for the Eastern District of Arkansas to declare that the 340B pricing mandate provisions of Act 1103 are unconstitutional and violate federal law.