July 16, 2018

[Submitted electronically to www.regulations.gov]

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services (HHS)
Attention: ID: HHS-OS-2018-0010-0001
200 Independence Ave. SW, Room 600E
Washington, DC 20201

Re: RIN:0991-ZA49, HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Dear Secretary Azar:

Our pharmacy organizations are pleased to submit these comments on the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.

APhA, founded in 1852 as the American Pharmaceutical Association, represents 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, physicians’ offices, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

The National Alliance of State Pharmacy Associations (NASPA), founded in 1927 as the National Council of State Pharmacy Association Executives, is dedicated to enhancing the success of state pharmacy associations in their efforts to advance the profession of pharmacy. NASPA’s membership is comprised of state pharmacy associations and over 70 other stakeholder organizations. NASPA promotes leadership, sharing, learning, and policy exchange among its members and pharmacy leaders nationwide.

We are well aware of the complexities involved in the multi-level decision-making determining the prices patients pay for their medications. Pharmacies are where millions of Americans are first exposed to the impact of intricate pharmaceutical pricing policies or confronted with changes in coverage, formularies, prior authorization, deductibles and co-payments, many of which they did not know or understand. Pharmacists are also the ones at the front lines with patients facing tough financial choices between purchasing medicine and other necessary items or the risk of forgoing them. As team-based care and value-based payments expand, the need for patients to have a consistent set of caregivers including their pharmacist will be increasingly key. We appreciate HHS’s leadership in helping patients access safe, effective
and affordable medications and offer the following responses to the request for information (RFI):

I. Underpricing or Cost-Shifting

The RFI seeks feedback regarding whether HHS programs contain the correct incentives to obtain affordable prices on safe and effective drugs. While the Food and Drug Administration (FDA) may approve drugs based on their safety and efficacy for an indicated population, a medication’s safety and efficacy is also dependent on patient-specific factors and the care received. Therefore, when considering the cost of a medication, we recommend HHS consider services needed to optimize medication use. Without doing so, medications’ value will not be assessed accurately, and costs associated with adverse events or misuse will be shifted to other segments of the health care system (see discussion in Section IX below).

Our organizations urge HHS to exercise its authority to adopt drug pricing and other health care-related policies that incorporate pharmacist-provided care services to increase the value of medications and medication regimens. Further, we stress the importance for HHS and other policymakers to consider drug costs in the context of a patient’s entire care to avoid cost-shifting from the Medicare Part D program or patients’ drug coverage to other parts of the Medicare program and health care system.

II. Distribution Restrictions

The RFI requests comment on the role of distribution restrictions in the context of generic drug development. However, it is important HHS also consider distribution restrictions negatively impacting competition in other areas besides drug development.

Some manufacturers impose distribution restrictions on certain products, limiting the pharmacies or network of pharmacies which can obtain the product.1 Although less common, some manufacturers own pharmacies for the sale and dispensing of their medications. These practices effectively prevent other pharmacies from obtaining medications and make it more challenging to discern a fair price for the medication.

In addition, plans and PBMs enforce similar restrictions whereby certain medications will only be reimbursed if dispensed by a specific pharmacy. Such distribution restrictions can prevent patients from receiving medications from the pharmacy of their choice and stifle competition. Our organizations recognize some medications need certain protections to ensure the medication is safe and effective for patient use; these protections are required by FDA upon a drug’s approval or by state law or regulations. However, it has become commonplace for pharmacists to encounter manufacturer and plan distribution restrictions and standards not

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required by FDA or a state. Pharmacists indicated several concerns related to these restrictions, including the negative impact they have on patients accessing prescription medications from the pharmacy of their choice.

