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U.S. District Court of D.C. Sets Aside the Accumulator Adjustment Rule

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On May 17, 2022, the U.S. District Court for the District of Columbia ruled in favor of the plaintiff pharmaceutical manufacturer trade group in *Pharmaceutical Research and Manufacturers of America ("PhRMA") vs. Becerra* in its challenge of the accumulator adjustment rule issued by the Center for Medicare & Medicaid Services in 2020 and set to take effect on January 1, 2023.[1] The rule, which makes significant modifications to the Medicaid Drug Rebate Program ("MDRP") patient assistance program exclusions, provides that a manufacturer can exclude from its best price calculation financial assistance it provides to patients "only to the extent the manufacturer ens*u*res the full value of the assistance or benefit is passed on to the consumer or patient."[2] If enacted, the rule would have had a significant impact on pharmaceutical manufacturers' popular and widely used commercial copay assistance programs—potentially resulting in changes to such programs that could have impeded patient access to manufacturer financial support. PhRMA argued, and the Court agreed, that the Department of Health and Human Services ("HHS") lacks the authority under the Medicaid rebate statute to adopt the accumulator adjustment rule, and therefore, violated the Administrative Procedure Act ("APA").[3]

This Alert summarizes the key portions of the Court's analysis and discusses the next procedural steps in the litigation, as well as potential implications of the decision.

Background

The Medicaid drug rebate statute requires pharmaceutical manufacturers to report to HHS—and to determine their Medicaid drug rebate liability on the basis of—their "best price."[4] "Best price" is defined as the "lowest price available from the manufacturer . . . to any [best-price-eligible purchaser]."[5] Under the statute, best-price eligible purchasers include wholesalers, retailers, providers, health maintenance organizations, nonprofit entities, or governmental entities within the United States.[6] Notably, under the statute, patients are not enumerated as best-price-eligible purchasers.[7]

In 2020, HHS proposed regulations addressing the impact of so-called accumulator adjustment programs on best price calculations.[8] Accumulator adjustment programs are payor-established programs that prevent manufacturer copayment assistance from being counted towards a patient's deductible or out-of-pocket maximum. Payors are able to benefit from the manufacturer's copayment assistance by not crediting those amounts towards the patient's deductible or out-of-pocket maximum requirements. Historically, there has been limited visibility into whether, or under what terms, accumulator adjustment programs exist in any given health plan or form of health coverage.

The final rule required that manufacturers "ensure the full value of the assistance or benefit is passed on to the consumer or patient" in order for any financial assistance to an insured patient not to count toward the best price.[9] In response to manufacturer comments, the agency delayed the effective date of the regulatory change to January 1, 2023, stating that the delay "will give manufacturers time to implement a system that will ensure the full value of assistance under their manufacturer-sponsored assistance program is passed on to the patient."[10]

In May 2021, PhRMA challenged the 2020 rule, arguing that the accumulator adjustment rule violates the APA because "it conflicts with the text, structure, history, and purpose of the Medicaid rebate statute."[11] In September 2021, the government moved to dismiss, under the theory that the Court does not have Article III jurisdiction to hear the case and the Medicaid rebate statute expressly authorizes the accumulator adjustment rule; however, as described below, the Court denied that request.[12]

Court's Ruling and Reasoning

The District Court found that (1) it had Article III jurisdiction to hear the case because the rule created new obligations for manufacturers, resulting in an injury directly traceable to the rule, and (2) HHS lacked the statutory authority to adopt the accumulator adjustment rule because the statute addresses prices made available from a manufacturer to a best-price-eligible entity, and a patient is not a best-price-eligible entity. The Court therefore granted PhRMA's motion for summary judgment and set aside the accumulator adjustment rule.

The Court Possesses Article III Jurisdiction

First, the Court addressed the procedural question of whether it had Article III Jurisdiction to hear the case. For the Court to have Article III jurisdiction over a matter, a plaintiff must demonstrate injury in fact, causation, and redressability.[13] The government raised the jurisdictional argument that PhRMA's alleged injuries stemmed not from the 2020 final rule, but rather from the earlier 2007 and 2016 final rules that addressed exclusions to best-price calculations, but that PhRMA did not explicitly challenge.[14]

The Court found the 2020 rule imposed on manufacturers new burdens that did not stem from the earlier rules—namely, that the 2020 rule "places [a] burden on manufacturers to "ensure" that patients receive the full benefit of assistance programs" to exclude any financial assistance from the calculation of best price.[15] Prior rules did not similarly burden manufacturers and instead only required that financial assistance be passed on to the patients and that the best-price-eligible-purchaser receives no "price concession." The Court highlighted that HHS delayed the rule's effective fate to January 1, 2023 as indication that the rule imposed new obligations on manufacturers, because, by delaying the effective date to provide manufacturers with time to implement new systems to come into compliance, CMS recognized that the 2020 rule imposed additional burdens on manufacturers.

