

July 16, 2018

Office of the Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Room 600E
Washington, DC 20201
Submitted Electronically: www.regulations.gov

RIN 0991-ZA49

**Re: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs – Policy Statement;
Request for Information**

Dear Secretary Azar:

The undersigned organizations thank you for issuing a Request for Information (RFI) regarding the ***HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket (OOP) Costs (Blueprint)***. We appreciate the Department’s interest in hearing from stakeholders regarding efforts to address “many of the challenges and opportunities impacting American patients and consumers” in obtaining affordable access to the medicines they need. We commend the U.S. Department of Health and Human Services (HHS) for its leadership on this important national issue. We agree with the HHS that we need a “national focus on lowering list prices and out-of-pocket costs” and to change “the system in a way that promotes the development of affordable innovations that improve health outcomes and lower both out-of-pocket cost and the total cost of care.” We support HHS’s goal of lowering both drug prices and OOP costs and while they are entwined in many ways, we wish to note that regardless of drug price, OOP costs impede access for far too many Americans. We stand ready to work with you and other policymakers to implement policies, which ensure all patients in need have access to the prescription therapies their healthcare providers prescribe for them while at the same time incentivizing the development of innovative new medicines that can help patients get well, stay healthy, keep their condition from worsening and/or have a higher quality-of-life.

Introduction

As organizations representing patients with serious, life-threatening, chronic, complex and disabling conditions, we have serious concerns regarding the adverse impact that out-of-pocket (OOP) costs have on patient access and adherence to medically necessary treatment. Cost sharing has far-reaching implications concerning the connection between access and health because delayed initiation of treatment or inability to remain on treatment due to OOP costs worsens health outcomes. Cost sharing creates a two-class system with respect to prescription medications: patients with adequate resources can access the full spectrum of health benefits from innovative advances in biotechnology and drug development while those with insufficient resources may have to settle for less-expensive treatments that may be less effective than newer options; skip doses; skip a refill; or forgo the medications altogether. Our organizations feel strongly that OOP costs should not prevent people from accessing the medications they need and remaining on treatment as long as their providers indicate is required.

We share HHS’s concern that too many people abandon prescriptions at the pharmacy counter after learning of the OOP expense. As HHS notes, “consumers asked to pay \$50 or more at the pharmacy

counter are four times more likely to abandon the prescription than a consumer charged \$10.”¹ The literature shows that patients who are unable to regularly access and afford the prescription drugs they need have lower adherence rates and poorer health outcomes than patients who can afford their drug OOP costs, including increased risk of mortality and higher hospital admission rates for patients with chronic conditions, among other adverse outcomes.²³ When patients cannot afford their therapies they cannot be adherent to their treatment plans, which can increase the total cost of care for these patients over time. Such an outcome hurts patients, their families, and taxpayers—all who bear the burden of the higher cost of care.

Thus, our organizations wish to underscore that patient assistance programs provide a much-needed safety net for so many patients—in both commercial and publicly funded health plans—who simply cannot afford the ever-growing costs of their medications. Until all patients have affordable, unencumbered access to the therapies they need, patient assistance programs must continue their critically important work of giving much-needed financial support to patients who require costly medications to maintain or regain their health, well-being and quality-of-life. As a threshold matter, while we appreciate that the drug access and reimbursement system is complex, we are broadly concerned that the RFI does not recognize the importance of this critical safety net that allows so many Americans, who otherwise could not afford to do so, to have access to the medications they need.

Below we provide comments on certain issues raised in the RFI, as well as suggest additional policies for HHS to consider to lower costs for patients. Most of our comments apply to patients in both public and commercial plans; however, when we have a concern specific to Medicare Part D policy and beneficiaries we note as such below. Our comments reflect our strong desire to partner effectively with HHS to achieve the goal we mutually share: ensure affordable patient access to innovative medicines that improve health outcomes and quality of life, particularly for the most vulnerable patients on limited incomes.

Overview of Feedback and Concerns

A combination of challenges—health plan benefit design, such as high deductibles, significant coinsurance or co-payment rates, structure of formularies, etc.—can make patient access to prescription medication difficult. Moreover, navigating the healthcare system often proves frustrating, confusing and problematic for too many patients, particularly those with serious, life-threatening, chronic, complex and disabling conditions. As such, while we appreciate the Department’s interest in boosting consumerism in healthcare, we have concerns regarding placing too much responsibility on patients. Shifting complicated decision-making onto beneficiaries cannot be a substitute for oversight.

