APhA
American Pharmacists Association

May 25, 2022

The Honorable Lina Khan
Chair
Federal Trade Commission (FTC)
600 Pennsylvania Avenue, NW
Washington, DC 20580

RE: Solicitation for Public Comments on the Business Practices of PBMs and Their Impact on Independent Pharmacies and Consumers

Dear Chair Khan,

Thank you for the opportunity to address the FTC on how the business practices of PBMs negatively impact our nation's pharmacists and our patients.

APhA is the only organization advancing the entire pharmacy profession. Our expert staff and strong volunteer leadership, including many experienced pharmacists, allow us to deliver vital leadership to help pharmacists, pharmaceutical scientists, student pharmacists, and pharmacy technicians find success and satisfaction in their work while advocating for changes that benefit them, their patients, and their communities.

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I. Background

As you know, the PBM marketplace is highly concentrated where over three-quarters of all equivalent prescription claims are processed by only **three vertically merged** companies: CVS Health (including Caremark and Aetna), Express Scripts (Cigna and Ascent Health Services), and OptumRx (UnitedHealth), which has increased barriers to market entry, raised prescription drug costs, and reduced choice for consumers and purchasers.[1] For clarification, the top six PBMs handle **more than 96% of total U.S. equivalent prescription claims (77% to the top 3 vertically merged PBMs).**[2] Ample and growing data analysis clearly shows increasing evidence that consolidation of PBMs with pharmacies and vertical integration in the healthcare space has led to increases in purchasers' and patients' drug prices through price discrimination, utilization of harmful retroactive direct and indirect remuneration (DIR) fees, and other "clawback" mechanisms on pharmacies, use of "list prices," "spread pricing," and "patient steering," for brand, generic and specialty drugs and to PBM-affiliated pharmacies.[3]

Vertically integrated PBMs can increase the costs of its rivals in either the upstream or downstream market.[4] Such a foreclosure effect can raise prices and require that firms seeking to enter one of the markets enter both markets which significantly increases the difficulty of entry. As a result, vertical PBM mergers that reduce the actual or potential number of competitors are likely to create serious competitive concerns. An increasing consolidated vertically merged healthcare marketplace has led to the big three vertically merged PBM companies of today which negates adding new market entrants that will be able to compete at the same level of competition in the healthcare space. It also discourages new market entrants as the big three vertically merged PBMs control such high market share. For example, such consolidation acts as a deterrent to smaller PBMs and community pharmacies' use of a Pharmacy Services Administrative Organizations (PSAOs) to contract on their behalf. These PSAOs are no match for the PBMs. In 2013, the Government Accountability Office (GAO) conducted a study on the role and ownership of PSAOs and stated that "over half of the PSAOs we spoke with reported having little success in modifying certain contract terms as a result of negotiations. This may be due to PBMs' use of standard contract terms and the dominant market share of the largest PBMs. Many PBM contracts contain standard terms and conditions that are largely non-negotiable."[5]

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[1] Drug Topics. The Top Pharmacy Benefit Managers of 2020: Vertical Integration Drives Consolidation. April 6, 2021, available at: https://www.drugchannels.net/2021/04/the-top-pharmacy-benefit-managers-pbms.html

[2] Ibid.

[3] APhA Internal Analysis.

[4] Gilman, AJ, Sheth, A. Antitrust Analysis of Vertical Health Care Mergers. Practical Law. April 1, 2020, available at: https://www.crowell.com/files/20200401-Antitrust-Analysis-of-Vertical-HC-Mergers.pdf

[5] GAO-13-176 The Number, Role, and Ownership of Pharmacy Services Administrative Organizations. February 28, 2013, available at: https://www.gao.gov/products/GAO-13-176

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According to FTC's 2010 vertical and horizontal merger guidelines, "[t]he Agencies are likely to challenge a merger if the following three conditions are all met: (1) the merger would significantly increase concentration and lead to a moderately or highly concentrated market; (2) that market shows signs of vulnerability to coordinated conduct; and (3) the Agencies have a credible basis on which to conclude that the merger may enhance that vulnerability."[6] For PBM vertical healthcare mergers, as explained in these comments, all three of these conditions are clearly met.

