Ryan White Clinics for 340B Access

340B DISCRIMINATORY REIMBURSEMENT MUST STOP!

Pharmacy benefit managers (PBMs) and other third party payers are attempting to usurp the benefit of the 340B drug discount program by offering 340B participating providers, called "covered entities", lower reimbursement rates than those offered to non-340B entities. These discriminatory practices are viewed by safety net providers as a direct attack on the 340B program and leave the 340B provider community with no choice but to fight them. They are problematic for numerous reasons.

- **Discriminatory reimbursement is contrary to the purpose of the 340B program.** As the legislative history of the 340B statute makes clear, the purpose of giving qualified safety net providers access to 340B pricing is to enable them to stretch their scarce resources so that they may "reach[] more eligible patients" and "provid[e] more comprehensive services.[1]" This purpose cannot be achieved if 340B providers have to pass their savings to third party payers. The 340B program was not intended to benefit private insurers and PBMs, especially those that are for-profit.

- **The Health Resources and Services Administration (HRSA), the federal agency that administers the 340B program, views discriminatory reimbursement as a threat to the 340B program.** HRSA is concerned that providers would have no reason to participate in the 340B program if insurers take the benefit of 340B savings from them. HRSA explains that "if covered entities were not able to access resources freed up by the drug discounts when they…bill private health insurance, their programs would receive no assistance from the enactment of section 340B and there would be no incentive for them to become covered entities.[2]"

- **Discriminatory reimbursement undermines the purpose of the 340B program.** According to HRSA, the 340B program was established to provide additional financial resources to covered entities without increasing the federal budget. The difference between a 340B drug's lower acquisition cost and standard non-340B reimbursement represents the very benefit that Congress intended to give covered entities when it established the 340B program. Covered entities use these savings to treat more vulnerable patient populations or to improve services for them.

- **Discriminatory reimbursement ultimately harms the low income and medically vulnerable patients served by 340B providers.** Covered entities use 340B savings in a variety of ways to benefit the vulnerable patients they serve. The Government Accountability Office has found that providers use 340B to: offset losses incurred from treating some patients, continue providing existing pharmaceutical and clinical services, lower drug costs for low-income patients and serve more patients, and provide additional services, such as case management to facilitate access to appropriate care[3].

- **This unfair practice is well documented.** Apexus, which is under contract with HRSA to provide 340B technical assistance and other services, has issued an informational paper that cautions that some private payers have been issuing contracts to 340B covered entities with significantly lower reimbursement than

[1] H.R. Rep. 102-384, 102d Cong., pt. 2, at 12 (2nd Sess. 1992).
[2] HRSA, *Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act* (July 2005).
[3] GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, at p. 17 (Sept. 2011).

they would offer other retail pharmacies. The paper portrays these discriminatory practices as problematic.[4]

- **Discriminatory PBM contracts raise issues under the Equal Protection Clause of the Fourteenth Amendment**. The Equal Protection clause prohibits the government from treating similarly situated entities unequally without a rational basis. Case law has recognized that the Equal Protection Clause prohibits the payment of unequal rates to similarly situated providers[5]. The same principle can be applied to PBM contracts which set different rates for 340B pharmacies compared to non-340B pharmacies, imposing a lower rate on 340B pharmacies simply because of their participation in the 340B program.

- **Discriminatory PBM contracts expose community health centers (CHCs) to a risk of violating federal health center grant requirements.** CHCs are required to make every reasonable effort (1) to secure from patients payments for services in accordance with applicable fee schedules and discounts; and (2) to collect reimbursement for health services rendered to persons covered by Medicare, Medicaid or any other public assistance program or private health insurance program on the basis of the full amount of fees and payments for such services without application of any discount.[6] CHCs are legally prohibited from providing discounts to entities that are able to pay the full fee schedule price. By accepting the terms of a discriminatory contract, the CHC would be imposing a statutorily prohibited discount on its fee schedules and would not be collecting the "full amount of fees" as required by the statute.

- **Medicaid compliance issues are implicated if 340B drugs dispensed to Medicaid beneficiaries participating in a managed care organization (MCO) are subject to discriminatory reimbursement.** Nothing in federal law suggests, let alone compels, that the pharmacy component of an MCO's capitation rate be based on 340B pricing, nor does federal law compel MCOs and/or their PBMs reimburse 340B drugs at reduced rates. To the contrary, capitation rates paid from the state to a Medicaid MCO must be actuarially sound and "reasonable, appropriate, and attainable … for the operation of the MCO…and the population covered under the terms of the contract."[7] States risk violating this capitation sufficiency standard if they underpay MCOs based on an expectation that the MCOs will make up the difference by cutting reimbursement on 340B drugs. Federal regulations also specify that MCOs are required to maintain a "network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollee in the service area."[8] MCOs risk violating this network sufficiency standard if, by cutting reimbursement to their participating 340B providers, the MCOs drive these providers (and/or the providers' 340B pharmacies) out of their networks or negatively affect the providers' ability to furnish quality care to Medicaid beneficiaries.

- **PBMs have a history of stockpiling profits at the expense of patients.**[9] (Tab I) Providers that participate in the 340B program are safety net providers by virtue of their 340B eligibility. Given their mission of caring for vulnerable and underserved patients, covered entities are both the intended and best stewards of savings from 340B program. Consolidation in the marketplace by large PBMs will increase the risk of discriminatory reimbursement.[10]

For more information, please contact Peggy Tighe at Peggy.Tighe@PowersLaw.com.

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[4] Apexus, *340B & Medicaid*, at p.1. Apexus has also issued guidance that encourages covered entities and payers to reach mutually beneficial "alternative business solution[s]". Apexus, FAQ 1336.
[5] See, e.g., *West Virginia Univ. Hospitals Inc. v. Rendell*, 2007 WL 3274409 (M.D. Pa. 2007).
[6] 42 U.S.C. § 254b(k)(3)(G)(ii).
[7] 42 C.F.R. § 438.4.
[8] 42 C.F.R. § 438.207(b).
[9] Ana Mulero, *Proposed Aetna-Humana merger under Antitrust Regulatory Fire*, HealthcareDIVE (March 21, 2016).
[10] David A. Balto, *Testimony Regarding Express Scripts-Medco Merger to Senate Committee on the Judiciary, Subcommittee on Antitrust, Competition Policy and Consumer Rights* (Dec. 6, 2011).