We believe that patients and families do maintain responsibility for their healthcare, but there must be a balance between the patient, provider, public and commercial health plans, and pharmaceutical manufacturers. Cost sharing generally is intended to ensure patients have some “skin in the game” and to serve as a check on over-consumption and inappropriate utilization of services; however, studies have

¹ HHS. “American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.” May 2018, page 16.

² Centers for Disease Control and Prevention. “[Overcoming Barriers to Medication Adherence for Chronic Diseases](#).” February 21, 2017.

³ Pollitz K, Cox C, Lucia K, Keith K. Medical Debt Among People With Health Insurance. January 7, 2014. Kaiser Family Foundation. <http://kff.org/private-insurance/report/medical-debt-among-peoplewith-health-insurance> (Accessed June 21, 2016).

found that cost sharing too often stands in the way of patients accessing the care and treatment they need. Shifting the burden to patients will not save money if the result is patients developing more serious and more expensive health problems. As HHS considers changes to OOP costs, we must look at the total cost of care and the aggregate impact on patients, families and payers. Further, responsibility falls not only on patients and families but to all stakeholders. The underlying system, including payers and purchasers, has an important oversight role to play. The circumstances necessitate shared responsibility between patients, drug plans, manufacturers and other players in the marketplace; just shifting costs to the patient as the principal consumerism strategy will not achieve the intended goal of increasing access and reducing costs. We have particular concerns about strategies that emphasize patient choice when in far too many cases for the patients we represent, there are few, if any, therapeutic choices available.

To that end, our organizations believe that there is a shared opportunity to work together to improve information that is available to patients and to improve access to care. As part of this effort, information provided to support patients as consumers must be meaningful, easy to understand and actionable. Specifically, with respect to prescription drug pricing and related information, we note the following:

- Patients should have affordable access to prescription therapies prescribed to them by their providers, and type of insurance should not impact their ability to get the treatment they need.
- Transparency is important, and while giving people price information when they do not have the ability to pay their OOP costs may not help in the moment, it can be helpful for future planning and budgeting.
- While pricing transparency has the potential to help patients budget and plan ahead with respect to OOP costs for their medicines, there also is concern that information about particularly expensive therapies could scare patients from seeking treatment in the first place or preclude them from submitting prescriptions to be filled. This is true especially for medications with particularly high list prices; patients could view the high list price as a deterrent without fully understanding their cost sharing is based on a percentage of a negotiated price that differs (and is typically lower than) the list price. Transparency in these cases works against adherence and could exacerbate health problems for patients with conditions that are expensive to treat. As such, it is important to understand how and when pricing transparency is a net positive for patients and when it could do more harm than good without other support services, such as health system literacy.
- Generic drugs are not necessarily inexpensive, and patients should not be misled into believing that when they receive a prescription for a “generic,” they will be able to afford the therapy. Currently, certain generics are treated more like expensive specialty products, which are not affordable for patients. One example is generic immunosuppressive drugs taken by individuals with an organ transplant. Immunosuppressive drugs are small-molecule pills that do not require any special handling, but both generic and brand versions have been placed on higher cost-sharing tiers or designated as specialty in Part D and commercial plans.

We strongly urge HHS to adhere to the “precautionary principle” when considering changes to policies, programs and regulations related to prescription drugs; we believe that evidence-based research (e.g., economic modeling, patient surveys, etc.) needs to be undertaken before changes are implemented. HHS must be confident that any changes it makes will have the intended positive impact on individuals and

families rather than unintended consequences that could harm patients, making prescription drugs more unaffordable and less accessible for patients.

RFI Commentary

The following are key issues from the RFI of concern and priority to the patient advocacy community. Wherever possible, we have cited the particular item and page number from the RFI and/or the Blueprint, for your reference.