While the FTC has taken action on vertical mergers in the past, no action has been taken by antitrust regulators in any of the recent multi-billion-dollar PBM vertical mergers.

In light of the increasing availability of data (detailed below) on the inherent conflicts of interest resulting from PBM vertical healthcare mergers, action is required from the FTC prohibiting vertical mergers of PBMs with pharmacies using the "unfair methods of competition authority" of the Federal Trade Commission Act (FTCA), the Administrative Procedure Act (APA), and related statutes to bring enforcement actions to prohibit and separate healthcare vertical mergers of PBMs with pharmacies.

The PBM industry claims that the research detailed below selectively chooses specific drugs and drug pricing data. These limitations in data are due to the opaqueness by the vertically merged PBM industry. Recognizing these limitations, due to PBM and industry practices, the Departments of Health and Human Services (HHS), Labor (DOL), and Treasury (DOT)) have finalized rules requiring all insurers in the individual and group markets to make available to the public, including stakeholders such as consumers, researchers, employers, and third-party developers, three separate machine-readable files that include detailed pricing information including the *in-network* [emphasis added] negotiated rates and *historical "net prices,"* [emphasis added] inclusive of any PBM-hidden "*reasonably allocated"* [emphasis added] rebates, discounts, chargebacks, fees, and any additional price concessions received by the plan or issuer with respect to the prescription drug or prescription drug service," for all covered prescription drugs by plan or issuer at the pharmacy location level.[7] Even with this action, the big three vertically merged PBMs will still be able to prepare historical net pricing data ("retrospective average amount") using different methods, making comparisons less effective, which only adds to the urgency for immediate federal regulatory action by the FTC to prevent bad actors and remove the unfair or deceptive acts and/or practices or actions that limit true competition.

[6] DOJ/FTC. Horizontal Merger Guidelines. August 19, 2010, available at: https://www.justice.gov/atr/horizontal-merger-guidelines-08192010
[7] DOT/DOL/HHS. Transparency in Coverage. Final Rule. November 12, 2020, available at: https://www.regulations.gov/document/HHS_FRDOC_0001-0784

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II. Vertically merged PBMs rely on "fake prices" to maximize arbitrage

For pharmacies, "list prices," for prescription drugs are wildly overinflated relative to their actual cost (for a markup of about 20% or more).[8] PBMs use those list prices or average wholesale price (AWP), also known in the industry as "ain't what's paid," as the basis for their pricing guarantees to pharmacies and plan sponsors. AWP does not include buyer volume discounts or rebates often involved in prescription drug sales and is subject to manipulation by manufacturers or even wholesalers.[9] Brand name drugs have high AWPs that are offset by negotiated rebates and discounts that make those net prices much lower. Generic drugs have high AWPs (derived from brand drugs[10]) that in no way reflect the actual prices pharmacies pay to acquire those drugs. **In both regards, the "actual" prices of both brand and generic drugs are hidden by PBMs from the plan sponsor and patient.**

A. Vertically Merged PBM Practices: Price Discrimination

Price discrimination is a strategy that charges customers different prices for the same product based on what the seller thinks they can get the customer to agree to.[11] PBM and drug manufacturers negotiate a "net price," but the extent to which that true net price is captured by the payer depends on the payer's access to information and negotiating leverage. Hidden rebates are the key enabler allowing the drug supply chain to capture benefits of drug price discrimination.[12]

Recent analysis of data for a group of small self-ensured employers found that total group spending on brand name drugs exceeded $110 million in 2018, including $5 million in rebates. In a world free from drug price discrimination, where all employers received the "best commercial price" (Federal Supply Schedule), their rebates would have been $30 million. PBMs (and/or affiliated insurance companies) appear to have retained these rebates.[13] The larger the

[8] Thomson Reuters MicroMedex. Website. AWP Policy. Accessed October 30, 2020, available at https://www.drugs.com/article/average-wholesale-price-awp.html?msclkid=d6c3adf8d13711eca9887abba687474c

[9] Gecarelli GM. Average Wholesale Price for Prescription Drugs: Is There a More Appropriate Mechanism? National Health Policy Forum. Issue Brief. No. 775. Accessed Sept. 20, 2020, available at https://www.ncbi.nlm.nih.gov/books/NBK561162/?msclkid=7ef624c5d13811ec916c6800ded152e1