a. Pharmacists’ Access to Information Regarding Distribution Restrictions

In general, it is difficult for a pharmacist to discover if a product has distribution restrictions, and if it does, why those restrictions exist. A pharmacist seeking to obtain a product for a patient which is designated for limited distribution often needs to contact the manufacturer, wholesale distributor, and payer/pharmacy benefit manager (PBM) to learn the intricacies of the distribution restrictions. This process is not only time consuming, but convoluted. Pharmacists must identify appropriate contacts at each entity and are often redirected to different departments and companies. There is no single source a pharmacist can reference to identify how to obtain products not widely distributed due to company-imposed limited distribution or payer coverage policies. Our organizations recommend HHS consider how it can work with members of the supply chain and payers/PBMs to make distribution requirements clear, transparent, and accessible to pharmacists.

b. Eligibility and Distribution Networks

Once a pharmacist is aware of an entity's limited distribution policy, the next set of barriers often involves eligibility. A manufacturer may refuse to expand its distribution network or demand costly measures beyond FDA's safety requirements without needing to justify the decision or link it to better patient care. Furthermore, because of the lack of transparency, pharmacists have no way of knowing if requirements are imposed uniformly on participating pharmacies. The result is inhibited competition and fragmented care due to patients obtaining medications from multiple entities. Our organizations encourage HHS to study the impact these distribution arrangements have on patient access, choice and outcomes.

c. Coverage

Lastly, assuming a pharmacy obtains a limited distribution product, payers and PBMs may also restrict patient access by requiring, as a condition of coverage, the medication be provided by a specific pharmacy. Frequently, it is a mail-order or a specialty pharmacy supplying these products for the payer’s entire network. Similar to concerns noted above, such coverage policies decrease competition and transparency and prevent patients from obtaining medications from the pharmacy of their choice and the site where they receive their other medications and care. Accordingly, our organizations encourage HHS to advance policies discouraging payers, and PBMs from steering patients to specific pharmacies through the creation of narrow medication-specific coverage policies that go beyond federal- or state-mandated safety requirements.
III. Biosimilar Development, Approval, Education and Access

a. Access

As HHS is aware, patient access to biosimilars is highly dependent on payer coverage and formulary placement. Like the patient, pharmacists are often not aware of how each payer or PBM treats both reference and biosimilar products until the point-of-sale. Our organizations believe patients would benefit from health care practitioners receiving more forward-looking information regarding formulary changes, especially those related to high-cost treatments like biologics. For patients who will use biological products long-term, increasing providers’ awareness of future formulary decisions could help streamline patient access to cost-effective medication regimens more efficiently and minimize the switching of products by not placing a patient on a product identified to be non-formulary in the near-term. Further, the receipt of payor coverage information, especially related to high-cost medications, well in advance of coverage or formulary changes could help pharmacists make cost-effective inventory decisions and prevent the stocking of medications patients are less likely to use. Thus, our organizations recommend payers, PBMs and HHS study how to more effectively communicate formulary rules and changes to pharmacists and other health care practitioners. Subsequently, HHS should work with payers and PBMs to promote earlier and better notification of upcoming formulary changes to health care providers to facilitate patient access to cost-effective medications and minimize unnecessary product switches.

b. Educating Patients and Providers

Our organizations encourage ongoing biological product education targeting providers and patients to improve awareness and comfort using biological products, including biosimilars and interchangeable biosimilars. These resources also would be useful in educating policymakers, including state legislators. We believe the lack of understanding about biological products has allowed the passage of disparate substitution laws at the state level for interchangeable biosimilar and generic products.

c. Interchangeability

Although an interchangeable biosimilar has yet to be approved by FDA, several states have adopted laws and regulations that place extra burdens (e.g., documentation, practitioner notice or communication, patient notice) on pharmacists. Once interchangeable biologics come to market, these laws will impede interchangeable products’ uptake, interrupt pharmacists’ workflow, and delay patient treatment. Our organizations recommend HHS use its influence to improve state understanding and decision-making related to biosimilars, including the impact of unnecessary, additional requirements for the substitution of interchangeable biosimilars on patients. For example, the Centers for Medicare and Medicaid Services (CMS) could issue a letter to state Medicaid directors to encourage the dissemination of the educational resources

mentioned above and caution against the adoption of policies restricting access to safe and effective biological medications.