- **Establishment of an OOP maximum in the Medicare Part D catastrophic phase to reduce OOP spending for beneficiaries who spend the most on drugs [83 FR 22694].** The Medicare Part D benefit is complex and imposes significant OOP costs on beneficiaries, through the application of both deductibles and co-payments/coinsurance. When beneficiaries meet the True Out-of-Pocket (TrOOP) threshold—\$5,000 in OOP spending in 2018—they pay 5 percent coinsurance for their drugs until the end of the calendar year. The cycle resets on January 1 and currently there is no annual OOP spending cap. While 5 percent coinsurance may seem relatively small, such an amount often can run into the thousands of dollars for beneficiaries with chronic, disabling, serious or life-threatening conditions—especially those taking high-cost specialty medicines. This is particularly concerning for beneficiaries on limited incomes who do not receive the Medicare Part D Low-Income Subsidy (LIS) to make their drug costs more affordable; they should not have to make impossible choices between purchasing the prescriptions drugs they need to get well and stay healthy or pay for everyday living expenses. As such, we strongly support the imposition of annual cap on OOP spending in Medicare Part D for Medicare beneficiaries. Moreover, it is crucial to recognize that many patients struggle to pay their OOP costs before reaching the catastrophic threshold or OOP limit; therefore, close attention needs to be paid to ways to reduce or spread out these up-front costs, which we discuss in more detail below.
- **Evaluating options to allow high-cost drugs to be priced or covered differently based on their indication [83 FR 22696].** The Blueprint inquires whether it could be appropriate to implement indications-based pricing in Medicare. In indications-based pricing, the price and associated cost sharing for a product would vary by indication, such that those indications deemed more efficacious and safe would have a higher price and coinsurance than those indications with less robust efficacy and safety data. This is highly concerning for patients for a number of reasons. Patients using the medications in higher-priced indications would be discriminated against through higher cost sharing, and could have impeded access as a result.

We have serious concerns about charging higher coinsurance for off-label usage rather than on-label usage. This change could pose a barrier to patients in need of life-saving and life-sustaining care and thus would strongly oppose further consideration of such a policy. Very often prescriptions used off-label are to treat cancer, autoimmune conditions and neurodegenerative conditions, such as multiple sclerosis. Medicare Part B has long-standing policy of providing coverage and payment for off-label therapies, so long as certain criteria are met. This long-standing policy of off-label usage, from its inception, has enjoyed broad support among a bipartisan group of members of Congress, as well as physicians, nurses, and other health professionals, and the patient advocacy community. Congressional intent in creating the existing Medicare Part B off-label policy was to facilitate and ensure beneficiary access to needed treatments and as part of that intent, envisioned that the policy would level the playing field for beneficiaries needing off-label prescriptions. As such, efforts to increase OOP spending associated with off-label usage would discriminate against beneficiaries with

certain diseases and conditions, impede patient access to much-needed treatment, and run counter to Congressional intent and long-standing Medicare payment policy. We feel strongly that patients need to be protected and assured access to off-label therapies their providers prescribe for them. Moreover, changes to the existing off-label policy could be confusing for providers and beneficiaries. Further, there also are privacy and discrimination concerns associated with changes to off-label; for example, for some off-label HIV/AIDS drugs, adding information about the indication on the prescription and bottle could divulge confidential patient information.

- **Updating the Medicare Drug Dashboard [83 FR 22695].** The current Medicare Drug Dashboard is not consumer-friendly and not geared toward the average beneficiary. For example, the prices reported refer to average spending per dosage unit, but the dashboard does not provide detail on the dosage unit for the particular therapy. The information could be presented in a different manner that would be more meaningful to consumers and providers, who—ideally—work together in shared-decision making on cost-effective, affordable treatment plans. Any changes that are made should be consumer-tested with patients to ensure that the modifications achieve the intended outcome with respect to providing “patients, families, and caregivers with additional information to make informed decisions and predict their cost sharing.”⁴
- **Make changes to specialty tiers and number of drugs covered in each category, including the Medicare Part D protected classes [83 FR 22695].** The patient advocacy community has long advocated that patients need choices and access to a range of therapeutic options. The long-standing protection under Medicare Part D of requiring two therapeutic options in each category and class of Part D drugs has helped ensure patient access to the treatments they need. Reducing the number down to one has serious adverse implications for patient access and patient health outcomes. For example, for people with epilepsy, epilepsy drugs are not interchangeable and thus requiring coverage of only one drug to treat epilepsy in a given category or class could result in patients not being able to access the one medication that treats their condition. This is true for a number of diseases and conditions where adequate access to multiple therapeutic options is critical to achieving optimal patient health outcomes. Thus, we urge HHS to continue current policy of requiring Part D plans to cover at least two therapies in each category and class of Part D drugs. Further, we urge that the six Medicare Part D protected classes be maintained. The Centers for Medicare and Medicaid Services (CMS) established the protected classes at the advent of Part D to protect those highly vulnerable patients who need certain life-sustaining or life-changing medications and ensure they have unfettered access to those treatments. We are very concerned that any changes to the broad coverage requirements for the Part D protected classes would result in adverse patient health outcomes and cause substantial anxiety and confusion for beneficiaries. Therefore, we urge HHS/CMS to maintain current policy and make no changes to the Part D protected classes requirements.