[10] 46Brooklyn. Drug price increases have slowed, but new analysis shows launch prices pushing costs into orbit. October 15, 2019, available at: https://www.46brooklyn.com/research/2019/10/11/three-two-one-launch-rfmyr

[11] FTC. Price Discrimination: Robinson-Patman Violations. Guide to Antitrust Laws. Accessed November 23, 2021, available at: https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/price-discrimination-robinson-patman

[12] See, https://www.drugchannels.net/2021/03/drug-channels-news-roundup-march-2021.html

[13] APhA Internal Analysis.

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gap between "list," and "net," prices, the greater disparity there is between the haves and have nots.

B. Vertically Merged PBM Practices: Using List Prices (Medicaid)

When comparing "list prices," (AWP) to actual pharmacy acquisition costs under the National Average Drug Acquisition Cost (NADAC), which is used by Medicaid programs and intended to be a national average of the prices at which pharmacies purchase a prescription drug from manufacturers or wholesalers, including some rebates, the Elsevier data (which is the industry gold-standard) from January 2017 to December 2020, shows, overall, actual generic drug prices (NADAC) go down (a 20% decrease), however, their sticker or list prices (AWP) go up (showing only 14% increase).[14] PBMs use this sticker/list price (AWP), a subjective, opaque price to provide the latitude to push dollars around underneath the top-line price.

C. Vertically Merged PBM Practices: Spread Pricing

"Spread pricing," is the difference between the reimbursements paid to pharmacies and the rates reported back to the payer where the PBM retains the difference. An Ohio Medicaid audit revealed $244 million from PBM "spread pricing" from Q2 2017 to Q1 2018.[15] Ohio's state Auditor conducted his own audit and found that spread equated to 31.4% of gross generic spending in Ohio Medicaid managed care.[16]

In a separate analysis of Medicaid managed care pharmacy claims in Michigan, for example, oral solid generics also showed that while drug costs going down ($6.09 in 2018 Q-1) and pharmacy margins are going down (pharmacy revenue per prescription $6.58 Q-1), vertically merged PBM spreads/profits are going up (managed care cost per prescription $9.98). This is unnecessarily increasing states Medicaid costs. Spread pricing also allows pharmacy-affiliated vertically merged PBMs to shift traditional pharmacy margins to the PBM side of their enterprise.[17]

An additional analysis commissioned by the Arkansas Insurance Commissioner to audit/review spread pricing and other reimbursement activities of PBMs providing prescription coverage for state funded health plans found that the PBM Express Scripts was charging the health benefit plan an estimated 15.26% more than was being paid to the pharmacies. In addition, the analysis

[14] Ibid.
[15] Ibid.
[16] Ibid.
[17] Ibid.

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showed that both CVS Caremark (9.71%) and ESI (4.55%) assessed DIR or "clawback" fees to the pharmacies during the audit timeframe. [18]

D. Vertically Merged PBM Practices: Patient Steering

Small Commercial Dataset

Another practice of vertically merged PBMs is drug "steering," which is the pushing of particular medications by vertically merged PBMs to their owned pharmacies. For example, analysis of the brand drug claims from a 2018 small commercial dataset, divided into drugs above and below $2,000, found PBM-owned pharmacies filled an overwhelming number of the expensive medications > $2,000 per claim (total 76%), but only a small fraction of the cheaper brand medications with cost < $2,000 per claim (total 16%).[19]

An additional analysis of the same small commercial payer dataset also found steering to vertically merged PBM-affiliated pharmacies with specialty generics. With generics, the PBM can set the price it chooses to pay its affiliated pharmacy with no oversight due to opacity of price. In 2018, vertically-merged PBMs in this data set directed more than half of $1,000+ generic claims to affiliated pharmacies and paid themselves a weighted average margin of $3,448 per claim.[20]

