NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

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**Via Electronic Submission at: www. regulations.gov**

July 16, 2018

The Honorable Alex Azar
Secretary
United States Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

**Re: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs; Request for Information; RIN 0991-ZA49**

Dear Secretary Azar:

The National Association of Chain Drugs Stores (NACDS) thanks HHS for the opportunity to comment on the Agency's Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs ("RFI"). We appreciate that the Trump Administration has already taken a number of significant steps to lower prescription drug costs and patient financial burdens. We support the Administration's policies to increase competition through fostering and accelerating the availability of generic drugs and biosimilars, to provide for better negotiation in the Medicare Part D program, and to reduce patient out-of-pocket costs in the Medicare Part D program. Moreover, we look forward to working with HHS on policy proposals that would incentivize lower list prices for prescription drugs.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate 40,000 pharmacies, and NACDS' more than 100 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3 million individuals, including 152,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 20 countries. Please visit nacds.org.

Our comments herein are in response to the questions and proposals that HHS presented in the RFI. As detailed below, we are providing our feedback on the document as a whole rather than responding question by question. These are NACDS' policy priorities for lowering drug prices and reducing patient costs.

## 1. The Impact of AMP on Pharmacy Reimbursement

In the RFI, there are several proposals in which HHS is seeking stakeholder input on what benefits would accrue to Medicare and Medicaid beneficiaries by allowing manufacturers to exclude from statutory price reporting programs discounts, rebates, or price guarantees included in value-based arrangements, and how would excluding these approaches from Average Manufacturer Price (AMP) and Best Price (BP) calculations impact the Medicaid Drug Rebate program and supplemental rebate revenue.

HHS also proposes to explore the effects of excluding payments received from, and rebates or discounts provided to PBMs from the determination of AMP, and the potential elimination of the provisions that exclude manufacturer discount programs from the calculation of AMP. Although we applaud HHS' goal of controlling and lowering prescription drug prices, we have grave concerns about the downstream effects on pharmacy reimbursement that will result from the adoption of any regulatory or statutory modifications to alter AMP and the program discounts, rebates, or price guarantees that are either currently included or excluded from the calculation of AMP.

Historically speaking, AMP was originally designed as a benchmark to determine manufacturer rebates in the Medicaid program. However, for more than a decade federal legislation has required the use of AMP to calculate pharmacy reimbursement for generic medications dispensed to Medicaid beneficiaries. Congress made it clear that AMP is defined and to be calculated to reflect the prices paid to manufacturers by retail community pharmacies and by wholesalers for medications distributed to retail community pharmacies.[1]

In addition to defining AMP, Congress also determined that sales to entities other than retail community pharmacies are not to be included in AMP calculations. Consistent with the requirements of the law, and as finalized by CMS' Covered Outpatient Drugs Final Rule[2] transactions with PBMs, managed care organizations (MCOs), health maintenance organizations (HMOs), insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or retail community pharmacy must not be included in AMP calculations. Furthermore, discounts or benefits from vouchers, or manufacturer-sponsored programs, or manufacturer-sponsored discounts are also to be excluded from AMP.

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[1] 42 U.S.C. § 1396r-8(k).

[2] CMS-2345-FC; RIN 0938-AQ41, Medicaid Program; Covered Outpatient Drugs; February 1, 2016, 81 *Federal Register* 5349; Section 447.504.

Considering the statutory requirements that Congress established for the proper calculations of AMP, manufacturers are to exclude specific discounts and fees from AMP calculations, as such discounts and fees that do not reduce the cost of a pharmacy purchasing a medication. Initiatives that would modify the standing definition of AMP, the criteria used to calculate AMP, or include price concessions from PBMs or manufacturer discount cards would be inconsistent with the statute, and lower AMP and further decrease pharmacy reimbursement to levels that are well below the cost of acquiring and dispensing prescription medications in the Medicaid program. While we fully understand that the goal of HHS' proposals is to decrease drug prices, NACDS strongly cautions against modifications to the definition of AMP as such proposals must consider the unintended impacts on pharmacy Medicaid reimbursement. Furthermore, it is important to note that any such AMP modifications would require statutory changes that may only be accomplished through Congressional legislation that would overturn longstanding federal policies of ensuring that pharmacies are fairly and adequately reimbursed for their services and ensuring Medicaid patient access to prescription medications.

In sum, to avoid substantial cuts in pharmacy reimbursement and unintentional disruptions in patient care, HHS must maintain all efforts to ensure fair and adequate reimbursement for prescription medications dispensed to Medicaid beneficiaries. Ensuring continued beneficiary access to needed medications reduces beneficiary utilization of more costly healthcare services, thus keeping overall healthcare costs to a minimum. NACDS strongly urges HHS to keep in mind that any efforts to control drug pricing through redefining AMP or changing the way AMP is calculated would not only severely affect pharmacy reimbursement but also would undermine Congressional and CMS intent and policy efforts to ensure fair and adequate reimbursement for retail community pharmacies that helps preserve patient access to needed medications.

## 2. 340B Issues

HHS' RFI asks a series of questions focused on the 340B drug discount program. Generally, HHS is focused on the growth of the program, program eligibility, and concerns about duplicate discounts for Medicaid patients who are also 340B patients. Starting with the growth of the 340B program, NACDS supports the current status of the 340B program. Undoubtedly, the growth of the 340B program has lowered drug prices, as more drugs are purchased at discounted 340B prices. Increasing the number of 340B contract pharmacies increases the number of access points at which lower cost 340B drugs can be provided to patients. Accordingly, regardless of how HHS decides to reform the 340B program, we urge the Agency to promote the low drug prices of the 340B program by preserving the 340B contract pharmacy program and the ability of 340B entities to contract with multiple contract pharmacies.

