American Pharmacists Association

AMERICAN PHARMACISTS ASSOCIATION
STATEMENT FOR THE RECORD

BEFORE THE U.S. SENATE JUDICIARY SUBCOMMITTEE ON COMPETITION POLICY, ANTITRUST AND CONSUMER RIGHTS

A PRESCRIPTION FOR CHANGE: CRACKING DOWN ON ANTICOMPETITIVE CONDUCT IN PRESCRIPTION DRUG MARKETS

TUESDAY, JULY 13, 2021

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American Pharmacists Association

Chair Klobuchar, Ranking Member Lee, and Members of the Subcommittee, the American Pharmacists Association (APhA) is pleased to submit the following Statement for the Record for the U.S. Senate Judiciary Subcommittee on Competition Policy, Antitrust, and Consumer Rights Hearing, entitled, "A Prescription for Change: Cracking Down on Anticompetitive Conduct in Prescription Drug Markets."

APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists in all practice settings, including community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care and enhance public health.

Pharmacies are where millions of Americans are first exposed to the impact of complex pharmaceutical pricing policies or confronted with changes in coverage, formularies, prior authorization, deductibles, and co-payments or co-insurance, many of which they did not know existed or understand.

Every day, pharmacists help our patients navigate through confusing and convoluted policies related to the cost and coverage of their medications and management of their out-of-pocket costs. Pharmacists are not compensated for this time or directly for most of our patient care services that support optimization of medication therapy.

Our comments focus on the following areas – cost versus value, anti-competitive actions by pharmacy benefit managers (PBMs), drug shortages, and importation concerns.

Cost Versus Value

As drugs become more expensive, complex, and personalized, the need to optimize their impact also increases. In order to get the greatest benefit from medications, patients must understand how to use their medications safely and effectively, and pharmacists are best positioned to help patients optimize the medication therapies available to them. Pharmacists have more medication-related education and training than any other health care professional. Pharmacists provide medication management services, which are especially important for patients who have complex care plans, take multiple drugs, or have chronic conditions, which disproportionately impact minority and underserved communities. Ultimately, the most expensive medication is one that is inappropriate for a patient or used incorrectly.

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The COVID-19 pandemic has highlighted how accessible pharmacists are and how they can be leveraged to improve the health of communities. Pharmacists and pharmacies' lights stayed on from the start of the pandemic and have unquestionably solidified pharmacies as essential components of public health infrastructure.

Many of the new authorities and flexibilities provided related to pharmacists' patient care services during COVID-19, including pharmacists' ability to order, authorize, test, treat, and administer immunizations and therapeutics against COVID-19 and other infectious diseases are temporary federal authorizations under the Public Readiness and Emergency Preparedness Act (PREP Act),[1] which can be revoked at any time. **Thus, as the Committee understands, Congress needs to act immediately to ensure these pharmacist patient care services authorities are maintained as they have significantly increased patient access and improved care while lowering health care costs and saving lives.**

Unfortunately, despite that many states and Medicaid programs are turning to pharmacists to increase access to health care and address medication-related costs, Medicare Part B does not cover many of the impactful and valuable patient care services pharmacists can provide. Pharmacists are trained to do more than place medication in a container. While over 90% of Americans live within 5 miles of a community pharmacy[2], many of our nation's seniors are medically underserved. As proven during the COVID-19 pandemic, pharmacists are an underutilized and accessible health care resource who can positively affect beneficiaries' care[3] and the entire Medicare program.

Accordingly, APhA strongly urges the Subcommittee to include S. 1362, the *Pharmacy and Medically Underserved Areas Enhancement Act* in the Committee's legislative package to allow pharmacists to deliver vital patient care services in medically underserved areas to help break down the barriers to achieving health care equity in this country, improve patient care, health outcomes, the impact of medications,[4] and consequently, lower health care costs and extend the viability of the Medicare program.

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[1] ASPR. Expanding the COVID-19 Vaccination Workforce. July 2021, available at: https://www.phe.gov/emergency/events/COVID19/Documents/covid19-vaccination-wrkfrc-factsheet-508.pdf

[2] NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department.

