



July 16, 2018

VIA ELECTRONIC SUBMISSION

Secretary Alex Azar
U.S. Department of Health and Human Services
200 Independence Ave, SW
Room 600E
Washington, DC 20201

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

Dear Secretary Azar:

The Medicare Rights Center (Medicare Rights) appreciates the opportunity to comment on the U.S. Department of Health and Human Services (HHS) Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.

Medicare Rights is a national, nonprofit organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Medicare Rights provides services and resources to three million people with Medicare, family caregivers, and professionals each year.

From our experience assisting people with Medicare and their families, we know that prescription drug affordability is an ongoing challenge. Every day, through our National Consumer Helpline, we hear from older adults and people with disabilities who are struggling to cover their drug costs. This is not surprising, given that nearly half of all Medicare beneficiaries live on annual incomes of \$26,200 or less, and one quarter live on \$15,250 or less.¹ Most people with Medicare simply cannot afford to pay more for health care. Accordingly, any forthcoming efforts to implement the Administration's strategy must make prescription drugs more affordable, without otherwise increasing costs or reducing access to care for people with Medicare.

General Comments

Medicare Rights supports efforts to make prescription drugs more affordable for the millions of people with Medicare, as well as for the Medicare program and health care system as a whole. Accordingly, we welcome the

¹ Jacobson, Gretchen, et al; Kaiser Family Foundation. "Income and Assets of Medicare Beneficiaries, 2016 – 2035" (April 21, 2017), <https://www.kff.org/medicare/issue-brief/income-and-assets-of-medicare-beneficiaries-2016-2035/>.

Administration's focus on prescription drug prices and the opportunity to work together to advance meaningful solutions.

We are disappointed, however, that the Administration's approach does not attempt to leverage the federal government's negotiating power. We understand there are statutory limitations on the Medicare program's ability to negotiate drug prices at the national level, but see that negotiation as a necessary tool in the toolbox to reduce drug spending. We encourage HHS to revisit and prioritize its use of this authority.

Similarly, our general support for reducing costs for people with Medicare is coupled with our concern that many of the ideas in the Blueprint and Request for Information (RFI) do not address the fundamental issue—high manufacturer prices. Instead, there is significant reliance on cost shifting from one payer to another. As a result, these ideas may at best lead to no direct improvement for beneficiaries, and at worst increase their out-of-pocket (OOP) costs and reduce their access to care.

For example, while we appreciate HHS' focus on increased transparency, we are concerned that many of the outlined proposals—such as adding list prices to consumer ads for prescription drugs—would do little to lower beneficiary costs but could greatly increase the burdens they face. Giving people information they may not readily understand or know how to use is not true transparency, especially when the information is confusing or potentially misleading. Additionally, we are concerned that transparency of pricing may be used as an excuse to shift responsibility for curbing spending onto beneficiaries, many of whom are not best equipped to determine the ultimate appropriateness or inappropriateness of a given course of treatment.

Five-Part Plan

The President's Fiscal Year (FY) 2019 Budget Request to Congress announced a five-part plan to "modernize" the Medicare Part D program. Throughout the Blueprint, the Administration states its intent that all five pieces of this proposal move together. We do not support this all-or-nothing approach. We are concerned the plan as a whole would do little or nothing to improve access to medications or reduce costs for people with Medicare. However, there is evidence that aspects of the proposal could help lower their out-of-pocket costs if implemented independently.² We encourage HHS to thoroughly review and consider the proposals individually, rather than only in the context of the five-pronged approach.

Requiring Medicare Part D Plans to Apply a Substantial Portion of Rebates at the Point of Sale. In November 2017,³ the Centers for Medicare & Medicaid Services (CMS) requested information on applying some manufacturer rebates and all pharmacy price concessions to the price of a drug at the point of sale. As we commented at the time,⁴ we support greater price transparency and are concerned that the incentives of Part D

²Swartz, Katherine; Harvard School of Public Health, Robert Wood Johnson Foundation. "Cost-sharing: Effects on Spending and Outcomes" (December 2010), <https://pdfs.semanticscholar.org/74a9/ebaf52a9b789415d476abfdca5f8097dc9fc.pdf>.

³CMS. "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), <https://www.federalregister.gov/documents/2017/11/28/2017-25068/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare>.

⁴ Medicare Rights Center. "Re: CMS-4182-P" (January 16, 2018), <https://www.medicarerights.org/pdf/Medicare-Rights-Center-C-D-Comments-CMS-4182-P.PDF>.

allow, and even encourage, a system of drug pricing and rebating that disguises true prices and shifts spending to beneficiaries and the federal government.