Turning to HHS' questions regarding the impact of restricting program eligibility, we believe that restricting 340B eligibility will reduce the size of the program and correspondingly the volume of lower priced drugs that can be offered through the program. A narrow patient or program eligibility definition means fewer discounted drugs. For example, if HHS were to narrow the patient definition of a 340B patient, fewer patients would be eligible for low cost 340B drugs, meaning that a larger volume of drugs will be sold at higher prices. Moreover, if the patient eligibility definition is too narrow and complex, it will be harder to determine which patients are truly 340B eligible, thereby increasing the risk of duplicate Medicaid discounts for Medicaid/340B patients.

Focusing on the duplicate discount issue, we recognize concerns about applying 340B discounts and Medicaid rebates to the same prescriptions. To alleviate such concerns, we support current efforts among state Medicaid agencies, 340B entities, and their third-party administrators to develop crosswalks of 340B claims to Medicaid claims. We encourage HHS to continue to facilitate these types of initiatives to help ensure integrity to the 340B program. State efforts to develop claims crosswalks will help ensure that 340B discounts and Medicaid rebates are not applied to the same drugs.

To help guard against duplicate discounts, we encourage HHS to work with state Medicaid agencies to require Medicaid managed care plans to issue unique BIN/PCN numbers for Medicaid managed care patients. With unique BIN/PCN numbers, pharmacies can better identify Medicaid managed care patients, and to the extent possible, flag those patients for 340B entities and their third-party administrators. Identifying Medicaid managed care patients through unique BIN/PCN numbers will help prevent duplicate discounts by identifying Medicaid managed care claims. Moreover, such identification can assist pharmacy providers, at the point-of-sale, to avoid the use of certain promotions or coupons for government program beneficiaries, as well facilitating pharmacy providers with internal establishment of prescriber integrity editing.

Without a crosswalk of claims or unique BIN/PCN numbers, we are concerned that states may simply require pharmacies to choose to be either 340B contract pharmacies or Medicaid pharmacies. Such a policy would unnecessarily limit the availability of drug price discounts available through the 340B program and would limit patient access to prescription medication as pharmacies would be forced to turn away patients. This would be particularly detrimental in the areas that serve the most Medicaid and 340B patients – rural and urban areas that have the least amount of pharmacy choice.

## 3. Medicare Part D

### a. Allowing Plan Adjustments and Flexibility to Manage Prescription Drug Costs

The RFI includes proposals that would give Part D plans more flexibility to manage high cost drugs that do not provide Part D plans with rebates or negotiated fixed prices and adjust formulary or benefit design during the benefit year to address a price increase for a sole source generic drug.

NACDS supports efforts to curb the rising costs of prescription drugs but cautions HHS that any actions it takes must be balanced with ensuring access to needed prescriptions drugs for Medicare beneficiaries. Plans should only be allowed flexibility to manage drugs and make mid-year formulary changes, including in the protected classes, to the extent that doing so does not reduce drug coverage. Limiting access to prescription drugs can have several unintended consequences, including leading to decreased medication adherence, which further leads to poorer health and increased costs down the road. The importance of medication adherence is very clear. A 2013 CMS report found that Medicare Part D MTM programs consistently and substantially improved medication adherence for beneficiaries with chronic diseases. This included savings of nearly $400 to $525 in lower overall hospitalization costs.[3]

A study of published research on medication adherence conducted by Avalere Health in 2013 concluded that the evidence largely shows that patients who are adherent to their medications have more favorable health outcomes such as reduced mortality and use fewer healthcare services, especially hospital readmissions and ER visits. Such outcomes lead to less expensive healthcare costs, relative to non-adherent patients.[4] A more recent study found that gaining prescription drug insurance through Part D caused approximately a 4 percent decrease in hospital admission rate, a 2–5 percent decrease in Medicare inpatient payments per person, and a 10–15 percent decrease in inpatient charges.[5]

HHS must ensure any changes to drug management or drug formularies do not come at the cost of patient access and medication adherence.

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[3] "Medication Therapy Management in Chronically Ill Populations: Final Report;" Centers for Medicare and Medicaid Services (CMS); August 2013 (http://innovation.cms.gov/Files/reports/MTM_Final_Report.pdf).

[4] "The Role of Medication Adherence in the U.S. Healthcare System;" Avalere Health; June 2013 (http://www.avalerehealth.net/research/docs/20130612_NACDS_Medication_Adherence.pdf).

[5] Robert Kaestner, Cuping Schiman and G. Caleb Alexander, "Effects of Prescription Drug Insurance on Hospitalization and Mortality: Evidence from Medicare Part D" Journal of Risk and Insurance (2017).

### b. Indication-Based Care, Utilization Management, and Point of Prescribing Information

The RFI contains a number of proposals designed to impact drug costs, such as indication-based coverage, incentivizing better utilization management practices though STAR ratings, and requiring the provision of information to beneficiaries about drug increases and lower-cost alternatives, for which HHS should consider application at the point of prescribing. While all these proposals could help reduce prescription drug costs to some extent, their impact would be maximized when performed at the point of prescribing.

For example, providing beneficiaries with information about drug price increases or lower cost alternatives can be very helpful. However, the usefulness of the information is time sensitive. Providing this information after a prescription has been filled, such as through an Explanation of Benefits (EOB) or through an end-of-the-year annual statement, may allow a beneficiary to make a more informed choice going forward, but misses the opportunity to make an immediate change, as could be done if the information was provided at the point of prescribing.

