

Federal and State Price Transparency Efforts Face Legal Challenges from Industry Groups

Price transparency in healthcare is a hot topic that has captured the attention of many policymakers. While both federal and state governments have made efforts to promote price transparency in recent years, the path to achieving it is expected to be a bumpy one, as powerful industry groups that resist such change, including hospitals and pharmaceutical companies, are quick to seek legal challenges to block such efforts. In this edition of Litigation and Enforcement Highlights, we examine the latest lawsuits that challenge legislation to promote price transparency in healthcare and how they fared in courts.

Hospitals Sue Trump Administration over Disclosure of Negotiated Price

Late November, the Trump administration issued a new federal rule that would require hospitals to publicly disclose the actual discounted rates they negotiate with insurers for medical supplies and procedures. The [Final Rule](#), set to take effect in 2021, targets the secretive nature of hospital pricing and seeks to promote consumer price shopping of healthcare services.[1] The hospitals, including the American Hospital Association (AHA), were quick to fight back, filing a [lawsuit](#) in the U.S. District Court for the District of Columbia just a week later to challenge the Final Rule.

In the complaint, plaintiffs argue that the administration does not have the legal authority to compel such disclosure of proprietary information. Specifically, while Section 2718(e) of the Public Health Services Act,[2] which the Centers for Medicare & Medicaid Services (CMS) cites as its legal authority to effectuate the rule, allows CMS to require disclosure of “standard charges for items and services provided by the hospital,” the section does not include payer-specific negotiated rates as part of the definition of standard charges.

Secondly, the hospitals contend that the Final Rule infringes upon their First Amendment rights, as “it mandates speech in a manner that fails to directly advance a substantial government interest.” Plaintiffs argue that the rates negotiated between hospitals and insurers do not provide actual cost information to patients, which are out-of-pocket costs, and the new rule “will generate confusion about patients’ financial obligations, not quell it.” Additionally, the Final Rule places undue administrative inconvenience and burden on the hospitals. As the negotiated charges are confidential and proprietary to both hospitals and insurers, plaintiffs argue that disclosure of such information would prevent arms’ length negotiation. The hospitals are also concerned that the complexity of compliance could crash hospitals’ existing computer systems. As a result, such burden is not sufficiently justified by government interests under the First Amendment.

Federal Rule to Require Disclosure of Drug Prices in TV Ads Blocked in Court

Another recent federal attempt to promote price transparency, this time in the comparably opaque pharmaceutical industry, was met with similar legal roadblock. In May, the Trump administration via the Department of Health and Human Services (HHS) finalized a rule to require drug manufacturers to disclose list prices of their drugs in television ads. Set to go into effect on July 9, [the rule](#) would have required drugmakers to include the list price of their medications if they cost \$35 or more for a month’s supply.

In this case, drug manufacturers Merck, Eli Lilly, and Amgen [launched arguments](#) strikingly similar to the ones alleged in the hospital challenge, namely the government’s lack of statutory authority and violation of the First Amendment, in the U.S. District Court for the District of Columbia, the same court in which the hospital lawsuit is filed. Similar to the hospital price disclosure lawsuit, the drug companies here argue that list prices do not reflect what most patients pay out of pocket, as it does not take into account any discounts, rebates, and insurance payments. Accordingly, the plaintiffs contend that disclosing the list price of drugs would only confuse consumers instead of achieving the intended effect on consumer behavior.

Given the lack of clear evidence that the rule would promote the intended goals, plaintiffs argue the government cannot justify the burden it places on free speech.

In the court's decision, Judge Mehta noted that the court did not question whether drugmakers should be required to disclose their prices or whether such policy could be effective in reigning in prescription drug costs. Additionally, the court also did not rule on the plaintiff's First Amendment argument. The court did, however, block the rule in favor of the plaintiffs the day before it was set to take effect based on HHS' lack of regulatory authority. Specifically, [the court opinion](#) states that the rule "is far afield of any other type of rulemaking authority HHS has previously exercised" under the Social Security Act, which the HHS cites its authority, and that "Congress... did not envision such an expansion of regulatory authority when it granted HHS the power to issue regulations."

This decision, while currently on appeal to the circuit court, could shed some light on how the same court may rule in the latest challenge against the hospital disclosure rule, particularly given their similarity in terms of legal arguments. While both cases challenge the government's statutory authority, the drug price rule is based on the Social Security Act. The hospital rate rule, on the other hand, rests on the Public Health Services Act. It remains to be seen whether the court would apply the same reasoning to limit the government's effort to extend its authority under a different statute.

Pharma Lawsuit Against California's SB 17 Allowed to Proceed

As federal policies to promote price transparency stumble on legal barriers, state efforts are not immune from resistance either. California's SB 17 has been under fire from the pharmaceutical industry since it was enacted in October 2017. The controversial state drug pricing transparency law requires drug makers to provide 60 days advanced notice and a reason for price hikes above a certain threshold.[3] The Source Blog previously reported that the U.S. District Court for the Eastern District of California dismissed the [initial lawsuit](#), PhRMA vs. Brown, on procedural grounds, but allowed Pharmaceutical Research and Manufacturers of America (PhRMA), the pharmaceutical industry's main lobbying group and plaintiff in this

case, to amend the complaint to satisfy procedural requirements.

Plaintiffs immediately refiled an [amended complaint](#) in September 2018, in the form of *PhRMA v. David*, alleging the California law violates the First Amendment and the Commerce Clause. Specifically, PhRMA claims that SB 17 improperly compels speech by forcing drugmakers to justify price changes and impermissibly regulates interstate commerce because it applies to wholesale acquisition costs that are national in nature. The complaint also raises due process concerns as it relates to potential retroactivity of the law.

Most recently, California federal judge Morrison C. England Jr., who tossed the initial lawsuit, gave the amended lawsuit the greenlight to move forward when he [denied](#) the state's motion to dismiss late this summer. The court opinion states that the plaintiff has adequately alleged that SB 17 may violate free speech and other constitutional rights.

As more federal and state policies target hospital and pharmaceutical prices and practices, the affected industry groups will no doubt vamp up their efforts to resist such changes in the form of additional litigation. With largely similar legal arguments cited as authority to block the intended policies, each case may set important legal precedents for other policy efforts to effectuate reform in healthcare price and competition. As the legal side of the equation may dictate the boundaries of healthcare reform, stay tuned as The Source Blog brings the latest developments and rulings from the courts.

[1]See [The Secret of Health Care Prices: Why Transparency is in the Public Interest](#) written by The Source for a detailed discussion of public interest in price transparency of healthcare prices.

[2]42 U.S.C. § 300gg-18(e).

[3]See [California's Drug Transparency Law: Navigating The Boundaries Of State Authority On Drug Pricing](#) written by The Source for a detailed discussion of the legal and regulatory aspects of SB 17.