Also, we would like to take this opportunity to speak to other possible changes to Part D formulary policies. First, we recommend creating, each year, a price ceiling for each Part D drug so a patient can budget what will be spent throughout the year and know it will go no higher. Nothing from such a requirement should prohibit Part D plans and drug manufacturers from lowering prices during the plan year. Second, irrespective of the creation of a price ceiling, patients should be made aware of pricing changes as quickly and frequently as possible. Third, adverse changes to formularies should only be allowed once a year no earlier than the middle of the plan year and patients should receive

⁴ 83 Fed. Reg. 22695.

frequent and prompt notifications if changes are made. Fourth, changes in the patient's favor—adding therapies, dropping prices, changing a therapy to a lower-tier category, availability of a cheaper generic, etc.—should be allowed throughout the plan year and patients should be informed in a prompt and clear manner. Finally, careful consideration should be given to requiring health plans to place at least one highly effective innovator drug for every indication on a non-specialty tier.

- **Prohibit Part D plan contracts from preventing pharmacists from telling patients when they could pay less OOP by not using their insurance – also known as pharmacy gag clauses [83 FR 22695 and 22699].** As noted earlier, we feel strongly that irrespective of type of insurance, patients should have affordable access to the treatment their providers have determined they need. We understand that in some cases for some patients and some therapies, it can be less expensive for a patient to purchase the drug outside of their healthcare plan. Pharmacists should be free to speak to patients about available options, particularly if a patient is inquiring about alternative ways to afford a therapy. However, we also note that patients will need to be educated about the impact of paying for a drug outside of their health plan and understand the implications for meeting deductibles and OOP caps. We further wish to acknowledge that pharmacists have many responsibilities and burdens and that patient education about OOP implications related to going outside of a health plan should not be placed on the community pharmacy staff.
- **Require Part D Plan sponsors to provide additional information about drug price increases and lower-cost alternatives in the Explanation of Benefits (EOB) they currently provide their members [83 FR 22695 and 22699].** Beneficiaries need easy-to-understand, timely and actionable information regarding the OOP costs of their prescription medicines. An EOB statement typically is provided to beneficiaries in response to claims being submitted and includes important information regarding their drug coverage (e.g., how much of any applicable deductible has been met, what has been paid year-to-date for OOP prescriptions, which part of the Part D coverage phase is the beneficiary in?). As EOBs are sent to patients after a drug has been purchased, there is a need to create and implement more timely ways of educating patients about the availability of less expensive, equally effective therapeutic alternatives in advance of their drug purchases. In some cases, a monthly or annual EOB can be a useful tool in helping beneficiaries understand and manage their Part D expenses. It could be used as an intentional information sharing and educational tool for beneficiaries, to make them aware of impending drug price increases and/or lower cost options. If the EOB includes information about drug price increases and/or lower cost options, the EOB should guide beneficiaries as to whom to contact regarding what these changes may mean for them and such information should be provided in writing. Some beneficiaries access their EOBs online while others may receive them in the mail. Either way, some beneficiaries may not look closely at their EOBs. As such, additional notifications of price increases or lower cost alternatives, such as follow-up email messages, might be appropriate and necessary. Moreover, it is imperative for beneficiaries to have meaningful information when they are choosing a Part D plan as well as throughout the course of their plan year. Beneficiaries report that choosing a plan can be overwhelming, confusing and difficult. Often, many beneficiaries do not change plans from year-to-year, not because they are satisfied, but because it is too cumbersome. It is important to strengthen the Medicare Part D Plan Finder tool and the accompanying information that is provided to help beneficiaries understand their plan options, the cost implications of different choices and formulary designs. In particular, the needs of the patients we represent—those with serious, life-threatening, chronic, complex and disabling conditions—are unique and information should be provided that is tailored to this special needs population. Further, individuals who are low-income, have low health literacy, or other challenges, must be provided information and support that helps them make a plan selection that most meets their needs.