Medicaid Managed Care Plans

A separate analysis of a percentage of brand drug claims filled by four affiliated pharmacy Florida Medicaid managed care plans (excluding 340B) found that, in Florida, specialty drugs (<$2,000 per prescription (brand drug AWP discount) are not only steered to affiliated pharmacies, they are also filled at more expensive PBM-affiliated pharmacies. For example, analysis reveals that one brand specialty drug, with 80% filled at a PBM-affiliated pharmacy would have resulted in over $1.5 million in savings on that drug alone if Florida Medicaid would have recognized the non-affiliated pharmacy cost on the claims within the affiliated pharmacies.[21]

Additional analysis shows that, in 2017, when a vertically merged PBM became the provider of a Medicaid health plan's PBM services in Florida, that month, the vertically merged PBM dramatically increased the rates reported on claims dispensed at its PBM-affiliated pharmacies on Florida Medicaid's #1 spend generic antipsychotic. At the same time, it dramatically reduced

[18] Lewis and Ellis Actuaries and Consultants. Et. al. Limited Scope Examination of Pharmacy Benefit Managers. Prepared for the Arkansas Insurance Department. July 27, 2020.
[19] APhA Internal Analysis.
[20] Ibid.
[21] Ibid.

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the rates paid to all other Florida pharmacies. Overall, in 2018, 94% of the margin (revenue above acquisition cost) reported on all generic drug claims by the Medicaid health plan was reported on claims dispensed at the vertically merged PBM-affiliated pharmacies.[22]

E. Vertically Merged PBM Practices: Specialty Steering

Utilization distortions of the prescription drug marketplace are all about getting lucrative specialty drugs into pharmacies owned by the vertically merged insurer and/or PBM. In commercial plans and Medicaid, this is accomplished by directly specifying the specialty pharmacy that will fill all "specialty" drugs – where specialty is defined by the vertically merged insurer/PBM. A recent analysis conducted by the American Society of Health-System Pharmacists (ASHP) identified that more than 70% of health systems reported that their specialty pharmacy was "frozen out or blocked by payers" from dispensing specialty drugs, highlighting the scope of the issue.[23]

In Medicare Part D, this is accomplished through a "loss leader" strategy, where: 1) vertically merged PBMs price generic maintenance drugs very cheaply for patients at preferred and/or PBM-owned pharmacies to pull patients over from standard pharmacies 2) charging inflated prices on specialty drugs to Part D after patients have been lured in with cheap generics and 3) "clawing" back considerable DIR fees from community pharmacies that have chosen to remain "preferred."

<u>Medicare Part D</u>
Specialty steering in Medicare Part D starts with cheap (or free) generics. For example, analysis shows for a hypothetical patient enrolled in a Part D plan who fills two inexpensive generic maintenance medications if the patient decided to go to an independent pharmacy contracted through a PSAO (non-preferred) they would have payed $90 for medications that cost $13.93 (NADAC). Afterwards, $50.50 is clawed back by the Part D plan from the pharmacy as a DIR fee.

If the independent pharmacy decides to contract directly with the vertically-merged PBM, total reimbursement for the same two drugs drops to $10.45 – all collected from the patient. There is no DIR fee, but the pharmacy still nets a loss of ($3.48) relative to the actual price (NADAC).

[22] Ibid.
[23] Stubbings, J, Pedersen, CA, Low, K. ASHP National Survey of Health-System Specialty Pharmacy Practice—2020. American Journal of Health-System Pharmacy, Volume 78, Issue 19, 1 October 2021, Pages 1765–1791, August 4, 2021, available at: https://academic.oup.com/ajhp/article-abstract/78/19/1765/6337959

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If the patient moves to a preferred pharmacy (affiliated with the vertically merged PBM) or chooses mail order (from the affiliated PBM), they will have no out-of-pocket cost.[24]

Next, the vertically merged PBM egregiously overprices specialty generics once they have secured the patient. For example, the same plan adds two new specialty (Tier 5) generic drugs to regimen. When it comes to specialty generics, there no longer is an advantage for patients going to the preferred pharmacy. Analysis of Medicare Part D data shows that preferred pharmacies are charging Medicare >$31,000 for these two drugs despite the fact that their actual cost is less than $2,000. In fact, for these two specialty generics, the patient will actually save money going to a standard pharmacy that is direct contracted with the vertically merged PBM. Meanwhile, analysis estimates that an independent pharmacy that has contracted with the vertically merged PBM through a PSAO will be assessed DIR fees of >$26,000 on these two drugs.[25]