In addition to ensuring the timely provision of information that allows a beneficiary to make an informed decision regarding their prescription drug treatment, NACDS has additional concerns related to indication-based pricing for prescription drugs. While coverage of prescription drugs may vary from plan-to-plan and state-to-state, we believe that, at a minimum, states and plans should be required to establish fair and adequate dispensing fees for all prescription drugs. The overall cost to acquire, maintain, and dispense a prescription drug is the same regardless of the indication the prescription drug was prescribed to treat. In current practice, pharmacists are required to follow the same process, level of effort, and utilize similar resources for all prescriptions, regardless of how the medication is being used. Accordingly, the dispensing fees should adequately reflect the true cost of dispensing these products. We believe that, at a minimum, HHS should strive to establish and maintain fair and adequate reimbursement for all drugs irrespective of indication. Additionally, HHS should ensure that the obligation is on the prescriber and the plan to determine and report the indication, not the pharmacy, as pharmacists may not diagnose patients and consequently cannot ultimately determine the indication or course of treatment and will not have access to such information at the time the prescription is filled. To achieve this goal, HHS should examine incorporating current commercial solutions that provide medication management and pricing transparency at the point of prescribing through the use of electronic health records and personalized, consumer-focused information for the provider.

### c. Report Identifying Savings Gained by Moving Part B Drugs to Part D

The RFI includes a section that would send the President a report identifying particular drugs or classes of drugs in Part B where there are savings to be gained by moving them to Part D. NACDS supports HHS examining the potential implications for reducing program costs and beneficiary out-of-pocket costs by moving some prescription medications from the Part B program to the Part D program.

NACDS recommends that as HHS examines which particular drugs or classes of drugs make the most sense to move from Part B to Part D, the Agency take into consideration potential changes to patient access and ensure any changes would not impede beneficiary access to medications, especially for beneficiaries who may not have Part D coverage. HHS should also look at the impact on cost-sharing (especially if it moves beneficiaries into the donut hole or catastrophic coverage), impacts on year-to-year drug pricing, coordination of care issues, and the possibility of wastage. Taking these into consideration, NACDS believes HHS should focus consideration on drugs routinely provided outside of the physician's office or hospital setting (i.e., self-administered drugs) as candidates for a potential shift from Part B to Part D coverage.

Furthermore, in examining proposed changes on drug coverage, NACDS also submits that shifting drugs between Parts B to D alone might not necessarily result in sufficient cost savings to Medicare or beneficiaries. While there may be therapeutic areas, patient populations, or other areas where savings may be realized, the proposed change may undermine broader goals to manage the total cost of care for a beneficiary – not just drug costs. To this end, CMS should examine how any changes to drug coverage (from B to D) would impact total cost of care. CMS also should explore how commercial plans and/or MA-PD plans view integration of medical and pharmacy benefits; whether there are opportunities to build on plan techniques; and whether there are opportunities to incentivize the inclusion of more providers and community-based settings (e.g., community pharmacists) value-based payment arrangements to improve health outcomes and reduce costs by managing transitions of care, chronic conditions, and delivering preventive care.

NACDS would appreciate the opportunity to work with HHS as it begins to examine this concept and provide any feedback.

### d. Reducing the Impact of Rebates

NACDS supports transparency in the Part D program and applauds HHS for looking at the impact manufacturer rebates, and other incentives or fees, have on drug

prices and the Part D program. As a part of a proposed Part D rule issued in the fall of 2017, CMS included a request for information (RFI) on potential proposals to require a portion of manufacturer rebates to be included in the negotiated price – the price used to determine a beneficiary's out-of-pocket costs at the point-of-sale. NACDS agrees that taking into account manufacturer rebates when calculating beneficiary cost share at the point of sale could lower out-of-pockets costs for beneficiaries and make medicine more accessible, leading to greater adherence and better health outcomes.

The RFI also addressed the use of direct and indirect remuneration (DIR) fees by potentially requiring all pharmacy price concessions to be included in the negotiated price. NACDS supports such a change and believes it would lead to lower costs and increased transparency in the Part D program. Last year, CMS released a fact sheet on the use and impact of DIR fees by plan sponsors in the Medicare Part D program.[6] The fact sheet reported that the use of DIR by Part D sponsors has been "growing significantly in recent years" and has led to an increase in beneficiary cost-sharing, an increase in subsidy payments made by Medicare, and an overall decrease in plan liability for total drug costs, despite the growth of Part D drug costs in recent years.

The increasing use of fees in the Part D program has been a growing burden for retail pharmacies as well. Retail pharmacies must conduct business in an environment where they are unsure if the reimbursement they receive today will be recouped weeks or months later, or if a fee will be applied to them at some future point. The unpredictable variability in the use of fees provides little visibility to retail pharmacy, particularly for performance-based fees and the goals necessary to achieve specified targets to "earn back" fee amounts.

In addition to restructuring the treatment of manufacturer rebates and pharmacy price concessions, we believe even greater transparency and benefits can be achieved by developing a meaningful and consistent pharmacy-specific performance-based incentive program that would be calculated separate and apart from the negotiated price to ensure such incentives do not increase costs for beneficiaries.

A pharmacy-specific performance program can be accomplished by requiring plans to determine payments based on achievable and proven criteria that actually measure pharmacy performance as opposed to criteria that focus on measuring plan performance and for which pharmacies may have little or no opportunity to influence. This should include pharmacy-specific measures that are standardized

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[6] Centers for Medicare and Medicaid Services. "Fact Sheet: Medicare Part D Direct and Indirect Remuneration." January 19, 2017 https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html

across and among plans. Currently, many plans have "performance programs" based on measures designated by the plans themselves. This leads to each retail pharmacy being subject to a varying number of potentially inconsistent and confusing performance measures.

In addition to implementing a pharmacy-based incentive program, NACDS recommends imposing a cap on the use of performance-based fees, along with a prohibition on the use of percentage-based fees for product reimbursement.[7] Limiting the amount of performance fees that can be collected related to a specific drug would facilitate greater transparency and predictability for pharmacies with fee amounts and ultimately reimbursement. Patients would benefit because cost variability would be minimized from drug to drug, as only a limited amount of fees could be subject to performance and outside of the negotiated price. A cap would also minimize the occurrence of DIR fees exceeding projected DIR in plan bids.

