PBMs and the 340B Program

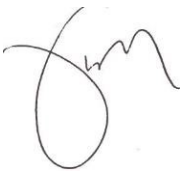
Next year, our nation's safety net hospitals and clinics will celebrate the 30th anniversary of the federal 340B drug pricing program. The 340B program operates on the simple principle that pharmaceutical manufacturers must do their part to address the problem of uncompensated care in this country as a condition of Medicaid and Medicare covering and reimbursing their products. As a result of drug companies' participation in the program, taxpayer-supported providers receive deep discounts on the drugs they purchase which helps them offset the ever-increasing costs of being unreimbursed or under reimbursed for patient care.

The program, however, is under attack on two fronts. Manufacturers are trying to scale back the program in any way they can, setting their sights most recently on 340B providers' use of retail and specialty pharmacies for dispensing their discounted drugs. Six manufacturers have unilaterally withheld 340B pricing on drugs dispensed through these contract pharmacy arrangements resulting in multiple lawsuits being filed and the federal government threatening to impose fines. Meanwhile, safety net providers are fighting to protect the 340B program on another front. Pharmaceutical benefit managers (PBMs) and other payers are increasingly singling out 340B drugs and pharmacies for reduced reimbursement which essentially transfers the benefit of the program from safety net providers to for-profit payers.

Over the course of the next year, we will issue a series of 340B White Papers that will focus on targeted issues to help explain original congressional intent, how the program may be being abused and targeted recommendations that elected officials could consider.

Our first White Paper takes a careful look at the relationship between PBMs and the 340B program. It provides an overview of how the PBM industry intersects with the 340B program and how reimbursement of 340B drugs, identification of 340B claims, 340B participation in PBM networks and related issues continue to be hotly contested by 340B stakeholders and their allies. The paper begins with a brief description of PBMs and the 340B program and then analyzes 340B discriminatory contracting practices by PBMs and advocacy efforts by the 340B safety net community to combat those practices.

We have come together as two advocates who believe in the importance of the 340B program today and tomorrow. While we may not always agree on every issue, we do concur on the most important matter: the long-term sustainability of the 340B program.



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Almost immediately after the 340B drug pricing program (340B program) was launched in 1992, the safety net hospitals and clinics participating in the 340B program – referred to as "covered entities" under the 340B statute – were forced to defend the program from efforts by drug manufacturers to narrow or place restrictions on the program both legislatively and administratively. It did not take long after that for a second front to emerge in the war to protect the 340B program. Pharmacy benefit managers (PBMs) and other payers began engaging in practices that threatened the 340B program in a different way. These practices, collectively known as "discriminatory reimbursement," involved PBMs (1) offering covered entities and their in-house or contract pharmacies lower reimbursement rates than those offered to non-340B entities, (2) establishing barriers to 340B pharmacies' participation in PBM pharmacy networks or to PBM members using 340B pharmacies, and/or (3) excluding covered entity pharmacies from PBM networks entirely.[1]

