340B UPDATE: SAFETY NET PROVIDERS FIGHT BACK AGAINST TWO-TIER PRICING MODELS

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Payors and pharmacy benefit managers ("PBMs") are increasingly implementing "two-tier" pricing models under the 340B Drug Pricing Program ("340B Program") providing lower reimbursement rates for 340B covered entities than non-340B entities. Safety net providers have started to challenge this practice in court and resort to state legislatures, arguing that the practice is impacting their ability to serve more patients and offer comprehensive services. Most recently, on December 20, 2019, the U.S. Court of Appeals for the District of Columbia Circuit ("D.C. Circuit") decided a challenge by Cares Community Health ("Cares"), a 340B safety net provider, claiming that the U.S. Department of Health and Human Services ("HHS") had unlawfully allowed Humana Health Plan ("Humana"), an insurer offering Medicare prescription drug coverage, to pay Cares less for drugs obtained through the 340B Program. Although the D.C. Circuit sided with Humana, the court noted that Congress may have intended for the benefit to remain with safety net providers rather than redound to the insurer's benefit. Separately, safety net providers have otherwise successfully petitioned state legislatures to take action on 340B two-tier pricing, with at least four states prohibiting PBMs from setting lower reimbursement rates. K&L Gates' Health Care and FDA Practice and Public Policy and Law Practice regularly advise clients on 340B Program matters and can help assess the potential impact of two-tier pricing models as well as potential avenues to address such models.

CARES COMMUNITY HEALTH V. HHS

Background

Federally Qualified Health Centers ("FQHCs") provide primary health services to medically underserved communities. [1] In recognition of their role as an integral part of the medical safety net, Congress has provided FQHCs with financial support through the Medicare statute and the Public Health Services Act.

The Medicare statute provides wraparound payments to make up the difference between what private insurers reimburse FQHCs for certain services and what Medicare would reimburse for the same services. [2] Medicare requires wraparound payment whenever a Medicare beneficiary "who is enrolled with a plan receives a service from [an FQHC] that has a written agreement with the organization that offers such plan." [3] To prevent insurers from lowering payments to FQHCs receiving support, the statute contains a provision commonly referred to as the "Not Less Than" provision, which requires the agreements to stipulate that payments to the FQHC are not less than the amount the plan would make available to a non-FQHC. [4] In addition, the Public Health Services Act provides support through Section 340B, which requires drug manufacturers to offer pharmaceutical discounts to

FQHCs and certain other safety net providers. [5] Savings from the reduced 340B rates allow providers to supply uncompensated care and expand their services.

340B Two-Tier Pricing

In 2009, Cares and Humana entered into a Pharmacy Provider Agreement for Humana to provide reimbursement to Cares for prescription drug services. Shortly after Cares became an FQHC, Humana sent Cares an amendment to the Agreement setting reimbursement rates for “340B pharmacy services” at roughly two-thirds the rate Humana pays other providers for retail pharmacy services, resulting in Cares recovering roughly $3 million less than it would have recovered absent the amendment as of 2018. [6]

Cares brought suit claiming that Humana's discriminatory reimbursement resulted from HHS' unlawful failure to enforce the “Not Less Than” provision with regard to pharmacy services in violation of the Medicare statute. A federal district court held that Cares had failed to state a claim because the “Not Less Than” provision does not apply to prescription drug plans' reimbursement of pharmacy services. The court reasoned, in part, that the “Not Less Than” provision applies to “services provided by such [FQHC],” which parallels the Medicare statute's definition of “[FQHC] services” that excludes prescription drugs. [7]

On appeal, the D.C. Circuit did not decide whether the term “services provided by such [FQHC]” excludes prescription drugs. [8] Instead, the appeals court found that Cares had not met its burden of showing that the “Not Less Than Provision” applies to prescription drug plans' reimbursement because it had not explained how the “written agreement” implementing the wraparound payment scheme applies. [9] The court noted in part that Cares had failed to identify whether the written agreement referred to contracts between the insurers and FQHCs for “FQHC services,” the Pharmacy Provider Agreement, or some other agreement. [10]

Notably, the D.C. Circuit addressed Cares' argument that, unless Medicare's “Not Less Than” provision applies to prescription drug plans' reimbursement of pharmacy services, insurers would try to capture the discounts that Section 340B provides through lower reimbursement rates. The appeals court found Cares' position “intuitive enough,” noting that “If Congress enacted both Medicare wraparound payments and Section 340B drug discounts to help fund FQHC's provision of uncompensated care … then Congress may have intended that both benefits remain with FQHCs rather than redound to insurers' benefit.” [11] Ultimately, however, the court held that it did not overcome the statute's plain language. The appeals court further noted that it did not need to decide whether HHS may issue a rule requiring Medicare prescription drug plans to include a “Not Less Than” provision in agreements with FQHCs to secure the benefits of 340B. [12]

FEDERAL AND STATE ACTION ON 340B TWO-TIER PRICING

Federal Guidance

HHS has generally declined to intervene on the issue of two-tier pricing under the 340B Program, with both the Centers for Medicare and Medicaid Services (“CMS”) and the Health Resources and Services Administration (“HRSA”) suggesting that they do not have authority to regulate this practice. In response to comments on the 2016 Medicaid Managed Care Organization (“MCO”) proposed regulations urging CMS to prohibit states from allowing Medicaid MCOs to impose two-tier 340B pricing models, CMS noted that, “Reimbursement by managed

care plans for drugs dispensed by 340B covered entities is negotiated between the managed care plans and covered entities and is outside the scope of this rule." [13]