- **Move some Medicare Part B drugs to Medicare Part D [83 FR 22697].** While we appreciate the Administration looking at innovative new ways to assist beneficiaries and facilitate access to affordable treatment, we are concerned that the full impact on patients from shifting Part B drugs to Part D is not fully understood; in certain cases, it could be helpful to patients and in other cases it could be deleterious. As such, we recommend HHS do more analysis before determining if this is a good policy to implement. For example, moving certain therapies from Part B to Part D could have significant OOP implications for patients and, in turn, rather than improving access and decreasing patient costs, could increase cost sharing; this could reduce, rather than improve, prescription drug affordability for patients, decrease patient adherence rates and increase demand for financial assistance. In many cases, particularly for high-cost specialty medications, the 20 percent patient cost sharing for therapies in Part B is lower than the 25 percent to 33 percent cost sharing for therapies on the Part D specialty tier; this is particularly concerning for beneficiaries using Medigap plans to supplement most or all of their cost sharing for Part B drugs. Further, shifting Part B drugs to Part D could result in some patients having to “brown-bag” or “clear-bag” with their therapies—having them delivered to home or picking them up from a pharmacy and bringing them to their physician’s office. In these cases, the provider cannot confirm the chain-of-custody of the drug or verify that the drug was handled or stored appropriately, which could harm patient safety; for example, by leading to an adverse drug reaction, or a waste of drug needing to be thrown away. Moreover, while there are some complex medications covered under Part D, the vast majority of complex therapies currently are covered under Part B and require unique approaches to storage, handling and administration, thus causing a challenge for providers without substantial experience handling these products. Therefore, in this case, even if the cost to the patient is less, the total cost to the system could be more. Given the significant number of unknowns with such policy and programmatic changes, we strongly suggest modeling or piloting these changes to ensure they do not harm patients.
- **Inform Medicare beneficiaries with Medicare Part B and Part D about lower-cost alternatives [83 FR 22699].** As noted above, beneficiaries need timely and useful information regarding the OOP costs of their prescription medicines. In addition to utilizing Part D EOBs, beneficiaries could be made aware of lower-cost alternatives through other methods, such as an online drug price and OOP cost comparison application, email or text messages, mailings, voicemail messages flyers or other inserts at the pharmacy accompanying prescriptions, etc. While providing information about lower-cost alternatives may help beneficiaries manage their costs, it is equally important to assist them in understanding what therapeutic alternatives mean for them and encourage them to seek guidance from their healthcare providers if considering a change. Information for beneficiaries should also include info on why medication adherence and treatment therapies are important (supplemented with safe and appropriate medication use education/messaging) not only for the well-being of the patient but also for their respective families and caregivers. It is not sufficient to notify patients about an increase in price or decrease in costs; in addition to this important cost data, it is critical to empower patients with information to support decision-making and provide information that helps patients know what actions to take. Just directing patients to be better shoppers is not a strategy or response to high list prices.
- **Considering changes to HHS regulations regarding drug co-payment discount cards [83 FR 22699].** In general, as a threshold matter, we wish to emphasize that co-payment coupons, discount cards, patient assistance programs and charitable foundations that offer cost-sharing assistance for patients are critical components of the safety net and are responsible for facilitating access to treatment, not

driving up drug prices.⁵ Unlike people with commercial insurance, it is unlawful for Medicare beneficiaries to use the coupons offered by pharmaceutical companies to help offset their OOP drug costs. To cover their OOP drug expenses, economically vulnerable Medicare beneficiaries often turn to safety net organizations such as charitable foundations as payers of last resort. As organizations representing patients with serious, life-threatening, chronic, complex and disabling conditions, we know first-hand the importance of co-payment coupons and patient assistance for the communities we serve. We also know that despite availability of both, there is significant and growing unmet need for co-payment support and charitable assistance among Medicare and commercially insured patients. Not all manufacturers offer drug co-payment coupons, coupons and discount cards often are not available for generic therapies, and many patients with serious illnesses and high OOP costs are unable to benefit from discount programs. When there is no lower-cost alternative, co-payment coupons can be the only way that a patient can afford treatment. Too many patients do not qualify for government subsidies to help pay for their cost sharing, such as the Medicare Part D LIS, but remain on limited incomes; without these and other forms of patient assistance from charitable foundations there would be no way these beneficiaries could access their therapies. We appreciate that the system by which patients access prescription drugs is complex, but we are concerned that the HHS plan does not include a discussion of the importance of this safety net and urge that the Department consider this essential safety net as it continues to develop and implement policies that make prescription drugs more affordable for patients.