Background on PBMs

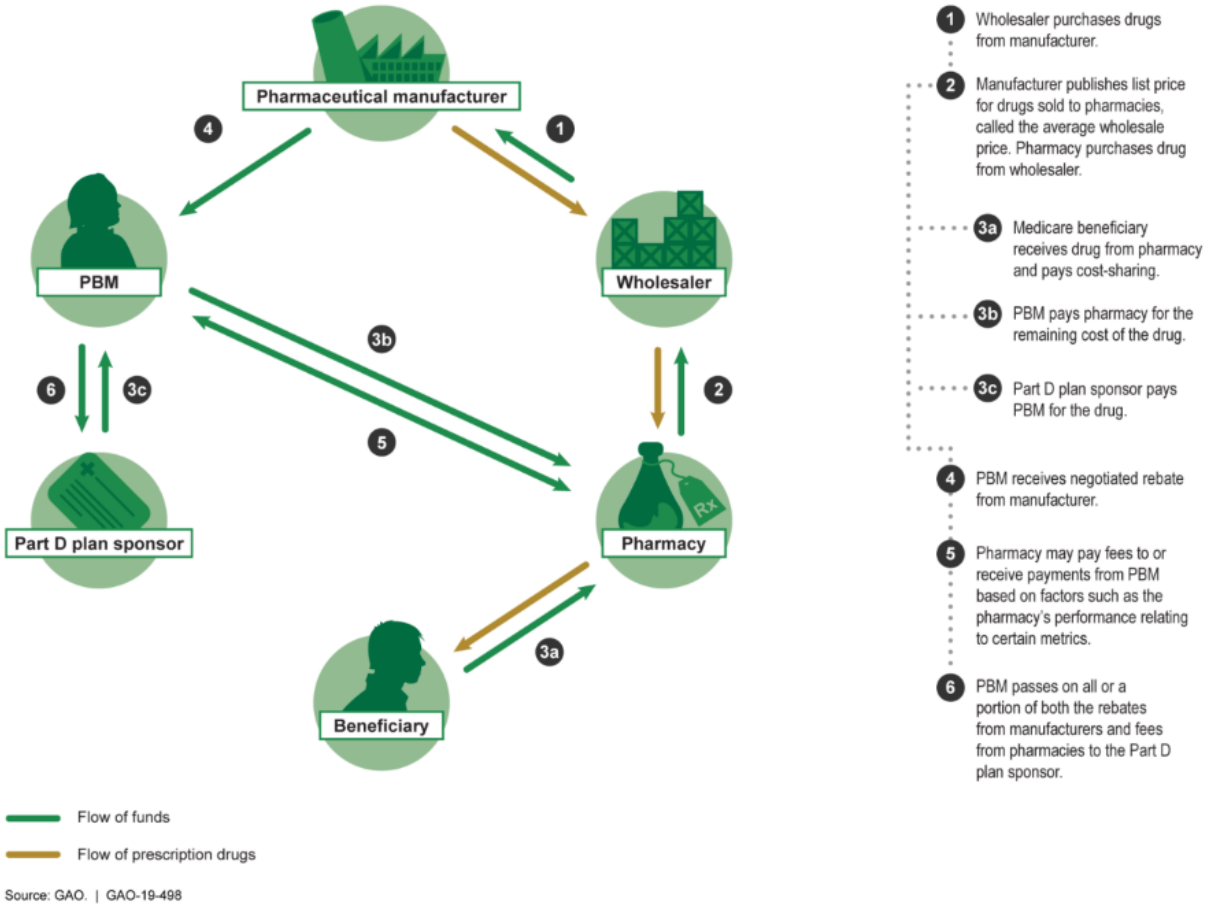
PBMs are the fiscal intermediaries that administer and manage prescription drug benefits on behalf of plan sponsors. PBMs dominate the center of the pharmaceutical supply chain and interact with plan sponsors, drug manufacturers, and pharmacies. PBMs manage plans for a variety of sponsors, including commercial health plans, self-insured employer plans, Medicare Part D plans, state government employee plans, and Medicaid managed care plans. The three largest PBMs – CVS Caremark, Express Scripts, and Optum Rx – account for over 70 percent of the pharmacy benefit market.[2] Plan sponsors pay PBMs for developing and maintaining formularies, processing claims, negotiating discounts, and furnishing related services. PBMs also contract with drug manufacturers to receive rebates from manufacturers in return for covering the manufacturers' drugs on their formularies or giving other kinds of preferences to a company's products such as elimination or relaxation of prior authorization requirements.

The value and profitability of the PBM industry received a huge boost in 2003 when Congress established the Medicare Part D program giving Medicare beneficiaries a comprehensive retail drug benefit for the first time.[3] The Medicare Part D program is built in large part around standalone prescription drug plans which are generally administered by PBMs.[4] As of last year, 46.5 million Medicare beneficiaries were enrolled in Medicare Part D.[5] When a beneficiary goes to the pharmacy to fill his or her prescription, the pharmacy will run the claim through the PBM to determine the beneficiary's coverage and copayment information.[6] Beneficiaries have access to a network of