[3] CMS. Evidence Supporting Enhanced Medication Therapy Management. Center for Medicare and Medicaid Innovation. 2016, available at: https://innovation.cms.gov/Files/x/mtm-evidencebase.pdf

[4] *See,* Avalere Health. Exploring Pharmacists' Role in a Changing Healthcare Environment. May 2014, available at: http://avalere.com/expertise/life-sciences/insights/exploring-pharmacists-role-in-a-changing-healthcare-environment Also, *See,* Avalere Health. Developing Trends in Delivery and Reimbursement of Pharmacist Services. October 2015, available at: http://avalere.com/expertise/managed-care/insights/new-analysis-identifies-factors-that-can-facilitate-broader-reimbursement-o

Specifically, S. 1362 would enable pharmacists to deliver Medicare Part B services that are already authorized by their respective state laws. These services include, but are not limited to:

- Medication management;
- Management of chronic conditions, such as diabetes and hypertension, and related medications;
- Cholesterol testing;
- Point of care testing (e.g., COVID-19, influenza, strep);
- Immunization screening and administration not currently covered by Medicare Parts B and D;
- Tobacco cessation services; and
- Transition of care services.

The importance of medication-related services cannot be overstated, especially in the Medicare program. Medications are the primary method of managing chronic disease that disproportionately impacts minority and underserved populations, which are involved in 80 percent of all treatment regimens. For example, regarding access to cancer medications, African Americans have the highest mortality rate of any racial and ethnic group for all cancers combined and for most major cancers, [5] and face greater obstacles to cancer prevention, detection, treatment, and survival. Overall, the United States spends nearly ***$672 billion*** annually on medication-related problems and nonoptimized medication therapy, including nonadherence.[6] Accordingly, not only will this legislation increase beneficiaries' access to health care; it will help improve their outcomes—particularly those impacted by medications.

We also encourage the Subcommittee, when considering policy changes to lower drug prices, to look beyond isolated components of health care to determine cost and value. Because health coverage is frequently analyzed by the benefit type such as inpatient, outpatient, and drug coverage, a patient's overall services, costs, and outcomes may never be reviewed comprehensively. Policies cannot continue to separately consider drug and medical coverage and their related costs and outcomes if we are to achieve true value in health care. Current coverage and payment policies related to prescription drugs place incentives on the short-term, focusing on cost containment for the product rather than weighing the overall clinical benefit to the patient and the impact on their medical costs. Breaking down the many silos within our

[5] HHS. Office of Minority Health. Cancer and African Americans. Last Modified: 2/28/2020, available at: https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=16

[6] Watanabe, Jonathan H. Et. al. Cost of Prescription Drug–Related Morbidity and Mortality. Annals of Pharmacology. First Published March 26, 2018, available at: http://journals.sagepub.com/eprint/ic2iH2maTdI5zfN5iUay/full

health care system will help address the billions of dollars spent on medication-related problems—many of which are preventable.[7]

PBMs

Both Congress and multiple Administrations have pointed out ongoing anti-competitive PBM practices in Medicare and Medicaid that are negatively impacting patient costs, care, and access. We would specifically like to commend Chair Klobuchar for her leadership in co-sponsoring S.2554, the Patient Right to Know Drug Prices Act (Public Law No: 115-263) that prohibits a health insurance plan or PBM from restricting a pharmacy from informing an enrollee of any difference between the out-of-pocket cost of a drug under the plan and the cost of the drug without health insurance coverage. Unfortunately, the problems do not stop there, as providers, employers, and taxpayers are also adversely affected by PBMs as well.

The PBM marketplace is highly concentrated,[8] (See, Appendix #1) whereby roughly three-quarters of all equivalent prescription claims are processed by only three vertically merged companies. This concentration has increased barriers to market entry, ballooned prescription drug expenditures, exacerbated cost inequities, and reduced choice for consumers and purchasers. Ample and growing data analysis clearly show 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 use of hidden "clawbacks," like direct and indirect remuneration (DIR) fees, artificially inflated list prices, price discrimination, spread pricing, mounting price shifts and administrative fees, and patient steering for brand, generic and specialty drugs and to PBM-affiliated pharmacies.

President Biden recently issued an "Executive Order [EO] on Promoting Competition in the American Economy,"[9] calling "on the leading antitrust agencies, the Department of Justice (DOJ) and Federal Trade Commission (FTC), to enforce the antitrust laws vigorously and recognizes that the law allows them to challenge prior bad mergers," with a focus on healthcare markets.[10]

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[7] Ibid.