Medicaid

In Ohio, after spread pricing was eliminated in Medicaid, analysis shows that vertically merged PBMs began overpaying pharmacies on "specialty" drugs, often steered through their own pharmacies. This enabled the vertically merged PBMs to margin-shift dollars from spread to specialty medications filled at their affiliated pharmacies.[26]

III. The FTC should issue a rule to prohibit vertical mergers of PBMs with pharmacies due to inherent conflicts of interest

As previously stated, in light of the increasing availability and analyses of data on the inherent conflicts of interest and market manipulation of prescription drugs resulting from vertically merged PBMs, a rule is clearly required from the FTC prohibiting PBMs from vertically merging with pharmacies due to inherent conflicts of interest using the "unfair methods of competition, or unfair or deceptive acts or practices in or affecting commerce," authority of the FTCA, the ACA and related statutes to bring enforcement actions to prohibit and separate healthcare vertical mergers of PBMs with pharmacies.

[24] See, Appendix.
[25] APhA Internal Analysis.
[26] APhA Internal Analysis.

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IV. Conclusion

Based on the clear evidence of the lack of competition in the PBM space and the "unfair or deceptive acts or practices" resulting in the manipulation of prescription drugs in the healthcare marketplace, the FTC need to fully utilize its antitrust enforcement authority to prohibit and separate vertical mergers of PBMs with pharmacies. The FTC is the nation's premier antitrust enforcer and in some respects a model of sound government enforcement. However, as stated by a former FTC official, FTC's track record(s) is concerning when it comes to PBMs. [27]

The FTC has a number of tools under the APA and the FTCA,[28] 15 U.S.C. § 45 to initiate a rulemaking to prohibit PBMs from vertically merging with pharmacies due to inherent conflicts of interest. The FTC could bring enforcement actions to prohibit and separate healthcare vertical mergers of PBMs with pharmacies that engage in unfair methods of competition, or unfair or deceptive acts or practices in or affecting commerce, or actions that have affected acquisitions[29] not "in the public interest."[30]

Furthermore, while APhA also supports a new section 6(b) study on the vertically merged PBMs, we already have mountains of data from Medicaid and commercial plans on PBMs' uncompetitive and deceptive trade practices that target patients with chronic conditions and force them to use PBM-owned specialty, mail order, and network pharmacies. The FTC should not allow the PBMs to weaken any FTC 6(b) study by expanding it to "look at the larger supply chain." More importantly, because of the abundance of anti-competitive data, the FTC should not only examine PBMs' anticompetitive practices, but it should end them. PBMs are putting independent pharmacies out of business and creating "pharmacy deserts" in minority and underserved communities, where the neighborhood pharmacy may be the only health care provider for miles.[31] Accordingly, APhA strongly believes the FTC should follow-the data, aided by our full comments above, and take action now.

Thank you for the opportunity to comment on the ways that large, vertically integrated PBMs are affecting drug affordability and access. We look forward to the continuing to work with the FTC to return competition to the PBM and healthcare marketplace in order to protect our nation's

[27] Balto, David. Statement before the U.S. House Judiciary Committee Subcommittee on Regulatory Reform, Commercial and Antitrust Law on "The State of Competition in the Pharmacy Benefit Manager and Pharmacy Marketplace." November 17, 2015, available at: https://docs.house.gov/meetings/JU/JU05/20151117/104193/HHRG-114-JU05-Wstate-BaltoD-20151117.pdf
[28] https://www.ftc.gov/legal-library/browse/statutes/federal-trade-commission-act
[29] Section 7 of the Clayton Act, 15 U.S.C. § 18
[30] See, The Antitrust Procedures and Penalties Act, 15 U.S.C. §§16(b)-(h), available at: https://www.govinfo.gov/content/pkg/STATUTE-88/pdf/STATUTE-88-Pg1706.pdf
[31] Guadamuz, Jenny. Et. al. Fewer Pharmacies In Black And Hispanic/Latino Neighborhoods Compared With White Or Diverse Neighborhoods, 2007–15. Health Affairs. May 2021, available at: https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2020.01699