In addition to restructuring pharmacy price concessions, NACDS continues to urge CMS to issue guidance that would create even greater transparency and consistency in the use of fees and incentives. Such guidance should address the need for:

1. consistency in terminology applied to pharmacy reimbursement in the Medicare program for Part D plans and downstream entities, and
2. consistency in disclosures to pharmacies, including:
    a. how fees and incentives are defined,
    b. how fees and incentives are calculated,
    c. the timing for fee collection and incentive payments, and
    d. how fees and incentives will be reported to pharmacies at the claim level and at the remittance level, thus allowing reconciliation of reimbursement.

We urge HHS and CMS to address the use of fees in this fall's rulemaking process for the Medicare Part D program.

**4. <u>Medicare Part B: Competitive Acquisition Program</u>**

The RFI includes a policy designed to leverage the authority created by the Competitive Acquisition Program (CAP) for Part B Drugs & Biologicals. The RFI states that physicians will be provided a choice between obtaining these drugs from vendors selected through a competitive bidding process or directly purchasing these drugs and being paid under the current average sales price (ASP) methodology. The CAP program was authorized by the Medicare Modernization Act

[7] However, our concerns about percentage-based fees do not apply to pay-for-performance programs in which pharmacies are eligible for a percentage of reimbursement that is tied to improving beneficiary outcomes.

and was implemented by CMS from 2006-2008. However, CMS suspended the CAP beginning in 2009 due to lack of vendor competition, lack of physician participation, and little to no cost savings for the Medicare program.

NACDS has serious concerns with a potential new version of the CAP program and believes that the same issues impacting the first attempt at CAP will still exist for any future attempt. In addition to low participation and the inability to produce the desired savings, NACDS is concerned that drastic reductions in reimbursement for Part B drugs could lead to access issues for patients, ultimately affecting medication adherence and overall health, leading to poorer health and costlier medical interventions in the future.

Retail community pharmacies already operate on razor thin profit margins. About 80 percent of the average retail prescription price represents the pharmacy's costs of purchasing the product from the manufacturer and the wholesaler, with the remaining 20 percent representing the pharmacy's gross margin on the prescription. Of that 20 percent, more than 14 percent is consumed by pharmacy operational costs, including salaries, rent, utilities, the costs of maintaining and transferring inventory, and computer systems infrastructure. An additional one to two percent goes to pay state and federal taxes. After all expenses, the remaining net pharmacy profit on the average retail prescription price is about 2 percent. Should HHS decide to move forward with a CAP program, it is critical that dispensing fees be reviewed and adjusted to take into consideration the true cost of dispensing prescription medications to Medicare patients.

For these reasons, NACDS urges HHS to look at alternatives to the CAP program to reduce drug costs in the Medicare program.

**5. <u>Value-Based Care</u>**

A major part of HHS' proposals to revise how AMP is calculated is tied to the development of value-based arrangements. With respect to Medicaid reimbursement, the impact on AMP could vary depending on the type of value-based arrangement that HHS is considering. Again, it is imperative that HHS keep in mind the downstream effects that changes to AMP could have on pharmacy reimbursement and ultimately patient access to the valuable services that pharmacies provide.

Regarding value-based agreements, NACDS believes that improved care coordination and chronic care management are the cornerstones of the value-based agreement models, and medication management is central to both objectives. Any effort to improve quality and reduce costs over the long term will be difficult to achieve if patients do not take their medications appropriately and/or their

adherence is poor.[8] Considering the growing evidence that pharmacists are uniquely positioned to improve medication management across the care continuum and provide a range of health services in the community and as part of care teams, NACDS advocates for the expansion of community pharmacy inclusion in value-based pricing models.[9]

Successful outcomes for a value-based agreement model and other coordinated care programs will be dependent on making sure multiple provider types are able to provide their services to beneficiaries. This should include the multitude of services provided by community pharmacies. Pharmacists play a key role in helping patients

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[8] Zhong, W., Maradit-Kremers, H., Sauver, J. et al. 2013. "Age and Sex Patters of Drug Prescribing in a Defined American Population". *Mayo Clinic Proceedings,* 88, 696-707. New England Health Institute. "Improving Patient Medication Adherence: A $290 billion opportunity." Accessed June 23, 2014. http://www.nehi.net/bendthecurve/sup/documents/Medication_Adherence_Brief.pdf