IV. Moving Prescription Drugs from Medicare Part B to the Medicare Part D Program

For pharmacists, obtaining payment for Part B drugs is administratively burdensome, delayed and often fails to cover the actual cost of the product. Patient access to many needed Part B medications is hindered because pharmacies cannot provide many of these products due to inadequate reimbursement. In addition to reimbursement rates not being adjusted since 2006, some Part B medications are extremely expensive, making it difficult for small and independent pharmacies to float the inventory expense of these products for an extended period. Therefore, Medicare Part D program reimbursement does have some advantages over Part B’s payment processes for medications and devices, including electronic and real-time eligibility and claims processing. However, as HHS is aware, there are PBM practices in the Medicare Part D program negatively impacting patient costs, care and access, such as direct or indirect remuneration (DIR) fees and narrow distribution networks (mentioned above). These practices impact the sustainability of community pharmacies and consequently, patient choice and access to care. Accordingly, prior to any discussion of expanding the purview of PBMs within the Medicare program, our organizations recommend HHS first eliminate problematic PBM practices in the Medicare Part D program to maintain patient access to medications.

Moreover, any reforms to Part B or D prescription drug coverage must contain requirements whereby products and related services are adequately reimbursed. Unfortunately, payers’ reimbursement to pharmacies are all too often failing to recognize both the product’s cost and the service related to providing the medication or treatment. The sustainability of community pharmacies, and therefore, patient access, is at risk as pharmacies, many of which are small businesses, cannot withstand reimbursement levels that do not even cover their actual cost of the product, let alone any related service. We are supportive of value-based payment and delivery reform. However, HHS must ensure any value payment is tied to the service and not the product, which is fixed for the pharmacist.

V. Indication-Based Payment for Prescription Drugs

Most pharmacists do not have access to coding and reimbursement systems to support indication-based pricing. More importantly, because the pharmacist’s cost for the product does not change based on the indication, our members are unsure how indication-based payment could be implemented, especially in the community pharmacy setting. Absent any details, our organizations are concerned indication-based payment will be used only to reduce pharmacists’ current payment (e.g., one indication will be paid at the current reimbursement level and all others at lower levels) and continue payment policies with no relationship to the pharmacist’s actual cost.

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VI. Fiduciary Duty for PBMs/ Rebates

Our organizations support a transparent pricing framework that would eliminate mechanisms like rebates between manufacturers and PBMs and post point-of-sale price fees imposed on pharmacies. These policies, as recognized by CMS and noted below, generally result in higher prices at point-of-sale and consequently, higher beneficiary co-pays. As stated in one of our organization’s response to last year’s Medicare Part D rule,\(^4\) DIR fees were originally designed to capture rebates and other mechanisms not included at the point-of-sale. However, DIR fees by PBMs 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 or copays paid by beneficiaries can be based on the contracted price before DIR fees are extracted, DIR fees charged retroactively to pharmacies generally do not positively impact what patients pay and may actually result in the beneficiary paying more. Consequently, PBM DIR fees and “clawbacks” mask the real price of medications, increase the price patients pay, and interfere with pharmacists’ ability to provide patient care.

As stated by CMS in the November 2017 proposed Medicare Part D rule, “[b]etween 2010 and 2015, the amount of all forms of price concessions received by Part D sponsors and their PBMs increased nearly 24 percent per year, about twice as fast as total Part D gross drug costs, according to the cost and price concession data Part D sponsors submitted to CMS for payment purposes.”\(^5\) CMS also affirmed that when price concessions between pharmacies and Medicare Part D plan sponsors or their PBMs (e.g., DIR fees) “…are not reflected in the price of a drug at the point of sale, beneficiaries might see lower premiums, but they do not benefit through a reduction in the amount they must pay in cost-sharing, and thus, end up paying a larger share of the actual cost of a drug.” CMS goes on to acknowledge that “[n]umerous research studies further suggest that the higher cost-sharing that results can impede beneficiary access to necessary medications, which leads to poorer health outcomes and higher medical care costs for beneficiaries and Medicare.”\(^5\) Accordingly, we are encouraged by recent testimony by HHS before the U.S. Senate Appropriations\(^6\) and House Education and Workforce\(^7\) Committees requesting the HHS Inspector General investigate PBMs’ harmful use of DIR fees. Similarly, we support CMS’s intention to require price concessions between pharmacies and plan sponsors or their PBMs (e.g., DIR fees and/or similar policies/terminology, such as “true up” practices) be reflected in the negotiated price made available at the time a medication is dispensed at the point-of-sale. This policy, according to CMS estimates, would significantly reduce net beneficiary


