UNITED STATES SENATE
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS
THE COST OF PRESCRIPTION DRUGS: HOW THE DRUG DELIVERY SYSTEM AFFECTS WHAT PATIENTS PAY, PART II

OCTOBER 17, 2017

Questions for the Record – Mr. Menighan

Chairman Alexander

1. What is the role of rebates, and do we need them?

A: During the October hearing, rebates were discussed in the context of those provided by manufacturers to pharmacy benefit managers (PBMs). Generally, APhA opposes rebates given from the manufacturer to the PBM because it sets up a framework that artificially raises point-of-sale prices, which can increase patients' costs and speed up the rate at which they reach the Part D coverage gap. In addition, because pharmacies do not receive any benefit from these rebates, they are unable to pass on savings to patients. With regard to manufacturers' pricing policies, APhA supports pharmaceutical industry adoption of a "transparent pricing" system which would eliminate hidden discounts, free goods, and other subtle economic devices. The lack of a transparent pricing framework negatively impacts the ability of CMS to oversee the Part D program.

2. How do rebates affect your industry? Do your members contract and get paid based on the public "list" price, or using a "net" price that takes into account rebates?

A: Savings from rebates given from manufacturers to PBMs are not passed on to pharmacies and APhA is not aware of such rebates' savings being passed onto patients. Due to a lack of transparency, it is difficult to determine the extent to which patients benefit from these rebates, if at all. In fact, rebates between manufacturers and PBMs can inflate the point-of-sale price of prescription medication.

Pharmacies purchase their drugs from wholesale distributors. That purchase price is generally based on the volume of purchases the pharmacy or chain or health system can achieve. The more volume purchased, the lower the price, just as in any supply chain in America. But these differences are generally narrow, and totally disconnected from the pricing offered by a PBM to a pharmacy to participate in a network. Simply, the contract price between a PBM and a pharmacy for medications is not based on what that pharmacy actually pays for the medications. Consequently, the amount reimbursed to the pharmacy by the PBM may be less than the pharmacy's cost to acquire the medication. In addition, it is not clear if the value PBMs give a drug in their formularies and benefit design incorporates the price the pharmacist pays to obtain it. Our member pharmacists have indicated they are experiencing more and more products with a negative payment, in which the payer's reimbursement does not cover the cost of providing the medication.

With regard to contracting and list pricing, there is no standard contract between pharmacists and insurers, PBMs and other payers. Therefore, there is no one set of "list" or "net" pricing used. Pricing

offered by PBMs is reported by our members to lag when prices rise and excel when prices fall. Many payer contract prices, as well as terms and conditions are 'take it or leave it', and do not provide an opportunity for meaningful negotiation between parties.

3. Would you support a policy that would allow supply chain participants to contract for lower prices on the front end rather than after the fact with rebates?

A: Currently, pharmacy chains, or pharmacies in buying groups, aggregate buying power to negotiate with suppliers (typically wholesalers) for small discounts on prices charged to wholesalers from manufacturers. Much of the wholesale industry trade with brand name manufacturers is pass through, with fees paid by manufacturers to wholesalers to distribute their products.

APhA would need to see details regarding the referenced policy. APhA would not support a policy that enables more members of the supply chain to retroactively clawback money from pharmacies. Regulations regarding Direct and Indirect Remuneration (DIR) were established to make transparent the rebates secured by PBMs from manufacturers. These rebates, as noted earlier, are not connected in any way to the prices paid by pharmacies to their suppliers for these medications. However, PBMs have taken their required reporting of rebates to CMS as an opportunity to "recover" their disclosed rebates from pharmacies, who do not benefit from the rebates in the first place.

APhA strongly opposes fees imposed by Medicare Part D plan sponsors and their PBMs that retroactively reduce the payments PBMs earlier approved and paid to pharmacies. These pharmacies have already paid the prices charged to them by their suppliers and have dispensed these medicines to Medicare beneficiaries. DIR disclosure was originally designed to capture rebates and other mechanisms not included at the point-of-sale. However, the DIR disclosure by PBMs to CMS are now being used beyond their original purpose to retroactively adjust pharmacies payment months after the sale, sometimes below the price paid by the pharmacy. Because point-of-sale prices paid by beneficiaries is calculated based on the contracted price before DIR is extracted, DIR fees charged to pharmacies do not positively impact what patients pay but rather, increase the point-of-sale price. This can result in the beneficiary paying more because the patient's cost-sharing may be based on sales prices.