[1] These practices have also been described as "pickpocketing."
[2] The Advisory Board Company, *Pharmacy Benefit Managers, Explained* (Nov. 13, 2019), https://www.advisory.com/en/daily-briefing/2019/11/13/pbms.
[3] Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, Title I (2003).
[4] Government Accountability Office, Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization, GAO-19-498, 9 (Jul. 2019), https://www.gao.gov/assets/gao-19-498.pdf ("GAO Medicare Part D Report").
[5] Kaiser Family Foundation, An Overview of the Medicare Part D Prescription Drug Benefit (Oct. 14, 2020), https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit.
[6] GAO Medicare Part D Report at 10.

pharmacies for filling their prescriptions and these networks are both created and managed by PBMs. The PBM will then reimburse the pharmacy for the cost of the drug dispensed, minus the beneficiary's copayment. The plan sponsor will, in turn, reimburse the PBM for the amount paid to the pharmacy. Set forth below is a chart depicting the complex array of relationships that PBMs must manage in the Medicare Part D environment. These relationships are very similar to those involved in commercial health insurance, employer plans, Medicaid managed care and other insurance markets in which a plan sponsor needs a PBM to manage and administer a pharmacy benefit for plan members.

Figure 1: Example of the Flow of Funds and Prescription Drugs through the Supply Chain when a Medicare Part D Beneficiary Purchases a Drug through a Part D Plan Sponsor Using a Pharmacy Benefit Manager (PBM)



Source: GAO. | GAO-19-498

The amount PBMs reimburse a pharmacy is typically based on the PBM's formularies or maximum allowable cost (MAC) for each drug. PBMs develop and administer their own unique MAC lists. Additionally, the amount a plan sponsor reimburses a PBM for administering the drug plan is negotiated and established in the contract between the PBM and the plan sponsor. Typically, PBMs set their MAC prices lower than what the plan sponsor is reimbursing the PBM. Thus, PBMs are keeping a portion of the amount paid to them by the plan sponsor instead of passing the full payment on to the pharmacy. The profit that PBMs retain from the plan sponsor is often referred to as "spread pricing."[7] PBMs have

[7] Alex Kacik, *PBMs' Spread Pricing Inflates Healthcare Spending, Commission Finds*, Modern Healthcare (Jun. 5, 2019), https://www.modernhealthcare.com/supply-chain/pbms-spread-pricing-inflates-healthcare-spending-commission-finds.

been under significant scrutiny for their current business practices and have faced pressure from both federal and state lawmakers and the Department of Health and Human Services (HHS) to curtail or minimize spread pricing.[8] Legislation prohibiting spread pricing by PBMs has been introduced and, in some cases, passed by state legislatures.[9] Last year, drug pricing bills passed by the House of Representatives and introduced by the Senate also would have prohibited spread pricing.[10]

340B Program

Established in 1992 under section 340B of the Public Health Service Act, the 340B program entitles covered entities to purchase outpatient drugs at substantial discounts from drug manufacturers.[11] The 340B discounts are limited to "covered outpatient drugs," which are prescription drugs and biological products (excluding vaccines, but including insulin) that are approved by the Food and Drug Administration and only dispensed after being prescribed by an appropriately licensed prescriber.[12] Participation in the 340B program is available to five categories of safety net hospitals and eleven categories of federal grantees and sub-grantees. If these covered entities meet the 340B program eligibility requirements, they may purchase 340B drugs from manufacturers and their wholesalers at 340B ceiling prices or lower. The 340B program is administered by the Health Resources and Services Administration (HRSA) through its Office of Pharmacy Affairs (OPA). Both HRSA and OPA are part of HHS.

Covered entities are subject to several restrictions under the 340B program. First, they are prohibited from reselling or transferring 340B drugs to a person who is not a patient of the entity.[13] Second, they must protect manufacturers from providing a 340B discount and a Medicaid rebate for the same drugs.[14] Third, certain hospitals are prohibited from utilizing group purchasing organizations or any other group purchasing arrangements to obtain covered outpatient drugs.[15] Fourth, other hospitals are precluded from using 340B pricing to purchase orphan drugs.[16] Lastly, when covered entities enroll in the 340B program, they are required to sign a certification stating that they will notify OPA if they lose their 340B eligibility status or if any information relevant to their eligibility status changes.[17] Also, under OPA's recertification process, covered entities certify annually that their registration information is correct and that they are in compliance with 340B program requirements.[18] The 340B statute imposes

[8] National Academy for State Health Policy, *Comparison of State Pharmacy Benefit Mangers Laws*, https://www.nashp.org/comparison-state-pharmacy-benefit-managers-laws (last visited Apr. 13, 2021); *see also Rutledge v. Pharmaceutical Care Management Association*, 141 S.Ct. 474 (2020).