costs by $10.4 billion and give community pharmacies greater predictability regarding reimbursement rates.

Our organizations are also supportive of the FDA Commissioner’s recent suggestion to have “…the federal government reexamine the current safe harbor for [manufacturer] drug rebates under the Anti-Kickback Statute” Additionally, we continue to encourage CMS to enact policies allowing any willing pharmacy to enter into contracts with insurers or PBMs to increase patient access and choice, which can improve adherence and health outcomes.

VII. Prohibiting PBM ‘Gag Clauses’

Our organizations support HHS’s and CMS’s recent actions to prohibit PBMs’ use of “gag clauses” in Medicare Part D program contracts to improve patients’ access to more affordable and cost-effective medicines. “Gag clauses” prevent pharmacists from informing patients when medication may be less expensive if purchased at the cash price, rather than through their insurance plan. For years pharmacists have been frustrated by their inability to help their patients who they knew were struggling with high co-payments. In addition, prohibitions of “gag clauses” will make the drug pricing system more transparent.

VIII. Inform Medicare Beneficiaries with Medicare Part B and Part D Program Coverage about Cost-Sharing and Lower-Cost Alternatives

As stated previously, pharmacists are the health care professional most often at the front lines of informing patients about their medication cost or copay amount and explaining complicated insurance coverage policies. Every day, pharmacists voluntarily assist patients to find lower price alternatives. Approaches to sharing this information with patients varies by pharmacy with both low and high-tech solutions used to leverage the pharmacist-patient relationship. However, lower-cost treatment does not always mean finding the lowest price product.

While pharmacists are in an excellent position to help patients and prescribers navigate drug product selection, knowing the lowest priced drug is only one part of the equation. The lowest priced drug may not be the optimal medication for a particular patient. Individual treatment decisions are best informed through team-based, coordinated care, including the pharmacist. Consequently, our organizations caution against imposing a requirement on pharmacists to ask about and inform patients about lower-cost alternatives as such a requirement is not a simple conversation or quick price calculation. As previously stated, our organizations agree with the movement to value-based payment and care delivery, however, any such reforms should not be conflated with using the cost of medications as the determinant. Accordingly, we believe it’s important to distinguish between the value of implementing technologies used to lower the overall cost of treatment (e.g., Pharmacist eCare Plan) versus simply identifying a lower price.

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11 The Pharmacist eCare Plan, developed by NCPDP and HL7, is a standardized way of capturing content from clinical service activities in a codified manner so that it may be exchanged electronically among many different entities (e.g., Dispensing Systems, EHRs, MTM vendors, Care
medication at the point-of-sale. Our organizations have long advocated for the importance of pharmacists’ access to the patient’s electronic health record (EHR) and the enhanced value that would result. The Pharmacist eCare Plan takes the value of shared electronic information one step further in optimizing the care the patient receives through even better care coordination. Therefore, we recommend HHS support and test technologies focused on value rather than systems that simply highlight product cost and/or a lower price in isolation of other factors.

In the RFI, HHS asks whether a pharmacist could inform patients about “price changes”. It is unclear from the language in the RFI what is meant by price changes. For example, is it the price paid by the patient, the payment to the pharmacist, what the payer/PBM pays the pharmacy before or after all price adjustments (manufacturer rebates, DIR fees, etc.)? While our organizations support mechanisms to add more transparency in the Medicare program, at the pharmacy level, informing patients of price changes would be nearly an impossible and/or futile task. Due to DIR fees, pharmacists often do not even know what they will be/were paid by the PBM for an individual drug. In addition, many drug cost changes do not impact the patient’s price as they pay a copay amount, questioning whether cost changes between the different supply chain stakeholders may be useful to beneficiaries.