<u>Ranking Member Murray</u>

1. In the written testimonies submitted to the committee, there is a lot of blame shifting when it comes to where the fault of high drug prices lays. We can all agree that our complex health system is inefficient, but, for that reason, the blame is shared, and everyone bears responsibility to fix the problem.

   Please provide more than one policy proposal, which does not involve any other members of the supply chain, that your industry in particular could implement, either with or without the help of Congress or the Administration, to bring down costs for patients and families, including the reasons why you believe it would bring down costs.

A: To efficiently use resources, meaning both dollars and clinicians, APhA suggests several reforms that enhance patient access and outcomes while improving transparency in the pharmacy marketplace:

1) Pass the *Pharmacy and Medically Underserved Areas Enhancement Act* (H.R. 592 / S. 109). This bill, with strong bipartisan support would enable medically underserved Medicare beneficiaries to better access health care through pharmacist-provided care services. As the medication expert on the care team, pharmacists possess knowledge and expertise to optimize the impact of medications, patient care, and health outcomes and consequently, the viability of the Medicare program. The importance of medication-related services cannot be overstated, especially in the Medicare program. Medications are the primary method of treating chronic disease and are involved in 80 percent of all treatment regimens. Moreover, the United States spends nearly $300 billion annually on medication-related problems, including nonadherence. Accordingly, not only will S.109 increase beneficiaries' access to health care, it will help improve their outcomes—particularly those impacted by medications. APhA appreciates the support by many Committee members for the *Pharmacy and Medically Underserved Areas Enhancement Act* and urges its swift passage to allow pharmacists to deliver these vital services as providers in medically underserved areas. APhA also requests the Committee's consideration of policies that include pharmacists as an eligible provider or clinician, such as in advanced payment models (APMs). These models often refer to Part B's named providers, which disincentivizes the optimal use of the entire patient care team, including pharmacists, to deliver effective and quality care efficiently.
2) We also encourage the Committee, when considering drug policy changes, to look beyond isolated components of health care to determine drug cost and value. Because health coverage is frequently analyzed in a silo 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 consider drug and medical coverage, and their related costs and outcomes, separately 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 to their medical costs. Breaking down the many silos within our health care system will help address that $300 billion dollars spent on medication-related problems—many of which are preventable.
3) Suboptimal health information technology (HIT) systems continue to be a barrier to the exchange of pertinent health information necessary for optimal coordination of care in various practice settings. For example, unless pharmacists are part of an integrated system or practice, pharmacists are frequently blocked from the electronic exchange of relevant clinical and billing information with other health care providers, insurers, etc. Such restrictions impede the ability of patients, the health care system and payers like Medicare, to benefit from coordinated, team-based care. Pharmacists are the most accessible health care professional and may be the only one in many communities. We encourage the Committee to look at mechanisms and incentives to facilitate pharmacists' ability to access and exchange information through Electronic Health Records (EHRs) – essential to team-based coordinated care.

Senator Bennet

1. In your testimony, each of you indicated that there is some role for value-based arrangements that health plans can set up with drug manufacturers for outcomes-based reimbursement. However, there are still relatively few of these arrangements in place.

   I recently sent a letter with Senators Cassidy, Warner, and Young to request a GAO study on value-based arrangements. We asked GAO to assess the savings potential for consumers and the government in outcomes-based arrangements.

   What do you expect we will find in this study?

A: There are a number of publicly disclosed value-based purchasing arrangements between pharmaceutical manufacturers and payers. While we anticipate the GAO study will not focus on pharmacists, if it did, we would expect the GAO would find most, if not all, of these arrangements fail to reimburse pharmacists for the services they provide to improve medication outcomes, thus impeding real value.

2. What impediments exist to creating outcomes-based reimbursements?

A: Numerous studies have shown that medication management and other pharmacist-provided services improve medication outcomes for patients, yet, pharmacists are often not reimbursed for these services under Medicare, or from private payers. Any value-based arrangements need to include and adequately reimburse pharmacists for the value of the services they provide.

As noted above, the health care system cannot continue to cover and evaluate the drug and medical benefit separately. New Medicare payment and delivery models, such as ACOs, focus on coordinated care and value, but do not include drug coverage.

3. We have seen reports that in some cases, patients who fill prescriptions are charged a copay that is higher than the cash price of the drug and may not be given the chance to choose the less costly option.

   What have you heard from pharmacists on how widespread this practice may be?