[9] Colleen Becker, *State Policy Options and Pharmacy Benefit Managers (PBMs)*, National Conference of State Legislatures (Mar. 17, 2021), https://www.ncsl.org/research/health/state-policy-options-and-pharmacy-benefit-managers.aspx

[10] Prescription Drug Pricing Reduction Act of 2020, S. 4199, 116th Cong. (2020); Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 116th Cong. (2019).

[11] Veterans Health Care Act of 1992, Pub. L. No. 102-585 §§ 601-03, 106 Stat. 4943, codified at 42 U.S.C. § 256b.

[12] 42 U.S.C. § 256b(b)(1), incorporating the definition in the Medicaid rebate statute at 42 U.S.C. § 1396r-8(k)(2).

[13] *Id*. § 256b(a)(5)(B).

[14] *Id*. § 256b(a)(5)(A)(i).

[15] *Id*. §§ 256b(a)(4)(L)(iii), (M), (O).

[16] *Id.* § 256b(e).

[17] *See, e.g.*, 340B OPAIS User Guide for External Users – Attesting to CE Registrations and Reinstatements, 38, https://340bregistration.hrsa.gov/help/external/Resources/PDFUserGuides/ExternalUserGuide.pdf (last visited Apr. 30, 2020).

[18] *Id*. at 49.

sanctions on covered entities for violations of the first two restrictions and covered entities are expected to take corrective action with respect to all five requirements.

Covered entities are subject to audits by HRSA.[19] HRSA began auditing covered entities in 2012 to determine whether they are in compliance with the 340B program's rules and guidelines.[20] HRSA typically performs approximately 200 audits of covered entities each year.[21] Covered entities are either selected randomly "from program types determined to be at higher program risk due to volume of purchases, increased complexity of program administration, and use of contract pharmacies," or targeted due to "allegations of violations of 340B requirements" made by whistleblowers, manufacturers, or through self-disclosure.[22] HRSA reviews the covered entity's compliance with various requirements under the 340B program, including the restrictions described above.[23] Covered entities are also subject to audits by manufacturers. HRSA issued guidelines in 1996 to address the process and procedures that a manufacturer must follow to audit a covered entity.[24]

340B Discriminatory Contracting Practices by PBMs

Back in the late 1990s, certain PBMs started to attract attention within the 340B safety net community when they began requiring participating pharmacies to enter unique contracts or contract addenda as a condition of the pharmacies being able to bill and get paid for 340B drugs. Pharmacies owned by or under contract with 340B hospitals and clinics were permitted to participate in the PBMs' pharmacy networks but only if they agreed to 340B-specific terms and conditions. In almost all circumstances, these terms and conditions included a reduction in drug reimbursement which, not surprisingly, elicited strong objections from safety net providers. Covered entities were quick to accuse PBMs and plan sponsors of usurping the benefit of the 340B program that Congress had intended to go to safety net providers. Allegations that PBMs are undermining the purpose of the 340B program in this manner have only increased over the past twenty-five years.