[9] Brennan TA, et al. An Integrated Pharmacy-Based Program Improved Medication Prescription and Adherence Rates in Diabetes Patients. *Health Affairs*. Available at https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2011.0931?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub%3Dpubmed. Last Accessed June 13, 2018. Vegter S, et al. Improving Adherence to Lipid-Lowering Therapy in a Community Pharmacy Intervention Program: A Cost-Effectiveness Analysis. *Journal of Managed Care & Specialty Pharmacy.* Available at https://www.jmcp.org/doi/10.18553/jmcp.2014.20.7.722. Last Accessed June 13, 2018. Spence MM, et al. Evaluation of an Outpatient Pharmacy Clinical Services Program on Adherence and Clinical Outcomes Among Patients with Diabetes and/or Coronary Artery Disease. *Journal of Managed Care & Specialty Pharmacy*. Available at https://www.jmcp.org/doi/10.18553/jmcp.2014.20.10.1036. Last Accessed June 13, 2018. Van Boven JF, et al. Medication monitoring and optimization: a targeted pharmacist program for effective and cost-effective improvement of chronic therapy adherence. *Journal of Managed Care & Specialty Pharmacy.* Available at https://www.jmcp.org/doi/10.18553/jmcp.2014.20.8.786. Last Accessed June 13, 2018. Fikri-Benbrahim N, et al. Impact of a community pharmacists' hypertension-care service on medication adherence. The AFenPA study. *Research in Social and Administrative Pharmacy.* Available at https://www.ncbi.nlm.nih.gov/pubmed/23391845. Last Accessed June 13, 2018. Lee JK, et al. Effect of a pharmacy care program on medication adherence and persistence, blood pressure, and low-density lipoprotein cholesterol: a randomized controlled trial. *Journal of the American Medical Association.* Available at https://jamanetwork.com/journals/jama/fullarticle/204402. Last Accessed June 13, 2018. Jahangard-Rafsanjani, Z, et al. Effect of a Community Pharmacist–Delivered Diabetes Support Program for Patients Receiving Specialty Medical Care - A Randomized Controlled Trial. Available at http://journals.sagepub.com/doi/abs/10.1177/0145721714559132?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dpubmed. Last Accessed June 13, 2018. Giberson, S., Yoder, S., and Lee, M. 2011." Improving Patient and Health System Outcomes through Advanced Pharmacy Practice. A Report to the U.S. Surgeon General." Accessed June 23, 2014. http://www.accp.com/docs/positions/misc/improving_patient_and_health_system_outcomes.pdf. Centers for Disease Control and Prevention. 2011. "State Law Fact Sheet: Select Features of State Pharmacist Collaborative Practice Laws." Accessed June 23, 2014. Giberson, S., Yoder, S., and Lee, M. 2011." Improving Patient and Health System Outcomes through Advanced Pharmacy Practice. A Report to the U.S. Surgeon General." Accessed June 23, 2014. http://www.accp.com/docs/positions/misc/improving_patient_and_health_system_outcomes.pdf; Centers for Disease Control and Prevention. 2011. "State Law Fact Sheet: Select Features of State Pharmacist Collaborative Practice Laws." Accessed June 23, 2014.

take their medications as prescribed and offer a variety of pharmacist-delivered services (e.g., medication management services) to improve quality and outcomes.[10] Access to these types of services will not only benefit the overall health of patients but will also result in a decrease in overall healthcare costs.[11]

It is important that with the establishment of any type of value-based agreement HHS ensures that pharmacists can continue to provide the greatest value to patients and reimburse pharmacies accordingly for the innovative services provided by community pharmacists to the extent pharmacists can provide those services to Medicaid and Medicare beneficiaries. Furthermore, this reimbursement should be based on the services provided and not in any way be tied to or negatively impact pharmacies' reimbursement (product and/or dispensing fees) for prescription medications.

We believe that making product reimbursement dependent on value-based agreements is inappropriate in the pharmacy setting. Outcome-based arrangements that focus on the medication should solely be between manufacturers and payors and should only be determined by the payor and manufacturer as post-pharmacy adjudication rebates or adjustments. In the pharmacy setting, all medications dispensed are rightfully purchased and paid for by the pharmacy. At the time that the drug is dispensed, there is no way for a pharmacist to determine or predict if the desired outcome will be reached. Because of the inability to adequately determine the outcomes of any prescribed regimen, placing value-based rates on prescription drug reimbursement would place pharmacies at a potential financial loss for prescription medications dispensed if the desired outcome is not attained. Therefore, value-based agreement models should apply to the other, cognitive services that pharmacists provide and not be tied to prescription drug reimbursement. In addition, all metrics and outcomes goals should be focused on modifiable measures where pharmacies can be more influential on the outcome of those measures, such as medication adherence, and not on measures that are beyond the control of a pharmacist.

It is important to note that while the intent of the proposal is to determine the benefit and risk to Medicaid and Medicare beneficiaries by allowing manufacturers

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[10] Skinner JS, Poe B, Hopper R, Boyer A, Wilkins CH. Assessing the effectiveness of pharmacist- directed medication therapy management in improving diabetes outcomes in patients with poorly controlled diabetes. The Diabetes educator. 2015;41(4):459-465. doi:10.1177/0145721715587563. Rodis JL, Sevin A, Awad MH, et al. Improving Chronic Disease Outcomes Through Medication Therapy Management in Federally Qualified Health Centers. Journal of Primary Care & Community Health. 2017;8(4):324-331. doi:10.1177/2150131917701797.

[11] Dalton K, Byrne S. Role of the pharmacist in reducing healthcare costs: current insights. Integrated Pharmacy Research & Practice. 2017; 6:37-46. doi:10.2147/IPRP.S108047.
Sokol MC, McGuigan KA, Verbrugge RR, Epstein RS. Impact of medication adherence on hospitalization risk and healthcare cost. Med Care. 2005; 43(6): 521 – 30.

to exclude discounts, rebates, or price guarantees included in value-based arrangements from AMP, it is important to keep in mind the goals and intent of such agreements on patient care and overall outcomes and the impact on providers.

Although value-based agreement models have traditionally focused on physicians and hospitals, they are now expanding to include additional providers. The value-based agreement goal is to align performance and health outcomes with compensation by assessing performance using quality and health metrics, and to provide tools and programs to improve patient health outcomes. The contribution of community pharmacy in helping achieve the goals of value-based agreement models is extremely promising but such goals will be thwarted if the value-based models negatively impact the way pharmacy providers are reimbursed for prescription drugs.

Value-based agreements have the potential to improve outcomes, enhance care coordination, and create more system efficiencies. To this end, NACDS submits that to sufficiently address total cost of medical care, HHS should consider the value of prescription drugs in lowering overall medical spending in the Medicaid and Medicare programs. In so doing, HHS should align and incent payors/providers to establish relationships with community pharmacies to: (i) support care transitions (e.g. medication reconciliation and management); (ii) chronic care management (e.g. medication therapy management); and (iii) prevention (e.g. vaccinations) and health promotion (e.g. health coaching) in communities of beneficiaries.