Additional Policies to Make Prescription Drugs More Affordable for Patients

We appreciate that the RFI provides the opportunity to make additional “suggestions to improve the affordability and accessibility of prescription drugs.” As such, we respectfully submit the following for your consideration:

- **Smooth out the OOP expenses/fix the “seasonality” of triggering catastrophic coverage.** To understand the impact of OOP costs for prescription drugs under Medicare Part D, consider Ted, a beneficiary who has chronic myeloid leukemia (CML), a rare blood cancer, as well as diabetes and high blood pressure. His income is at 400 percent of the Federal Poverty Level, which makes him ineligible for Medicare’s Part D LIS. CML guidelines call for treatment with drugs called tyrosine kinase inhibitors (TKIs), a relatively new class of chemotherapeutic medications. Medicare beneficiaries who do not receive the LIS have high coinsurance requirements for drugs like TKIs because they are often designated as expensive specialty medications subject to the Part D specialty tier, where patients can pay up to 33 percent coinsurance. Further, under Part D, the coinsurance percentage for specialty drugs fluctuates across the coverage year, with the highest costs at the beginning of the year. The average Medicare patient with CML accumulated \$6,322 in OOP drug expenses for their health conditions. Of these OOP expenses, 95% were linked to their specialty medications. Of the \$6,322 in OOP drug expenses that Ted incurs during the year, he was responsible for \$2,456 in January alone. Of this amount, \$2,374 was linked to his specialty medications. Ted must therefore pay 40 percent of all of his OOP drug costs in the first month of the calendar year, with the vast majority of these unevenly distributed expenses being accounted for by his CML treatment. Although Ted pays only 5% coinsurance once he enters the Catastrophic Coverage Phase, the high cost of his medication results in the accumulation of 56 percent of his total OOP costs during this phase.⁶ This is due in part to the

⁵ Existing law can address those limited, inappropriate uses of patient assistance programs to mask price increases taken by drug manufacturers.

⁶ <https://panfoundation.org/files/PAN-Issue-Brief-2-Updated2018.pdf> (Accessed July 3, 2018)

absence of a spending cap during the Catastrophic Coverage Phase. The seasonality of OOP expenses and hitting one's annual OOP cap is not just a concern with Medicare Part D but also for patients with commercial insurance, where the OOP expenses are front-loaded in the plan year, placing significant financial burden on individuals and families. Therefore, we urge HHS to consider policies that would smooth out the substantial up-front financial burden that patients often face, particularly when taking high-cost specialty medications.

- **Consider the creation of a monthly OOP cap.** As noted above, the structure of Medicare Part D drug plans and many commercial health plans results in an uneven distribution of OOP expenses during the calendar year, with beneficiaries paying very high OOP costs for their drugs in the early part of the year and significantly lower amounts as the benefit year progresses. This creates a number of problems and places a particularly high financial burden on patients in a relatively short period of time. One idea that should be considered and explored is whether the creation of a monthly OOP cap would help protect patients from experiencing untenable costs in any one month and allow them to receive some support and relief once a particular threshold is hit in any respective month. If instituted, a monthly OOP cap should be a hard cap and any prescriptions that need to be filled after the cap is met should be covered at first-dollar coverage. We recommend this approach be examined and modeled to assess the impact on patients, premiums and access to and cost of care.
- **Help patients understand implications of their OOP caps, meeting deductibles, etc., when they pay for prescription therapies outside of their insurance plan and include those payments outside of health insurance toward OOP spending.** As noted above, beneficiaries and their caregivers report significant frustration and confusion regarding understanding the Part D benefit. Non-Medicare patients, including younger patients covered by commercial insurance, also indicate they experience challenges in understanding their health insurance coverage and benefit designs. As noted under the "pharmacy gag clause" item above, while it may sound consumer-friendly to offer patients the option of paying OOP for their prescriptions at-the-pharmacy if the cost will be lower than the "insured" amount, there are other important implications to consider. Patients may not understand that if they pay "at-the-counter" without using insurance, the money they spend may not be "counted" toward their meeting their deductibles or OOP spending thresholds. As such, the "real cost" to them may be different than first meets the eye. Helping all consumers have better understanding of health insurance and their coverage plans will further the HHS goal of a more consumer-friendly system and a consumer-driven marketplace. We encourage HHS to create a public awareness effort and health literacy campaign to help individuals and families generally gain better understanding of their health insurance benefits and, specifically when it comes to prescription drug coverage, to understand what choices are in their best interest in the long-run—not just immediately at the pharmacy counter. Further, information about the patient's total cost and impact on their benefit spending threshold should be provided in writing. Additional resources, such as patient navigators or advocates, should be made available to help the consumer understand available options and implications. We feel strongly that any money patients spend for prescription drugs—even if outside of their health plan—should count toward OOP. Patients should be able to submit the receipts to their health plans for reimbursement or calculation toward OOP.
- **Include co-payment and premium assistance in OOP costs and strongly discourage accumulator adjustment programs.** More and more people—Medicare beneficiaries and those with commercial insurance—are finding they cannot afford their prescription therapies. As the RFI notes, "Millions of Americans face soaring drug prices and higher OOP costs." As a community, we share HHS' concern