On its face, the PBM practice of paying pharmacies less for 340B drugs than for non-340B drugs appears discriminatory and, even worse, a brazen attempt to increase PBM and plan profits at the expense of safety net providers. PBMs have a history of squeezing pharmacy reimbursement to increase their profit margin so PBM critics naturally assumed that cutting payment of 340B drugs was just another form of spread pricing. And while the profit motive may have played a role in these practices, PBMs defend their actions by explaining how the 340B program has gradually eroded their rebate revenue from manufacturers which, in turn, has forced them to implement these 340B-specific measures. As explained above, PBMs negotiate rebate arrangements with manufacturers as a way of being compensated for placing a manufacturer's drugs on the PBM's formulary or otherwise making it easier for physicians to prescribe the manufacturer's drugs or for pharmacies to dispense the drugs. These rebate arrangements generate significant revenue that PBMs use to pay pharmacies and lower premiums. Manufacturers have increasingly refused to pay these rebates when they must sell the drugs at a deeply discounted price through the 340B program. Absent the rebate revenue on 340B drugs,

[19] 42 U.S.C. § 256b(a)(5)(C).
[20] *See* OPA, Program Integrity, https://hrsa.gov/opa/programintegrity/index.html (last visited Apr. 30, 2021).
[21] *See* OPA, Program Integrity, Audits of Covered Entities Results *at* https://hrsa.gov/opa/programintegrity/index.html (last visited Apr. 30, 2021)
[22] OPA, Clarification of HRSA Audits of 340B Covered Entities, Release No. 2012-1.1 (Feb. 8, 2013), https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/auditclarification020813.pdf.
[23] *See* OPA, Program Integrity, *supra* note 20.
[24] Manufacturer Audit Guidelines and Dispute Resolution Process 0905-ZA-19, 61 Fed. Reg. 65,406, (Dec. 12, 1996).

PBMs must make up the difference somehow so they reduce payment on the drugs that, in their view, are the source of the problem.

Covered entities are unsympathetic to PBMs' rationale for cutting 340B reimbursement. PBM rebate arrangements with manufacturers are private transactions that, according to safety net providers, are driven more by an interest in increasing profits for PBMs and plan sponsors than lowering costs for patients. For covered entities, losing rebate dollars is a problem of the PBMs' own making and does not justify shifting the revenue loss to safety net providers. And there is evidence that HRSA agrees with covered entities on this point. HRSA has gone on record to express its concern that discriminatory reimbursement, if left unchecked, will undermine the purpose of the 340B program. Apexus, which is under contract with HRSA to provide 340B technical assistance and other services through its 340B Prime Vendor Program, has issued an informational paper that cautions that some private payers have been issuing contracts to 340B covered entities with significantly lower reimbursement than they would offer other retail pharmacies. The paper portrays these discriminatory practices as problematic.[25]

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. HRSA explains that "[i]f the 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."[26] Indeed, 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 provide "more comprehensive services."[27] 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.

Covered Entity Advocacy Against PBMs

Covered entities have engaged in several strategies at both the federal and state levels to combat discriminatory reimbursement by PBMs. At the federal level, covered entities reached out to HRSA with the hope that, as the federal agency charged with implementing the 340B program, it would be in a position to help. HRSA acknowledged the threat discriminatory reimbursement poses to the 340B program but declined to take action citing its lack of authority.[28] Federal legislative efforts to address

[25] Apexus, *340B & Medicaid,* 1, https://www.dropbox.com/s/rfn4jbf4dz86pcy/Apexus%20-%20340B%20and%20Medicaid%20%28D0687631%29.pdf?dl=0. Apexus has also issued guidance that encourages covered entities and payers to reach mutually beneficial "alternative business solution[s]". Apexus, FAQ 1336 https://www.340bpvp.com/hrsa-faqs/faq-search?Ntt=1336 (last modified Nov. 10, 2014).

[26] HRSA, *Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act*, 14 (July 2005), https://www.hrsa.gov/sites/default/files/opa/programrequirements/forms/hemophiliatreatmentcenter340bmanual.pdf.

[27] H.R. Rep. 102-384, 102d Cong., pt. 2, at 12 (2nd Sess. 1992).

[28] Letter from Krista Pedley, Director of OPA, to Greg Doggett, Associate Counsel for the Safety Net Hospitals for Pharmaceutical Access (Nov. 30, 2011), https://www.340bhealth.org/images/uploads/OPA_Response_to_Argus_Letter_113011.pdf; Letter from Joyce G.

the problem have also fallen short, at least so far. At least one bill prohibiting 340B discriminatory reimbursement has been introduced in Congress, but the bill was never enacted.[29] As a result, covered entities have increasingly sought relief at the state level.