[8] Fein, Adam. Drug Channels. Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies, and Providers, 2021, The 2021 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. Section 12.4.1. March 21, 2021, available at: https://www.drugchannels.net/2021/03/drug-channels-news-roundup-march-2021.html

[9] The White House. Executive Order on Promoting Competition in the American Economy. July 9, 2021, available at: https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/

[10] https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/09/fact-sheet-executive-order-on-promoting-competition-in-the-american-economy/

The EO partners well with the new leadership at the FTC which recently voted to authorize priority investigations into vertically merged PBMs as a key enforcement priority, whom the independent anti-trust agency describes as "repeat offenders."[11]

APhA would be pleased to serve as a resource to the Subcommittee to provide examples of PBM abuses to assist in the forthcoming report also included in the EO directing, "HHS to issue a comprehensive plan within 45 days to combat high prescription drug prices and price gouging."

APhA looks forward to working with the Subcommittee, Biden Administration, and the FTC to combat the harmful impacts of vertically merged PBMs on pharmacists and our patients—consolidation which has led to increases in patients' drug prices at the pharmacy counter through utilization of DIR fees and other "clawback" mechanisms, delaying prescribed treatments through patient steering and prior authorization, and limiting options for patients by controlling access to insurance networks.

A few of these harmful PBM practices include:

- DIR Fees: The Centers for Medicare and Medicaid Services (CMS) has acknowledged a notable growth in PBMs' use of harmful DIR fees, **which have increased more than 91,500 percent between 2010 and 2019[12] (double the previous 45,000% increase between 2010 and 2017 in 2 years).** Yet, CMS has failed, on multiple occasions, to address the ongoing threat to patients' access to trusted community pharmacists. **Congress needs to act.** As the Subcommittee understands, DIR fees were originally designed to capture rebates and other mechanisms not included at the point-of-sale.[13] However, the term "DIR fees" have been re-defined by PBMs and are now being used beyond their original purpose to retroactively adjust pharmacies' payment months after the sale, often resulting in reimbursement that is below the cost of drug acquisition by pharmacies. There is simply no connection between price concessions given by drug manufacturers to PBMs and the prices paid by pharmacies to their wholesalers. Thus, DIR fees "recovered" from pharmacies by PBMs are illogical (i.e., recovering money

[11] FTC. FTC Authorizes Investigations into Key Enforcement Priorities. July 1, 2021, available at: https://www.ftc.gov/news-events/press-releases/2021/07/ftc-authorizes-investigations-key-enforcement-priorities
[12] CMS. Justification of Estimates for Appropriations Committees. Fiscal Year 2022. May 2021, available at: https://www.cms.gov/files/document/fy2022-cms-congressional-justification-estimates-appropriations-committees.pdf
[13] *See,* CMS. Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program. Final Rule. 83 FR 16440. April 16, 2018. Available at: https://www.federalregister.gov/documents/2018/04/16/2018-07179/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare

from pharmacies that pharmacies did not "receive" in the first place). Because current point-of-sale prices or copays paid by beneficiaries can be based on the contracted price before DIR fees are extracted, many beneficiaries pay higher out-of-pocket costs for prescription drugs. CMS has cited numerous research that further suggests higher cost-sharing can impede beneficiary access and adherence to necessary medications, which leads to poorer health outcomes and higher overall medical care costs for beneficiaries and Medicare. Therefore, APhA strongly urges the members of the Subcommittee to work with their colleagues to pass the "Pharmacy DIR Reform to Reduce Senior Drug Costs Act (S. 1909)," in the Senate to move retroactive pharmacy DIR fees to the point of sale to ensure consistency throughout the Part D benefit and limit this abusive practice.

- Artificially Inflated List Prices: Within the prescription drug supply chain, "list prices" for prescription drugs are significantly overinflated relative to their actual cost (for a markup of about 20% or more).[14] PBMs use those list prices or average wholesale price (AWP), 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.[15] 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) that in no way reflect the actual prices pharmacies pay to acquire those drugs.[16] In both regards, the "actual" prices of both brand and generic drugs are hidden by PBMs from the plan sponsor, patient, and pharmacies.