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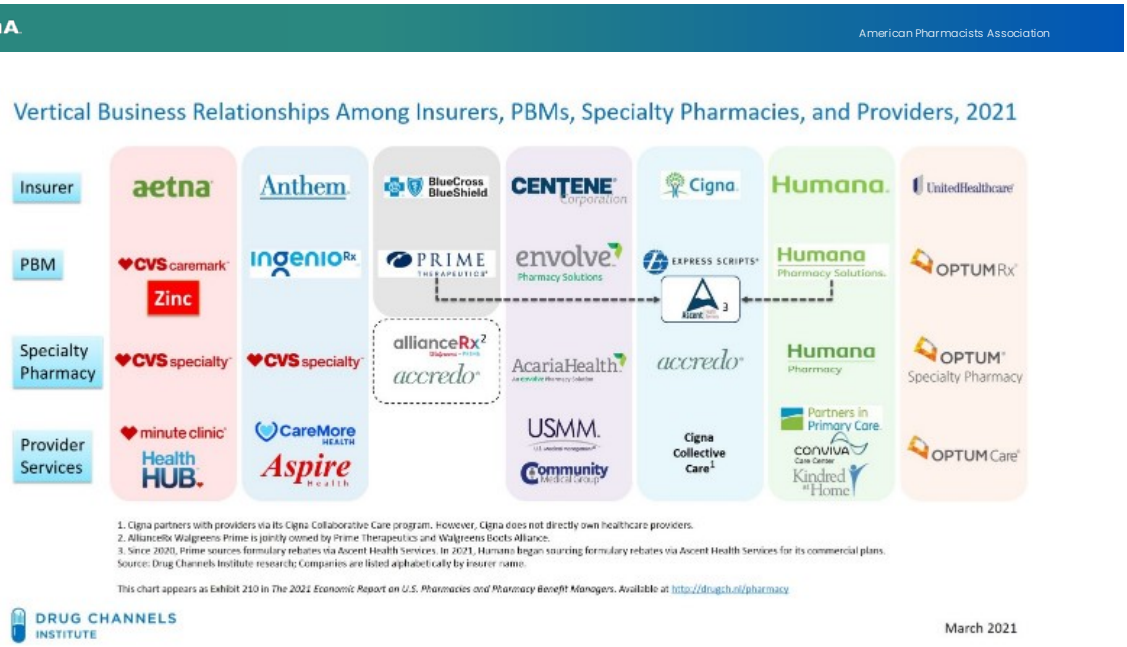
community pharmacies, our patients and promote healthcare equity in rural and underserved communities. If you have any questions, would like to meet with our staff to discuss additional data on the vertically merged PBMs, or require additional information, please contact Michael Baxter, Senior Director, Regulatory Policy at mbaxter@aphanet.org.

Sincerely,

Ilisa BG Bernstein, PharmD, JD, FAPhA
Senior Vice President, Pharmacy Practice and Government Affairs

Appendix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Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies, and Providers, 2021
Insurer
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Provider Services
aetna
Anthem
BlueCross BlueShield
CENTENE Corporation
Cigna
Humana
UnitedHealthcare
CVS caremark
Zinc
ingenioRx
PRIME THERAPEUTICS
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accredo
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Humana Pharmacy
OPTUM Specialty Pharmacy
minute clinic
Health HUB
CareMore HEALTH
Aspire Health
USMM
Community Medical Group
Cigna Collective Care
Partners in Primary Care
conviva Care Center
Kindred at Home
OPTUM Care
1. Cigna partners with providers via its Cigna Collaborative Care program. However, Cigna does not directly own healthcare providers.
2. AllianceRx Walgreens Prime is jointly owned by Prime Therapeutics and Walgreens Boots Alliance.
3. Since 2020, Prime sources formulary rebates via Ascent Health Services. In 2021, Humana began sourcing formulary rebates via Ascent Health Services for its commercial plans.
Source: Drug Channels Institute research; Companies are listed alphabetically by insurer name.
This chart appears as Exhibit 210 in The 2021 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. Available at http://drugch.nl/pharmacy
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March 2021