Some states have enacted any willing pharmacy (AWP) laws that, among other things, prohibit PBMs from applying different terms and conditions on pharmacies except in specified circumstances. Although these laws were not specifically designed to address the problem of 340B discriminatory reimbursement, some of them have strong enough language to afford protection. Mississippi, for example, has a particularly strong AWP law. The relevant language states:

> (3) A health insurance plan, policy, employee benefit plan or health maintenance organization may not:
> (a) Prohibit or limit any person who is a participant or beneficiary of the policy or plan from selecting a pharmacy or pharmacist of his choice who has agreed to participate in the plan according to the terms offered by the insurer.
> (5) .... All pharmacies in the geographical coverage area of the plan shall be eligible to participate *under identical reimbursement terms for providing pharmacy services*, including prescription drugs.[30]

A covered entity in Mississippi could invoke this law to challenge a PBM contract that contains reduced reimbursement rates for 340B drugs or other 340B-specific barriers. Arkansas, Delaware, North Carolina, Illinois, Maine, New Jersey, South Dakota, Tennessee, and Virginia have similarly strong AWP and consumer protection laws.[31] However, because these laws were not drafted with the 340B program in mind, PBMs can argue that their standard non-340B contracts should not extend to pharmacies dispensing 340B drugs due to the regulatory and operational issues unique to the 340B program.

The most effective solution for fighting discriminatory reimbursement at the state level is to mobilize an advocacy campaign to convince a state legislature to enact a statute specifically prohibiting PBMs from discriminating against 340B pharmacies in their contracting and reimbursement practices. A growing number of covered entities have pursued this approach with success. To date, ten states have passed laws prohibiting PBMs and other payers from reimbursing 340B providers and their pharmacies less than is paid to non-340B entities or discriminating against 340B entities in other ways. West Virginia passed such a law in 2019. It states:

> A pharmacy benefit manager, or any other third party, that reimburses a 340B entity for drugs that are subject to an agreement under 42 U.S.C. §256b *shall not reimburse the 340B entity for pharmacy-dispensed drugs at a rate lower than that paid for the same drug to pharmacies similar in prescription volume that are not 340B entities,* and shall not assess any fee, charge-back, or other adjustment upon the 340B entity on the basis that the 340B entity participates in the program...[32]

Somsak, Associate Administrator of HRSA to Representative Tim Murphy (Dec. 22, 2011), https://www.dropbox.com/s/8otkkj08lacrwrh/12-22-11%20LTR%20from%20HRSA%20RE%20340b.pdf?dl=0.

[29] SERV Communities Act, H.R. 6071, 115th Cong. (2018).

[30] Miss. Code Ann. § 83-9-6 (emphases added).

[31] Ark. Code Ann. § 23-99-204; Del. Code Ann. tit. 18, § 7303; N.C. Gen. Stat. § 58-51-37; 215 Ill. Comp. Stat. Ann. 134/72; Me. Rev. Stat. Ann. tit. 24-A § 4317; N.J. Stat. Ann. § 17B:26-2.1i; S.D. Codified Laws § 58-18-37; Tenn. Code Ann. § 56-7-2359; Va. Code Ann. § 38.2-3407.7.

[32] West Virginia SB 489 (emphasis added); W. Va. Code § 33-51-9(d).

The 340B advocacy organization RWC-340B tracks state legislation prohibiting discriminatory reimbursement and has prepared a comprehensive chart identifying and describing such laws. The RWC-340B chart is available at https://www.rwc340b.org/wp-content/uploads/2021/04/Chart-of-340B-Discriminatory-Reimbursement-State-Laws.pdf.

It is important to note that, although collaboration among covered entities and covered entity groups can strengthen advocacy efforts, it can also raise concerns about collusion and group boycotts in violation of state and federal antitrust laws. For this reason, covered entities should avoid suggesting that purchasers engage or refrain from engaging in negotiations with a given PBM or payer. They should also avoid sharing pricing information, contract terms or fee arrangements. These risks can be avoided by working with state and national advocacy organizations because collaboration as part of an advocacy effort is immune from antitrust liability.