A: We have heard from our members that this is a common practice of PBMs. A June 2016 survey of 600 pharmacists by the National Community Pharmacists Association confirms this position. The findings from the survey stated, "Sometimes PBM corporations impose "gag clauses" that prohibit community pharmacists from volunteering the fact that a medication may be less expensive if purchased at the "cash price" rather than through the insurance plan. In other words, the patient has to affirmatively ask about pricing. Most pharmacists (41 percent) said they encountered these restrictions at least 10 times during the past month."[1] While it may be difficult to measure the prevalence of such restrictions, it is also difficult for pharmacists to remember which plan restricts, and which one allows these disclosures. Prohibitions of "gag clauses" would make the system more transparent.

[1] *See*, http://www.ncpa.co/pdf/dir_fee_pharamcy_survey_june_2016.pdf

Senator Cassidy

1. In determining Direct & Indirect Remunerations, do you believe Part D plan sponsors should utilize quality and performance measures that are applicable to the services provided by retail and specialty pharmacies?

A: It is important to clarify that pharmacists services are not covered under Medicare Part B, and Part D does not cover most pharmacist-provided services with the exception of medication therapy management (MTM) and immunizations. However, pharmacists are willing to engage in value-based delivery and payment systems and have the outcomes of their services be measured. Therefore, APhA encourages Medicare statutes and policy be amended to treat pharmacists like other health care practitioners which lays needed groundwork to improve access and quality. In addition, we reiterate the need to measure outcomes, quality and cost comprehensively rather than separately in each Medicare program (e.g. Parts A, B, D).

APhA supports the *Improving Transparency and Accuracy in Medicare Part D Drug Spending Act*, S. 413, which prohibits Medicare Part D plan sponsors/PBMs from retroactively reducing payment on clean claims submitted by pharmacies under Medicare Part D, which would:

- **Lower Medicare costs for taxpayers.** Virtually all catastrophic costs in Part D are borne by the government. These costs are fueled by pharmacy DIR fees, which have more than tripled in recent years.
- **Boost transparency in drug pricing.** Prohibiting these pharmacy fees will make Medicare Plan Finder more accurate and facilitate better CMS oversight.
- **Give seniors reduced cost-sharing and greater budget predictability.** Beneficiaries who use their drug plan to fill prescriptions are negatively impacted by pharmacy DIR fees. This is because retroactive fees lead to inflated drug costs that are the basis for beneficiary cost-sharing amounts.
- **Preserve access to independent community pharmacies.** Locally owned pharmacies provide enhanced patient care, and are often located in underserved rural and inner-city areas. The number of U.S. independent community pharmacies has declined the past five years and a recent study estimated 3 million rural residents are at risk of losing the only pharmacy in their community with the next nearest pharmacy over 10 miles away, a trend exacerbated by DIR.

2. What role do you believe retail and specialty pharmacies should play in combating the opioid abuse epidemic?

A: Pharmacists Role/ Pharmacists' Care Services. As the medication experts on the patient's health care team, pharmacists play an important role in preventing prescription drug misuse and abuse. Pharmacists are involved in pain management programs that include medication tapering services, work in medication assisted treatment programs, and furnish naloxone where authorized. Depending on state authority, pharmacists working under collaborative practice agreements can initiate, monitor, modify, and discontinue medication therapy, including opioids, and order and interpret laboratory tests in collaboration with other members of the health care team. Pharmacists see the patient's complete medication profile and can help bridge the communication gap between health care providers by coordinating and providing medication-related services. Pharmacists are part of the team helping

patients with legitimate pain management needs achieve treatment goals. Pharmacies often serve as an access point for patients to receive care and to dispose of their medications through take-back receptacles.

In addition, pharmacists are required by DEA regulations to ensure that prescriptions for controlled substances are issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice (See United States Drug Enforcement Administration, Practitioner's Manual, 2006:30 "Federal courts have long recognized that it is not possible to expand on the phrase 'legitimate medical purpose in the usual course of professional practice' in a way that will provide definitive guidelines to address all the varied situations physicians may encounter"). [Pharmacist's corresponding responsibility]

Medication Assisted Treatment (MAT). Pharmacists' roles in the provision of medication-assisted treatment continues to grow, however, their ability to help patients is stunted because they are not eligible to obtain a DATA-waiver. Currently, 48 states and the District of Columbia allow pharmacists to enter into collaborative practice agreements[2] with physicians and other prescribers to provide advanced care to patients, which may include components of MAT. APhA is aware of at least six states that allow pharmacists to prescribe Schedule III, IV and V controlled substances under a collaborative practice agreement. The Comprehensive Addiction and Recovery Act (CARA) of 2016 expanded the law to allow nurse practitioners and physicians assistants to obtain a DATA waiver and provided SAMHSA with authority to modify eligibility requirements to obtain DATA waiver. Pharmacist involvement in MAT for opioid use disorders helps improve access and outcomes, while reducing the risk of relapse.[3,4] Pharmacists' capabilities are recognized by the Food & Drug Administration (FDA)[5] and in SAMSHA's 2015 Federal Guidelines for Opioid Treatment Programs.[6] The pharmacy community is united and has taken a cohesive position regarding the need to allow pharmacists to obtain a DATA waiver.[7] Allowing pharmacists to obtain a DATA-waiver will increase access to MAT and address treatment gaps that become more apparent as the opioid epidemic evolves.