**6. <u>Long-Term Financing Models</u>**

Included in the RFI are proposals to help states, insurers, and consumers pay for high-cost treatments by spreading payments over multiple years. We have an initial question whether long-term financing models could actually lower prescription drug costs. We are concerned that it would merely spread drug costs out over time and could instead actually increase costs by adding the cost of long-term interest into the drug pricing equation. More specific to pharmacy, while the RFI is unclear on which entities would be affected by the proposed long-term financing models, NACDS has concerns that long-term payment models would cause delayed prescription drug reimbursement to pharmacies and interruptions in patient access to needed pharmacy services. However, as outlined in more detail above, as with value-based care there may be opportunities for pharmacies to participate in long-term financing models related to cognitive services that pharmacies provide that are not specifically tied to the effectiveness of a particular medication. As above, examples include supporting care transitions, chronic care management, and prevention and health promotion.

It may be possible for some healthcare providers to extend the courtesy to their patients to make payments over time for services when they cannot pay for those

services at the point of care; however, pharmacies generally do not have the ability to offer this option for prescription drug payments due to the nature of pharmacy operations and finances. Imposing long term financing models that would reimburse pharmacy providers over multiple years would cause substantial financial burden and hardship on pharmacy providers that rely on reimbursement to cover the cost of products that have been fully ordered and paid for prior to dispensing to the patient. As a result, these types of payment models could potentially cause pharmacies and similar providers to discontinue business and ultimately cause interruptions in patient access to much-needed healthcare services.

Retail community pharmacies cannot bear the risk of acquiring and dispensing prescription drugs and then waiting years to be reimbursed. Pharmacies and other providers are required to pay for prescription drugs upon receipt. Moreover, although there may be substantial differences among the prices of the various prescription drugs, the pharmacy's overall cost to dispense is not dependent on the price of the drug. Regardless of the actual price of the drug, pharmacists are required to follow the same process, level of effort, and utilize similar resources for all drugs at the time the prescription is dispensed. In addition to the cost of pre-purchasing prescription products, there are other added costs that pharmacies incur when dispensing prescription drugs. These added costs include prescription department costs (e.g. inventory and warehouse carrying costs, prescription claim transmission expenses, pharmacy specific equipment, and computer systems); total facilities cost; and other pharmacy specific costs (e.g. professional services, systems support), which all contribute to the overall cost to a pharmacy of providing prescription drugs to patients.

Because the proposed long-term financing models appear to follow those types of financing models that are typically available for other very high cost products or services, such as housing (mortgages), education (student loans), or cars (auto loans), it is imperative that HHS considers the payment structures and parties of responsibility that are used in those situations. In these instances, the payor is responsible for financing the payment over time, and the provider of the service or good does not bear the financial risk. Thus, if purchasers require assistance in financing the purchase of prescription drugs over time, the cost of financing these purchases should not be forced upon pharmacies. Instead, we believe the financial risk should be borne by a financial intermediary as is done for other long-term financing models used for other high cost products.

In light of these concerns, we urge HHS to reconsider the proposal for long-term prescription drug financing models and instead focus on proposals to improve the existing mechanisms that are available to help patients cover their prescription drug costs. Specifically, similar to other long-term financing models, the current design of insurance premiums is to spread out the cost of drugs over time, regardless of how

much an individual incurs in drug costs at a particular point in time. Similarly, for insurers there is reinsurance (essentially insurance for insurers) which works on the same principles.

Pharmacies and other providers cannot control prescription drug pricing, and thus should not be required to bear the financial risks that flow from the economics of long-term prescription drug financing initiatives. Prescription drug long-term pricing models that include retail community pharmacies could potentially place pharmacies and patients in the unfortunate position of having to make decisions about the continuation of prescription drug therapy that could cause harm to patients' health. Poorly designed programs that would require pharmacies to take on long-term financial risk may force pharmacies out of business, which would reduce healthcare access particularly in the areas where healthcare options are the most limited and pharmacies are the most needed, rural and inner-city urban areas. Ultimately, this would lead to higher overall healthcare costs as patients would be forced to utilize more costly care down the road.

Lastly, in addition to the financial burden placed on pharmacies, it is also important to consider the administrative and systems challenges pharmacies would face with the adoption of prescription drug long-term financing models. For the drug benefit, the outpatient prescription drug industry uses standards developed and maintained by the National Council for Prescription Drug Programs (NCPDP). The NCPDP Telecommunication Standard is the Health Insurance Portability and Accountability Act of 1996 (HIPAA) named standard used today for the real time submission of claims billing by a pharmacy and the corresponding claim adjudication/payment response by the payor/processor. The current version as well as the more recently balloted versions of the standard are unable to accommodate any financial fields that exceed a certain amount. Unfortunately, the timeframe for industry modification of the standard, for HIPAA rulemaking, and for resulting industry system design, development, testing, and rollout of an updated version of the standard to accommodate drugs that exceeds such amount is conservatively estimated to be six years. As a result, it would be prohibitively difficult for pharmacies to accommodate any type of payment models that are outside of traditional payments that are billed under a medical or prescription drug benefit.

**7. <u>Pharmacy Benefits Managers and Gag Clauses</u>**

The RFI proposes that gag clauses should not be allowed in contracts between health plans and pharmacies, as such clauses prevent pharmacists from informing patients when a medication can be purchased at a lower price without using insurance. The RFI addresses this issue in the broader context of federal preemption of such clauses as well as specifically within Part D plans. NACDS fully supports the prohibition and/or removal of gag clauses in contracts between PBMs and pharmacies. We strongly believe this will enhance patient access to medications,

enable pharmacists to have improved relationships with patients, and keep healthcare costs for patients to a minimum.

In conjunction with eliminating gag clauses, we also support legislative and regulatory efforts to prohibit an insurance company or a PBM from requiring patients to pay an elevated cost at the point of sale. More specifically, the patient should not pay more than the lesser of his or her co-pay or the usual and customary retail price of the drug. We encourage HHS to consider this proposal as it refines the blueprint to lower prescription drug costs.