IX. Other Policies or Legislative Proposals HHS Should Consider to Lower Drug Prices While Encouraging Innovation

As drugs become more and more expensive, complex, and personalized, the need to optimize their impact also increases. Therefore, our organizations cannot emphasize enough the importance for patients to understand how to use their medications safely and effectively in order for medications’ benefits to be enhanced. Although HHS’s particular focus in the blueprint is on identifying ways to more effectively pay for medications and produce savings in Medicare, there is no reference to incorporating pharmacists, the health care professional with the most medication-related education and training, into the patient’s health care team.

Pharmacists have more medication-related education and training than any other health care professional. Pharmacists can and do assist patients in optimizing the impact of medications and decreasing patients’ costs by providing services focused on safe and appropriate medication use. For example, pharmacists provide medication management services, which are especially important for patients who have complex care plans, take multiple drugs or have chronic conditions. Additionally, to address hospital readmissions, pharmacists help patients transition between care settings. Unfortunately, despite the fact 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 the services pharmacists can provide. Pharmacists are trained to do more than place medication in a container and while 89% of Americans live within five miles of a community pharmacy, many of our nation’s seniors are medically underserved.


12 NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department.
Pharmacists are an underutilized health care resource which can positively affect beneficiaries’ care\textsuperscript{13} and the entire Medicare program.

Our organizations strongly believe H.R. 592/ S.109, the Pharmacy and Medically Underserved Areas Enhancement Act, is a bipartisan legislative proposal that will improve patient care, health outcomes, and impact of medications,\textsuperscript{14} and consequently, the viability of the Medicare program. The legislation will enable Medicare patients in medically underserved communities to better access health care through state-licensed pharmacists practicing according to their own state’s scope of practice. In medically underserved communities, pharmacists are often the closest health care professional and accessible outside standard business hours. Helping patients receive the care they need when they need it is a common sense and bipartisan solution that will improve outcomes and reduce overall costs.

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 as much as $672 billion on medication-related problems, including nonadherence.\textsuperscript{15} Not only will H.R. 592/ S.109 increase beneficiaries’ access to health care, it will help improve their outcomes—particularly those impacted by medications. Pharmacists help achieve the best possible health outcomes from the use of medications through various types of medication-related services. These services include working collaboratively with physicians and other health care providers in recommending specific medications or changes in medications. Therefore, we strongly encourage HHS/ CMS to better include pharmacist-provided care in the effective and efficient delivery of team-based care into policies to lower the overall costs of patient treatments. Our organizations recommend HHS take advantage of any regulatory discretion to remove barriers preventing physicians and eligible clinicians from utilizing and empowering pharmacists under team-based, patient-centered payment and delivery structures.

In addition, when considering policy changes to improve the cost of medications, our organizations strongly encourage HHS 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 care, outpatient services, 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 and increasing the utilization of pharmacists will help address the possible $672 billion spent by the U.S. annually on medication-related problems.\textsuperscript{16}

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problems—many of which are preventable.\textsuperscript{16} Ultimately, the most expensive medicine is the one not purchased, not taken, or not used correctly by patients which is why it is critical to include the pharmacist, the medication expert, as part of the overall health care team in the delivery of care.

Thank you for the opportunity to provide comments on the blueprint/RFI. Pharmacists stand ready to help. If you have any questions on the positive role pharmacists can and do play in reducing patients’ prescription drug prices, or require more information, please contact Michael Baxter, APhA Director of Regulatory Affairs, at mbaxter@aphanet.org / by phone at (202) 429-7538 or Krystalyn Weaver, PharmD, NASPA Vice President, Policy and Operations, at kweaver@naspa.us / by phone at (571) 969-6012.

Sincerely,

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