- Price Discrimination: This 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. PBMs and drug manufacturers negotiate a "net price," but the extent to which that true net price is captured by the payer (CMS/plans, etc.) depends on the payer's access to information and negotiating leverage. As a result, PBMs pass along some discounts and rebates to some clients but choose to retain those rebates from others. Viewed from the lens of a patient, a PBM can use all their covered patient lives as a means to elicit larger rebates from drugmakers, but they can then turn around and require those same patients to pay the full list price of their medications through use of high deductible

[14] Thomson Reuters MicroMedex. Website. AWP Policy. Accessed October 30, 2020 at https://www.micromedexsolutions.com/micromedex2/4.31.0/WebHelp/RED_BOOK/AWP_Policy/AWP_Policy.htm
[15] 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 at https://www.nhpf.org/library/issue-briefs/IB775_AWP_6-7-02.pdf
[16] 46Brooklyn. Inside AWP: The arbitrary pricing benchmark used to pay for prescription drugs. November 8, 2018, available at: https://www.46brooklyn.com/research/2018/11/7/visualizing-how-aint-whats-paid-awp-really-is

plans. Hidden rebates are the key enabler allowing the drug supply chain to capture the benefits of drug price discrimination.

- Spread Pricing: This is the difference between the reimbursements paid to pharmacies and the rates reported back to the payer where the PBM retains the difference. Numerous studies and audits have found spread pricing amounts ballooning to excessive amounts, reaching more than $8 per prescription in some instances. While spread pricing adds unnecessary costs for plan sponsors, it also raises anti-competitive issues, as PBMs (who often have pharmacies of their own) can directly profit off underpayments to network pharmacies. As more states eliminate spread behavior from their Medicaid managed care programs,[17] APhA believes CMS and other plan sponsors should follow suit.

- Mounting Administrative Fees: As scrutiny has mounted on costly PBM practices like DIR fees, rebate capture, and spread pricing, the industry has been able to evade cost containment efforts by recategorizing that revenue as something different or by shifting those dollars to other lesser-known layers of their vertically integrated enterprise. For example, as scrutiny grew on drug rebates, PBMs began pushing more of the drugmaker concessions to "rebate aggregators" and in addition, relabeling many of those "rebates" instead as "fees."[18] And as controversy grows on the increasingly bloated DIR fees that PBMs assess on pharmacy practices, PBMs have begun diversifying and recategorizing their "clawbacks," as "effective rates."[19]

- 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. As an example, a 2020 analysis of the Florida Medicaid program uncovered specialty drug steering issues. For pharmacy claims dispensed at retail pharmacy groups, the reported weighted average margin was $2-$4 per prescription. Meanwhile, claims dispensed at PBM/MCO-owned specialty pharmacies had a reported weighted average margin of up to $200 per prescription. The study also found growing trends of expensive brand prescriptions being steered to PBM/MCO-affiliated pharmacies, and once dispensed at those affiliated pharmacies, the claims appeared to

[17] Milliman. Florida Agency for Health Care Administration. Pharmacy Benefit Manager Pricing Practices Affecting Statewide Medicaid Managed Care Program. December 2020, available at: https://cdn.ymaws.com/www.floridapharmacy.org/resource/resmgr/docs_2021_legislative_session/milliman_report.pdf
[18] https://www.benefitspro.com/2021/04/15/cautionary-tale-plan-sponsors-losing-manufacturer-rebate-dollars-to-pbms-through-rebate-aggregators/?slreturn=20210403162749
[19] https://www.frierlevitt.com/articles/service/pharmacylaw/generic-effective-rate-ger-a-new-type-of-post-sale-clawback-by-pbms/

be more expensive than those filled at other pharmacies. The same study found that despite only accounting for 0.4% of the prescription claim volume, specialty pharmacies affiliated with MCOs and/or PBMs captured 28% of the available pharmacy dispensing margin in 2018, suggesting the growing pressure on non-MCO/PBM-affiliated pharmacy providers, as well as the lack of incentives that exist for affiliated pharmacies increased costs to the state on specialty drugs – the biggest cost driver in the state's drug program.[20]

- Network Access: An additional problem facing some pharmacies' ability to offer low-cost medications to patients is the inability to enter into contracts with PBMs and health plans due to the growth in narrow networks. Accordingly, APhA urges the Subcommittee to pass H.R. 2608, the "Ensuring Seniors Access to Local Pharmacies Act" that would give seniors more convenient access to discounted or "preferred" copays for prescription drugs at their pharmacy of choice. Increasing patient choice will not only improve patients' access to benefits and services, but will also positively impact patient satisfaction and outcomes.

