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MEDICAID DRUG REBATE PROGRAM (MDRP)

No developments to report.

340B PROGRAM

Further State Legislation Seeks to Regulate PBMs in Relation to 340B: Florida, Kentucky, Missouri, Nebraska, and New Hampshire recently introduced legislation aiming to regulate pharmacy benefit managers (PBMs) in relation to their treatment of 340B covered entities and their contract pharmacies. Broadly speaking, such legislation seeks to prohibit PBMs from reimbursing 340B covered entities and their contract pharmacies at a lower rate than they do for other providers or pharmacies, and from otherwise imposing specific policies on covered entities or their contract pharmacies on the basis of 340B participation, such as through the imposition of differential terms and conditions.

As reported in previous editions of this digest (Issue No. 1, Issue No. 2, Issue No. 3, Issue No. 5, and Issue No. 11), a number of other states have already introduced and enacted such legislation. Similarly, H.R. 4390, the PROTECT 340B Act of 2021, was introduced in the House of Representatives last July with the aim "to ensure the equitable treatment of covered entities and pharmacies participating in the 340B drug discount program."
Source: 340B Report

New Report Analyzes Drug Supply Chain and 340B Trends: Berkeley Research Group (BRG), with funding from the Pharmaceutical Research and Manufacturers of America (PhRMA), published a study titled "The Pharmaceutical Supply Chain, 2013-2020." The study's goal is "to bring greater clarity to the drug distribution and payment process and estimate the share of total prescription medicine spending realized by pharmaceutical manufacturers and other stakeholders in the supply chain." Among other things, BRG found that 2020 marked the first year in which stakeholders other than manufacturers — such as PBMs, health plans, hospitals, the government, and pharmacies — received the majority of total spending on brand-name medicines. PhRMA stated in a press release that "[f]or the first time, the supply chain and other stakeholders received a larger share of total brand medicine spending than the companies that developed them."

Moreover, BRG found that brand medicine spending received by 340B providers and their contract pharmacies increased by a factor of 12 between 2013 and 2020. BRG also found that more than half of provider and pharmacy profits on brand medicines now come through the 340B program, compared with a much smaller share in the early part of last decade. BRG identifies two 340B program trends that are contributing to such rapid and ongoing growth: (1) provider expansion of 340B sales through new enrollments and the registration of hospital outpatient facilities (i.e., "child sites"), and (2) the growing use of contract pharmacies for 340B purchasing, with over 94,600 contract pharmacy relationships

established from 2013 to 2020. The contract pharmacy expansion followed the 2010 issuance of revised contract pharmacy guidance by the Health Resources and Services Administration (HRSA).
Sources: BRG, PhRMA, The Pharma Letter, 340B Report

Ongoing Antitrust Litigation Related to Contract Pharmacy Policies: Briefing remains underway in federal court litigation brought against four pharmaceutical manufacturers by Mosaic Health and Central Virginia Health Services in relation to the manufacturers' 340B contract pharmacy policies. The plaintiffs are federally qualified health centers (FQHCs) that comprise numerous clinics participating in the 340B program. The plaintiffs allege that the manufacturers unlawfully conspired to deprive them of 340B discounts by implementing policies restricting 340B purchasing through contract pharmacy arrangements — allegedly unjustly enriching themselves in violation of federal and state antitrust laws. The manufacturers filed motions to dismiss the claims, arguing, among other things, that the FQHCs failed to satisfactorily plead their claims and are effectively seeking to make an end-run around the Supreme Court's decision in *AstraZeneca USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110 (2011), which held that the 340B statute does not permit 340B covered entities to pursue private enforcement of the 340B statute (outside the 340B administrative dispute resolution process). The FQHCs filed a memorandum in opposition to the manufacturers' motions to dismiss, arguing that their claims are sufficient to be heard by the court and that the *AstraZeneca* decision has no bearing on their claims, which they allege are permissibly brought under federal and state antitrust laws and state unjust enrichment laws. The manufacturers have the opportunity to file replies on or before Feb. 4, 2022. The case is *Mosaic Health, Inc. v. Sanofi-Aventis U.S., LLC*, No. 6:21-cv-6507-EAW (W.D.N.Y.).
Source: 340B Report

Other Contract Pharmacy Updates: Litigation related to manufacturer contract pharmacy policies continues.
Sources: InsideHealthPolicy, In Vivo, 340B Report (link, link, link, link)

MEDICARE PART B

No developments to report.

STATE LAW DEVELOPMENTS

No developments to report.

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