that “[t]oo many people abandon their prescriptions at the pharmacy when they discover the price is too high, and too many patients are never informed of lower cost options.” Fortunately, sometimes, because of the involvement and advocacy of a pharmacist, nurse, physician, financial navigator or other healthcare provider, patients learn of the availability of co-pay and/or premium assistance from charitable foundations or pharmaceutical companies (for patients not in federally-funded healthcare programs). This financial support often means the difference between a prescription purchased and taken according to doctor’s orders or a prescription left at the pharmacy or a script never dropped off in the first place. There is concern that, increasingly, some health plans could change the way in which such co-payment or premium assistance is factored into a patient’s OOP expenses. For example, recently some health plans have stopped “counting” the value of the manufacturer co-payment coupon cards with respect to patients meeting their OOP requirements. Called accumulator adjustment programs, these practices can impede patients’ ability to meet their deductible and co-payment thresholds, leading patients to face the full costs of their drug expenses for a longer period of time and needlessly spend more OOP each year. We also have heard reports of charitable premium assistance and charitable co-payment assistance being excluded from OOP. Given the safety net support that these manufacturer and independent charitable foundation programs provide to the patients we represent, we feel strongly that all of these patient support programs be counted toward OOP costs and that patients who need and benefit from premium and cost-sharing assistance programs should not face significant restrictions in accessing the medications they need to get well and stay healthy.

- **Eliminate cost sharing for generics for beneficiaries in the Medicare Part D program and eliminate co-insurance for brands when no generics and biosimilars are available.** We wish to take this opportunity to voice our support for the provision in the President’s FY 2019 budget proposal that would eliminate cost sharing on generic drugs for low-income beneficiaries. We appreciate that HHS took steps to lower OOP costs for Medicare Part D LIS enrollees by reducing co-payment amounts for biosimilar products for these patients, as noted in the RFI.⁷⁷ However, as organizations representing patients with a range of diseases and conditions, it is important to note that generic and biosimilar products often are not available for many serious illnesses—particularly for other low-income patients in commercial and federal health programs who do not benefit from the Part D LIS. Therefore, we believe it is equally important to find ways to reduce or waive co-payments for brand products when no generics are available, especially high-cost specialty products. Co-payments and coinsurance, as noted earlier, theoretically are designed to manage utilization and ensure “skin-in-the-game.” However, there are significant concerns—especially among economically vulnerable patients and families—that cost sharing restricts access to medically necessary treatment and excludes low-income patients from the benefits of new drugs, specialty drugs and high-cost generic medications. Making generics and biosimilars available without any OOP expense can help ensure that more patients have access to the therapies they need to adhere to the treatment plans their healthcare providers prescribe for them. Again, we wish to note that for too many of the patients we represent, a generic or lower-cost alternative is not available to them and therefore other efforts to facilitate their access to treatment will be imperative.
- **Undertake research to further understand barriers to treatment adherence and develop patient-centered programs that can help resolve them, particularly in underserved and underinsured communities and communities with high rate of aging populations.** We know that OOP cost is a

⁷⁷ 83 Fed. Reg. 22694.

significant factor in adherence, however, the challenges are likely multifactorial. Better understanding of barriers to treatment adherence will help improve outcomes and decrease costs.