Drug Shortages

Drug shortages are another factor that can negatively affect patients in terms of cost and the availability of their treatments. APhA urges the Subcommittee to consider mechanisms to both better control the price of medications in shortage and improve tracking and prediction systems used to identify drugs in shortage. For example, FDA issued temporary guidance granting flexibility for pharmacists to compound certain necessary medications under sections 503A[21] and 503B[22] for hospitalized patients without patient-specific prescriptions to address COVID-19. Many of our members have told us FDA's compounding flexibility is the only reason hospitals were able to keep up with patient demand. Accordingly, the recent flexibility to compound medications under both sections 503A and 503B are likely to be necessary for the foreseeable future, and we strongly urge the Subcommittee to pass legislation to codify this flexibility to address drug shortages. We believe maintaining stability within the supply chain during the global COVID-19 pandemic is crucial. We strongly urge the Subcommittee to focus on solutions that harness existing relationships with international trading partners to promote supply chain resiliency and diversity while avoiding measures that could undermine our ability to work with the international community. APhA also strongly supports the appropriate prosecution of

[20] 3AA. 2020 Florida Medicaid analysis.
[21] https://www.fda.gov/media/137125/download
[22] https://www.fda.gov/media/137031/download

entities that engage in price gouging and profiteering of medically necessary drug products in response to drug shortages.

Importation Concerns

Although APhA supports Congressional efforts to address patients' medication costs, APhA has significant concerns with turning to drug importation to achieve lower prices. We believe proposals to legalize importation of non-FDA approved prescription drugs is not a comprehensive solution to the complex issue of drug pricing, threatens patient safety, disrupts care, and directly conflicts with efforts by Congress and federal agencies to increase the integrity and security of the U.S. drug supply pursuant to the Drug Supply Chain Security Act (DSCSA). By commingling FDA-approved and imported versions of medicines in the marketplace, drug importation programs would create disruptions and confusion in the supply chain and may limit patient access to medications by complicating insurance coverage and reimbursement at the pharmacy. APhA is also concerned that there is no data or information that demonstrates significant cost savings to American patients from importation programs.

In addition to state or tribe-sponsored drug importation programs, APhA also opposes allowing personal drug importation as we believe that it will further fragment care and hinder the progress made by Congress to move U.S. health care delivery and payment towards coordination and value. Value-based care models and other efforts to produce cost savings and promote quality, such as outcomes-based reimbursement, will be more difficult to measure and optimize if patients receive uncoordinated care from providers outside the model's mechanisms to drive results.

Because drug importation policies effectively encourage patients to buy medications online from unknown foreign sources, APhA fears patients will be at an even greater risk of taking ineffective, adulterated, or harmful medications, including controlled medications they were not prescribed. The lack of a strong regulatory framework for internet pharmacies in certain foreign countries has led to a large number of illegitimate foreign internet pharmacies. APhA's concerns are compounded by the large number of internet "pharmacies" which have increased and become more sophisticated in recent years, making them difficult to track and permanently stop.

Obtaining safe and effective medications is only one part of appropriate medication use. It also requires a health practitioner's knowledge of the patient's complete medication profile and an understanding by the patient of how to take the medication, side effects and/or potential interactions — all of which could be negatively affected by importation. APhA believes importation of non-FDA approved drugs could hurt the very patients intended to benefit from

importation proposals. Consequently, the risks to patient safety from harmful or ineffective products or avoidable medication errors due to fractured care outweigh any potential cost-savings from drug importation proposals.

Conclusion

APhA would like to thank the Subcommittee for continuing to work with us and other pharmacy stakeholders by including S. 1362 in your legislative package to improve the value of prescription drugs by increasing access to pharmacist-provided patient care services in medically underserved areas to improve health care equity and reducing the harmful anti-competitive practices of PBMs on prescription drug costs for our nation's pharmacies and patients. Please contact Alicia Kerry J. Mica, Senior Lobbyist, at AMica@aphanet.org or by phone at (202) 429-7507 as a resource as you consider these important issues.

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Appendix #1

Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies, and Providers, 2021

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

DRUG CHANNELS INSTITUTE

March 2021