HRSA has similarly taken the position that there is no provision in Section 340B of the Public Health Service Act that prohibits two-tier pricing. In response to a request to take action against Argus Health Systems for requiring 340B covered entities to sign a contract addendum limiting their reimbursement to a rate below what it offered its non-340B participating providers, HRSA acknowledged that such discriminatory reimbursement "may make it cost prohibitive for certain safety net providers to participate in the 340B program," but noted that there is no statutory provision otherwise prohibiting such discriminatory practice. [14]

HRSA's 340B Program Prime Vendor Apexus has confirmed HRSA's position, noting in response to a Frequently Asked Question that, "There is no statutory provision in section 340B of the Public Health Service Act prohibiting a payer from reimbursing a 340B covered entity at a level that may be different than a non-340B entity." [15] According to Apexus, HRSA "strongly encourages the covered entity to reach out to the payer to craft an alternative business solution that permits each of the parties to fulfill their goals." [16]

State Response

Given the position of CMS and HRSA, safety net providers have petitioned state legislatures to take action on 340B two-tier pricing models, with at least four states prohibiting this practice. Oregon, Minnesota, South Dakota, and West Virginia have enacted legislation to address two-tier pricing models by PBMs, prohibiting them from setting lower reimbursement rates for drugs provided by 340B covered entities. [17]

Oregon and South Dakota, for example, generally prohibit PBMs from reimbursing a 340B pharmacy differently than any other non-340B network pharmacy. [18] West Virginia's statute more specifically prohibits a PBM or third-party that reimburses a 340B entity for drugs from reimbursing the entity for pharmacy-dispensed drugs at a rate lower than what the PBM pays for the same drug to non-340B pharmacies with similar prescription volume, as well as from assessing any fee, charge-back, or other adjustment upon a 340B entity on the basis that the entity participates in the 340B Program. [19] In addition, West Virginia's statute prohibits PBMs and third-parties from discriminating against a 340B entity "in a manner that prevents or interferes with the patient's choice to receive such drugs from the 340B entity." [20] The law specifies that the prohibition applies to Medicare Part D [21] and Medicaid Managed Care Organizations, except for state Medicaid programs when Medicaid is providing reimbursement on a fee-for-service basis. [22]

CONCLUSION

As payors and PBMs continue to implement 340B two-tier pricing models, safety net providers must assess the billing requirements and potential impact of these models. The Cares case—even if ultimately unsuccessful—and state legislative actions noted above make clear that covered entities have potential avenues to address such models. K&L Gates' Health Care and FDA Practice and Public Policy and Law Practice regularly advise clients on 340B Program matters and can help assess the potential impact of these models and the laws impacting them and facilitate engagement with payors and policymakers.

NOTES:

[1] 42 U.S.C. § 254b(a).
[2] 42 U.S.C. § 1395l(a)(3)(B).
[3] 42 U.S.C. § 1395w-23(a)(4).
[4] 42 U.S.C. § 1395w-27(e)(3)(A).
[5] 42 U.S.C. § 256b.
[6] *See* Cares Community Health v. U.S. Department of Health and Human Services, No. 18-5319 2019, slip. op. at 10 (D.C. Cir. Dec. 20, 2019).
[7] *Id.* at 11-12.
[8] *Id.* at 15-16.
[9] *Id.* at 16-17.
[10] *Id.* at 17.
[11] *Id.* at 20.
[12] *See* Cares Community Health v. U.S. Department of Health and Human Services, No. 18-5319 2019, slip. op. at 21 (D.C. Cir. Dec. 20, 2019).
[13] 81 Fed. Reg. 27498, 27546-47. In addition, as part of a 2018 guidance document discussing the 340B Program reimbursement cut under the Medicare Outpatient Prospective Payment System, CMS noted that "MAOs that contract with a facility/provider eligible for 340B drugs can negotiate the terms and conditions of payment with the provider / facility. CMS cannot interfere in the payment rates that MA organizations and providers enter into through contracts." *See* CMS, Billing 340B Modifiers under the Hospital OPPS: Frequently Asked Questions, Q9 (Apr. 2, 2018).
[14] *See* Letter from the Health Resources Services Administration to Safety Net Hospitals for Pharmaceutical Access (Nov. 30, 2011), https://www.340bhealth.org/images/uploads/OPA_Response_to_Argus_Letter_113011.pdf.
[15] *See* Apexus, FAQ 1336, https://www.340bpvp.com/resourceCenter/faqSearch.html?category=content&Ntt=1336.
[16] *Id.*
[17] ORS 735.534; Minn. Stat. Ann. § 62W.07(f); S.D. Codified Laws § 58-29E-15; W. Va. Code § 33-51-9(d).
[18] ORS 735.534(2)(h); S.D. Codified Laws § 58-29E-15.
[19] W. Va. Code § 33-51-9(d).
[20] W. Va. Code § 33-51-9(e).
[21] W. Va. Code § 33-51-9(f).
[22] W. Va. Code § 33-51-9(e).

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