**8. Policy Solutions to Promote the Use of Cost-Effective Biosimilars**

NACDS strongly supports policies that will facilitate timely access to biosimilar products and promote the development of a robust biosimilars market. To that end, it is imperative that policies be implemented by FDA and other federal and state policymakers to facilitate the dispensing of less expensive biosimilar medications. This is critically important to ensuring patient access to biosimilar medications and to lower costs within the healthcare system.

**a. Biologic Naming Policies**

To further support adoption and use of biosimilar products in the broader healthcare system, NACDS urges revision of FDA's current naming policies for biological products wherein biosimilar medications are assigned a "core name" plus a nonsensical four-letter suffix. This naming practice deviates from historical naming conventions and can lead to general confusion relative to the appropriate use, safety, and efficacy of these medications, as well as therapeutic duplication that would be detrimental to patients' health. Moreover, naming practices for biological and biosimilar products that are different from other medications undermines healthcare provider and patient confidence in biosimilars and perpetuates the notion that biosimilars are not comparable to the innovator biologic.

To remedy this, FDA naming policies for biological medications should be updated so that they are consistent with naming practices for small molecule medications and assign each biological medication the same nonproprietary name. This naming paradigm is familiar to healthcare providers and patients alike and promotes confidence in and use of biosimilar medications.

**b. Biologic Interchangeability**

We believe that FDA should prioritize efforts that clarify that interchangeability is merely a requirement for additional data and does not mean that the product has met some degree of higher standard of safety and efficacy. FDA does not have more than one standard of product quality for the approval of biologics.

Over the years, state generic substitution laws have enabled pharmacists to dispense cost-effective generic medications. While the overwhelming majority of states have enacted legislation to similarly allow pharmacists to substitute biosimilar products that FDA has deemed to be interchangeable, none of the biosimilar products approved by FDA have been designated as interchangeable. Consequently, pharmacists remain limited in their ability to substitute more cost-effective, interchangeable biosimilar medications given that currently available biosimilars have not been approved simultaneously with an "interchangeable" designation.

Notably, the current system disincentivizes biosimilar manufacturers from seeking an interchangeability designation for approved biosimilar products. Instead, biosimilars manufacturers are likely to only seek biosimilar approval and not complete the required studies to demonstrate interchangeability, as completing the studies necessary to demonstrate interchangeability may not be a cost-effective strategy for many manufacturers. To resolve this conundrum, NACDS urges Congress, AHRQ and/or FDA to take appropriate action to encourage and expedite the availability of interchangeable biosimilars. Recognizing that it may not be cost-effective for many biosimilar manufacturers to perform the studies necessary to demonstrate interchangeability, we encourage Congress, AHRQ, and/or FDA to explore new approaches to facilitate the performance of the required interchangeability studies. FDA could achieve this by securing federal funding for interchangeability studies of approved biosimilars, or by accepting studies performed by health systems or other private entities that demonstrate interchangeability.

Additionally, in the meantime, we urge HHS and other policymakers to encourage federal and private programs to recognize the benefit of pharmacist therapeutic interchange for biosimilars as a cost savings measure.

### c. Improvements to Increase the Utility of the Purple Book

Policies and resources to facilitate the dispensing of more affordable biosimilar medications. Enabling pharmacists to substitute more affordable therapeutic alternative biological products, it is critical that FDA provide tools and resources, like the *Purple Book*, to support such dispensing.

The format of the *Purple Book* must be designed to clearly group and identify both therapeutic alternative biosimilars and interchangeable biological products with their respective reference products. This is especially important given that there are unlikely to be a significant number of interchangeable products on the market for years due to the market disincentives discussed above, and pharmacists will need to

know which products relate to a specific reference product and may therefore be appropriate for therapeutic interchange.

Finally, we believe that the terms describing biosimilars in the *Purple Book* are confusing to most laypersons. We recommend that FDA use the simplified term "Clinically Equivalent" to mean "no clinically meaningful differences."

### d. Educating Providers and Patients

As HHS noted in the RFI, physician and patient confidence in biosimilar and interchangeable products is critical to the increased market acceptance of these products. NACDS supports the education and outreach efforts to physicians, patients, and others to facilitate awareness, understanding, and adoption of biosimilars. We encourage FDA to continue efforts to educate healthcare providers and the public about biosimilar medications. Initiatives such as continuing education programs designed to familiarize healthcare providers with biosimilar medications and multi-media public awareness campaigns can be useful to promote further understanding and adoption of biosimilar medications.

Specifically, biosimilar education should stress that biosimilars are designed to match the structure and function of the reference biologic; patients should be assured that FDA-approved biosimilars have the same safety and efficacy as their reference products. Moreover, FDA should convey that the Agency approves biosimilars utilizing the same high standards for manufacturing and quality that apply to all biologics. The Administration should educate that the availability of biosimilars is anticipated to lower cost burdens for the U.S. health care system.

### e. Development and Product Review

To foster timelier biosimilar development and uptake, we recommend that FDA prioritize hiring to fill the remaining Biosimilar User Fee Act positions to ensure that manufacturer and FDA plans for the biosimilar market may be fully realized. Moreover, a fully-staffed biosimilar team at FDA is critically important for the development and evolution and FDA biosimilar policy, as well as education efforts, considering the need to counter ongoing misinformation campaigns that are frustrating the uptake and utilization of biosimilars.

## 9. Preventing REMS Program Abuses that Otherwise Impede the Availability of Generic and Biosimilar Drug Products

In the list of potential HHS responses to the President's call to action on drug prices, HHS has indicated that it will be taking steps to prevent the gaming of regulatory processes to impact the availability of generic drug products. To that end, the RFI notes that FDA will issue guidance to address ways in which some drug

manufacturers manipulate risk evaluation and mitigation strategy (REMS) requirements to delay or block market competition from new generic products. Since the RFI was originally published, FDA has announced plans to advance policies that address REMS system abuses to ensure that the REMS program is not misused to limit access to generic and biosimilar medications. We applaud the Agency's efforts to improve the REM process by stopping the gaming of the system to promote vigorous competition, but more action may be needed. To this end, we also support necessary legislative efforts to stops this anticompetitive conduct.