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Second, the Court addressed the merits in the case, which is whether a manufacturer's financial assistance to a patient in the context of an accumulator adjustment program can count as the "lowest price available from the manufacturer . . . to any [best-price-eligible purchaser]?"[16] The Court found that it does not.

The Court's decision hinged on its interpretation of the statutory text. It found that a manufacturer's financial assistance to a patient does not qualify as a price made available to a best-price-eligible purchaser because a patient does not qualify as a best-price-eligible purchaser.[17] The same is true, the Court reasoned, even where commercial health insurers create accumulator adjustment programs to capture some or all of the financial assistance.[18]

The Court's also raised "feasibility" concerns because the rule "would make the calculation of the best price turn on information often in the sole possession of commercial health insurers."[19] Further, because manufacturers would need to conduct detailed investigations into accumulator adjustment programs on a case-by-case basis, often with little information and no control over those programs, the Court found that it would be infeasible for manufacturers to conduct those analyses and still report the best price to HHS in a timely fashion, as Congress required in the statute.[20]

Lastly, the Court reflected on the government's position that statutory "references to other transactions that adjust prices either directly or indirectly to the best price eligible entities…[is intended to] include[] the transactions made by the manufacturer indirectly to health plans via manufacturer-sponsored assistance programs." The court reasoned this position is inconsistent with the government's position in 2016.[21] Previously, HHS had stated that the direct-indirect language was meant to require manufacturers to include adjustments made to eligible entities, but the agency never suggested that the revised language swept in best-price-ineligible entities such as patients.

For these reasons, the Court found that the accumulator adjustment rule violated the plain language of the Medicaid drug rebate statute and therefore constituted invalid agency action under the APA. The Court vacated and set aside the accumulator adjustment rule of 2020.

Looking Ahead

The government has 60 days to appeal the District Court's decision. In the absence of a successful appeal, the rule would not go into effect and manufacturers will revert to the existing regulatory language, which generally requires that patients receive the full value of manufacturer assistance but does not require that manufacturers take action to "ensure" that patients do so. Barring any future rulemaking by the agency on this topic, manufacturers would not face the challenge of implementing new mechanisms to "ensure" patient assistance remains with the patient. The decision may also help ensure the continued availability of copay assistance for patients from manufacturers.

If you have any questions related to this decision, please feel free to contact your usual Ropes & Gray advisor or one of the authors listed above.

1. *See Pharmaceutical Research and Manufacturers of America vs. Becerra*, Civil Action No. 1:21-cv-1395 (CJN) (D.D.C. May 17, 2022).
2. *See Revising Medicaid Drug Rebate and Third Party Liability Requirements,* 85 Fed. Reg. 87000, 870049 (emphasis added) (December 31, 2020).
3. *Pharmaceutical Research and Manufacturers of America,* Civil Action No. 1:21-cv-1395 at 2; *see* 42 U.S.C. § 1396r-8.
4. *See* 42 U.S.C. § 1396r-8.
5. *See* 42 U.S.C. § 1396r-8(c)(1)(C).
6. *Id*.
7. *See* 85 Fed. Reg. 87000, 87052.
8. *See Revising Medicaid Drug Rebate and Third Party Liability Requirements*, 85 Fed. Reg. 37286 (June 19, 2020).
9. 85 Fed. Reg. 87000, 87102.
10. *Id*. at 87053.
11. *Pharmaceutical Research and Manufacturers of America,* Civil Action No. 1:21-cv-1395 at 6.
12. *Id*.
13. *Spokeo, Inc. v. Robins,* 136 S. Ct. 1540, 1547 (2016); *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021).
14. *Pharmaceutical Research and Manufacturers of America,* Civil Action No. 1:21-cv-1395 at 8.
15. *Id*. at 9.
16. *Pharmaceutical Research and Manufacturers of America,* Civil Action No. 1:21-cv-1395 at 10; 42 U.S.C. § 1396r-8(c)(1)(C)
17. *Pharmaceutical Research and Manufacturers of America,* Civil Action No. 1:21-cv-1395 at 10.
18. *Id*.
19. *Id*.
20. *Pharmaceutical Research and Manufacturers of America,* Civil Action No. 1:21-cv-1395 at 11; See 42 U.S.C. § 1396r-8(b)(3)(A) (requiring that manufacturers report their best price to the agency within thirty days after the end of each quarterly rebate period).
21. 85 Fed. Reg. 87000, 87052.