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[2] Collaborative practice agreements create a formal practice relationship between a pharmacist and another health care provider and specify what patient care services – beyond the pharmacist's typical scope of practice- can be per

[3] DiPaula, B.A. & Menachery, E. (Mar/Apr 2015). Physician-pharmacist collaborative care model for buprenorphine-maintained opioid-dependent patients, Journal of the American Pharmacists Association, 55(2), 187-192.

[4] Raisch, W. (2002). Opioid Dependence Treatment, Including Buprenorphine/Naloxone, *Pharmacology & Pharmacy,* 36(2), 312-321.

[5] Food & Drug Administration, *Information for Pharmacists SUBOXONE® (buprenorphine HCl/naloxone HCl dihydrate, sublingual tablet) and SUBUTEX® (buprenorphine HCl, sublingual tablet),* available at: http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM191533.pdf (last accessed November 16, 2015).

[6] Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services, (March 2015), *Federal Guidelines for Opioid Treatment Programs,* available at: http://store.samhsa.gov/shin/content/PEP15-FEDGUIDEOTP/PEP15-FEDGUIDEOTP.pdf, last accessed: May 18, 2016.

[7] *See* Joint Statement for the Record: American Pharmacists Association (APhA), Academy of Managed Care Pharmacy (AMCP), American Society of Consultant Pharmacists (ASCP), American Society of Health-System Pharmacists (ASHP) , College of Psychiatric and Neurologic Pharmacists (CPNP), National Association of State Pharmacy Associations (NASPA) and National Community Pharmacists Association (NCPA), available at: http://www.pharmacist.com/sites/default/files/files/Joint%20Statement%20for%20the%20Record%20on%20%20MAT%20to%20Energy%20and%20Commerce%20Hearing_10_25_2017.pdf

Senator Whitehouse

1. During the hearing, we discussed "de facto" monopolies of prescription drugs, or monopolies that occur outside of the patent and exclusivity protections granted to new drugs. You all acknowledged that we have seen instances of industry outsiders taking advantage of these de facto monopolies and dramatically increasing the prices of drugs. Addressing this unfair price manipulation in a targeted way will require the proper identification of de facto monopolies. How can we ensure de facto monopolies are correctly identified?

   A: APhA recognizes the difficulty in identifying patterns indicative of a de facto monopoly. We encourage Congress to require research regarding factors that can be used to better predict when a de facto monopoly may occur. Such research should incorporate members of the supply chain, including pharmacists, and also include recommendations regarding steps that FTC, FDA, and other government agencies may take to prevent price increases. In addition, APhA notes that stakeholders have indicated manufacturers are using Risk Evaluation and Mitigation Strategy (REMS) Programs inappropriately to delay generic drug development and marketing. APhA recommends research include reviewing REMS programs and whether they are serving as barrier to generic drug development and supporting de facto monopolies.

2. While we want to make sure people can afford their medications, it strikes me that patient assistance programs that reduce out-of-pocket costs for patients also serve to help companies maintain their market share, even when there is a lower-cost drug available that is just as effective. What effect do patient assistance programs have on costs to patients and to the overall health care system? How could Congress help ensure patient assistance programs don't mean wasteful spending of our health care dollars, while still preserving patient access?

   A: Patient assistance programs may be created for a variety of purposes, including helping patients to access medications. The components and requirements of these programs vary. In some circumstances, pharmacists act as an intermediary to identify patient assistance programs for patients to help maintain their access to needed medications. Because patient assistance programs vary substantially and change, APhA and our members do not have the resources to perform a review of current programs in attempt to determine their value and impact on patients and the overall health care system. APhA encourages research be conducted to better answer Senator Whitehouse's question.

   With regards to transfer incentives which may be provided via patient assistance programs, APhA advocates for the elimination of coupons, rebates, discounts, and other incentives provided to patients that promote the transfer of prescriptions between competitors.