Pharmacies are committed to providing cost-effective healthcare to patients. For example, pharmacists engage in generic substitution practices that have saved patients and payors trillions of dollars over the years.[12] Given that access to generic drugs is critical for fostering price competition and lowering drug prices, we strongly oppose any efforts by manufacturers to misuse the REMS program and any other regulatory processes to limit access to generic and biosimilar medications.

While we support the FDA's goals of ensuring that the REMS program is not manipulated by brand manufacturers to preventing generic competition, we have concerns with one of FDA's proposed policy solutions for addressing such REMS abuses. In the draft guidance on *Waivers of the Single, Shared System REMS Requirement* which is applicable to REMS with elements to assure safe use (ETASU), FDA outlines the criteria that the agency will use to potentially grant waivers to single, shared system REMS requirements in certain circumstances. We strongly discourage FDA from waiving single, shared system REMS requirements for REMS with ETASU, as this can create significant burdens for healthcare providers which may discourage the prescribing and dispensing of generics (which is contrary to the agency's goal).

Particularly for drugs with REMS that have ETASU, a single, shared system REMS for brand and generic drugs is critical to ensure that any associated healthcare provider training, enrollment and/or authorization requirements are practical and workable for healthcare providers. If there are numerous REMS programs for the same medication, pharmacies filling prescriptions for medications subject to multiple manufacturers' REMS programs would have no way of knowing which program a particular prescriber and patient may have completed, making pharmacy compliance challenging. This could lead to significant delays in patient care as pharmacists would need to contact prescribers to determine which REMS would apply. Moreover, it is conceivable that prescribing healthcare providers may choose to prescribe *only* the brand product so that they do not have to go through the trouble of completing the requirements of separate REMS programs for generic versions of the brand medication, thereby undermining what FDA had intended to

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[12] GPhA, Generic Drug Access & Savings in the U.S. (June 2017)

accomplish by waiving the shared system REMS requirement in the first place. Such an outcome would force patients toward higher priced brand versions.

Federal law allows FDA to waive the single, shared system requirement for generic drugs if "the burden of creating a single, shared system outweighs the benefit of the single system," and the law directs FDA to "tak[e] into consideration the impact on health care providers [and] patients" (among others).[13] Given the significant burden that multiple REMS for the same drugs would have on healthcare providers, and subsequent burdens on the patient community, reversing course by waiving the single, shared system requirements would likely not meet the standard wherein "the burden of creating a single, shared system outweighs the benefit of a single system."

In light of the various concerns discussed above, we urge FDA to refrain from issuing waivers to single, shared system REMS requirements. Instead, we encourage FDA to further revise the draft guidance to identify and address the systemic loopholes that are being exploited to prevent new generic products from using single, shared system REMS.

**10. <u>Direct to Consumer Advertising</u>**

In the RFI, HHS indicates that the agency may call on FDA to evaluate the inclusion of list prices in direct-to-consumer ("DTC") advertising as a possible strategy to lowering drug list prices. Although drug prices ultimately are a reflection of prices set by manufacturers, there are many factors involved in the prices that consumers pay for their medications. Accordingly, if FDA does pursue this strategy and require manufacturers to include their list prices in DTC advertisements, any such consumers advertisements should make clear that the pricing information presented includes the manufacturer's price but does not necessarily reflect pharmacies' prices or patients' copays.

**11. <u>Disparity Between Drug Prices in US and other Countries</u>**

HHS raises concern that U.S. consumers and taxpayers generally pay more for brand drugs than do consumers and taxpayers in other OECD countries, and seeks input on what can be done to reduce this pricing disparity and share the cost of incentivizing new drug development more equally among the U.S. and other developed countries. NACDS supports policies that balance pharmaceutical innovation and access. We urge HHS to pursue policies that: (1) support requisite intellectual property and regulatory exclusivity rights of brand manufacturers, and (2) foster robust generic and biosimilar competition. We agree that HHS should seek appropriate legislative and regulatory solutions that put American patients first by ensuring that there are sufficient incentives that encourage innovation of novel pharmaceuticals while also ensuring that patients have access to affordable medications.

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[13] 21 U.S.C.A. § 355-1 (i)(1)(B)(i)

## 12. Drug Pricing Transparency

To provide patients, families, and caregivers with information to make more informed decisions and predict their cost sharing, the HHS RFI suggests directing CMS to make prices more transparent, hold drug makers more accountable for their price increases, and recognize when competition is working with an updated drug pricing dashboard. NACDS supports this HHS proposal and we are pleased that CMS has already unveiled updates to the Agency's drug pricing dashboard. We agree that patients should be provided with as much transparency as possible with respect to prescription drug pricing, so they may make highly informed decisions regarding their care. Moreover, providing this level of transparency should foster competition to keep patients' out of pocket costs to a minimum.

## 13. Conclusion

Again, we thank HHS for the opportunity to comment on the Agency's Blueprint to Lower Drug Prices through this RFI. As outlined above, we believe there are numerous opportunities to achieve the goals of lowering the financial burdens on patients and making prescription drugs more affordable and accessible. However, we caution HHS that policy proposals to achieve these goals should also ensure patient access to their prescription medications and critical pharmacy services by continuing to ensure that pharmacies are reimbursed fairly and adequately for their products and services. We look forward to further engagement with HHS on our mutual goals of utilizing prescription drugs and pharmacy services to save overall healthcare dollars.

Sincerely,

Steven C. Anderson, IOM, CAE
President and Chief Executive Officer