- **Update the Medicare Part D LIS.** We feel strongly that it is time to update the LIS and modernize the associated asset test to reflect current needs and increase access for vulnerable patients. Charitable assistance foundations were created because the LIS falls far short of the Medicare population in need. There are hundreds of thousands of Medicare beneficiaries who do not qualify for the LIS yet still need “extra help” in affording their treatment. With an LIS that more adequately addresses the population in need, there likely would be less demand for coupons and charitable assistance. Again, as noted earlier, until we address access to affordable treatment for the nation’s most vulnerable, through changes such as boosting the LIS, we should not make other changes that would reduce access to therapies (e.g., restricting access to charitable assistance.)
- **Eliminate the 2020 Part D OOP “cliff”:** The Affordable Care Act (ACA) slowed the rate of growth in the Part D catastrophic threshold. At the end of 2019, however, the ACA provision will expire and beneficiaries will have to incur likely more than \$1,200 in additional out-of-pocket spending before reaching the catastrophic threshold. Without fixing the “cliff,” Medicare Part D enrollees will be subject to significant new out-of-pocket spending that they likely do not expect. As such, we urge the Administration to work with the Congress to fix the “cliff” as soon as possible and not subject patients to even more OOP spending on prescription drugs.
- **Passing on Medicare Part D rebates to beneficiaries at point-of-sale (POS).** In a separate November 2017 RFI, CMS solicited feedback specifically on whether to require Part D plans to pass on a minimum rebate to beneficiaries at point-of-sale (POS).⁸ Passing on a minimum rebate to the beneficiary at POS will lower cost sharing for patients who need help paying for their medications, particularly for those expensive high-cost specialty medicines that can generate thousands of dollars in OOP spending. While, because of such policy, Part D premiums may be slightly higher for all enrollees, passing on rebates at POS will meaningfully lower OOP costs for those patients who really need assistance. Thus, we support CMS implementing a policy that would require Part D plans to pass on a minimum rebate to beneficiaries at POS.

Conclusion

On behalf of the millions of patients our organizations represent, we thank you for this opportunity to provide feedback on the RFI for the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. Patients with serious, life-threatening, chronic, complex and disabling conditions need access to the care and treatment their healthcare provider determines is appropriate. We must do more to ensure access for people in need, and as part of that, strengthen the nation’s safety net, which includes Medicare, Medicaid, charity care and co-payment assistance. We appreciate your attention to and consideration of our comments and stand ready to partner with you on these important issues. If we can be of any assistance to you and your staff, please do not hesitate to contact any of the undersigned organizations directly.

⁸ CMS. “Medicare Program; Contract Year Policy and Technical Changes to Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program.” November 28, 2017. 82 FR 56336.

Sincerely,

Undersigned Organizations Listed Alphabetically

ADAP Advocacy Association
ADAP Educational Initiative (ADAPEI)
Alliance for Aging Research
American Brain Tumor Association
American Liver Foundation
American Parkinson Disease Association
Aplastic Anemia and MDS International Foundation
Asthma and Allergy Foundation of America
Caregiver Action Network
Caregiver Voices United
Colorectal Cancer Alliance
Community Access National Network (CANN)
Crohn's & Colitis Foundation
Cutaneous Lymphoma Foundation
Digestive Disease National Coalition
Dystonia Medical Research Foundation
FamilyWize Community Service Partnership
Family Reach
GBS|CIDP Foundation International
Good Days
International Myeloma Foundation
Living Beyond Breast Cancer
International Foundation for Functional GI Disorders
Interstitial Cystitis Association
Lung Cancer Alliance
LUNGeivity Foundation
Lymphatic Education & Research Network
Medicare Rights Center
Melanoma Research Foundation
Mended Hearts and Mended Little Hearts
Men's Health Network
METAvivor
MPN Advocacy & Education International
National Alopecia Areata Foundation
National Kidney Foundation
National Multiple Sclerosis Society
National Osteoporosis Foundation
National Ovarian Cancer Coalition
NeedyMeds
NephCure Kidney International
Ovarian Cancer Research Fund Alliance
Patient Access Network (PAN) Foundation
Patient Services, Inc.

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Policy Statement; Request for Information***

Prevent Blindness
Pulmonary Hypertension Association
Restless Legs Syndrome Foundation
Scleroderma Foundation
The Marfan Foundation
The Pink Fund
US Hereditary Angioedema Association
Us TOO International Prostate Cancer Education & Support
ThyCa: Thyroid Cancer Survivors' Association, Inc.
WomenHeart