While passing through a percentage of rebates and pharmacy price concessions to people with Medicare at the point of sale may increase price transparency, the projected premium increases associated with this policy are concerning. Before moving forward, CMS should determine the percentage of rebates and price concessions to pass through using a strong evidence base so as to maximize transparency while minimizing increases to premium rates. We understand that premiums are set according to a multifactorial process. Accordingly, were this proposal to advance, we would urge CMS to closely monitor premiums and other Part D plan components, making appropriate changes if necessary. It is important to note that while this proposal may lead to lower cost sharing for some beneficiaries, it will not solve the larger problems with drug pricing. Medicare Rights continues to encourage CMS to develop strategies to address the high costs of prescription drugs faced by beneficiaries and the program as a whole.

Establishing an Out-of-Pocket Maximum in the Part D Catastrophic Phase. The Administration identifies the potential to establish a beneficiary out-of-pocket maximum for Medicare Part D. We agree that Part D should have a cap in order to reduce the incredible financial burden on beneficiaries who have the highest drug costs. Research shows that mean out of pocket costs have increased significantly in the catastrophic phase; thus, an OOP maximum is a critical avenue to lower OOP costs for beneficiaries.⁵ An OOP maximum would also allow beneficiaries to adequately plan their expenses for the coming year, as those with high OOP costs would know that their OOP costs are limited.

Excluding Manufacturer Discounts from the Calculation of Beneficiary Out-of-Pocket Costs in the Medicare Part D Coverage Gap. Medicare Rights opposes removing the manufacturer discounts from the determination of a beneficiary's True Out-of-Pocket (TrOOP) costs. This policy change would extend the amount of time some beneficiaries spend in Part D's coverage gap, unacceptably shifting additional burdens onto people with high drug costs. A recent analysis found that if implemented in 2016, this policy would have increased beneficiary out-of-pocket costs by \$4.1 billion between 2017 and 2020—an annual per capita increase of up to \$1,080 for over one million beneficiaries.⁶

Increase Medicare Part D Plan Formulary Flexibility. Beneficiaries need access to a range of therapeutic options and their access to needed medication would suffer if plans were permitted to offer only one drug per category or class. 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 patients have access to the treatments they need. Moreover, careful consideration should be given to ensuring health plans do not place all drugs for a given indication on a specialty tier.

⁵ Trish, Erin, Jianhui Xu, et al.; Health Affairs. "Medicare Beneficiaries Face Growing Out-Of-Pocket Burden for Specialty Drugs While in Catastrophic Coverage Phase" (September 1, 2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5573178/>.

⁶Frieder, Miryam. "Proposed Changes to Part D Would Increase Beneficiary Costs" (March 30, 2016), <http://avalere.com/expertise/managed-care/insights/proposed-changes-to-part-d-would-increase-beneficiary-costs>.

Eliminating Cost Sharing on Generic Drugs for Low-Income Beneficiaries. Medicare Rights supports eliminating cost sharing on generic drugs for low income beneficiaries. As the Administration suggests, this would encourage beneficiaries to utilize lower priced drugs, in addition to lowering OOP costs for beneficiaries.

Increasing competition

Underpricing or Cost-Shifting. HHS asks if current programs contain the correct incentives to obtain affordable prices on safe and effective drugs. The current Medicare Part D system encourages a lack of transparency and high list prices, which shift costs onto beneficiaries. In addition, the lack of negotiation at the Medicare program level leads to high variability in benefits for consumers and higher than necessary out-of-pocket costs. Many of the proposals in this RFI would simply shift costs from one pocket to another rather than tackling the underlying problem.

Better Negotiation

Demonstration Projects. In the RFI, HHS suggests that it may take action to support better negotiation by directing CMS to develop demonstration projects to test innovative ways to encourage value-based care and lower drug prices. We caution that any demonstration project must have beneficiary protections built in, from design through implementation. Such projects must engage and offer more effective information and assistance to consumers, caregivers, and families, as well as improve transparency and oversight.

Allowing Part D Plans to Adjust Formulary or Benefit Design During the Benefit Year. HHS also suggests allowing Part D plans to adjust formulary or benefit design during the benefit year if necessary to address a price increase for a sole source generic drug. However, beneficiaries do not have the freedom to change plans whenever there is a change in formulary or pricing; therefore beneficiary access to needed medications should be protected from formulary changes or price increases.

Similarly, Medicare Rights continues to strongly oppose recent changes to Part D that will allow for faster mid-year substitution of generic drugs onto formularies. The current law 60-day notification period gives the beneficiary adequate time to understand what to expect at the counter, and how a generic drug may affect their treatment regimen. Without this notification, beneficiaries may experience a sudden change in cost sharing and/or unexpectedly receive a drug that differs in size, shape, or color from the medication they are used to. Such changes can cause undue stress for beneficiaries, regardless of whether their treatment regimen could withstand a change to generic drugs. This disruption could, in turn, negatively affect adherence and health status.

Updating the Methodology used to Calculate Drug Plan Customer Service Star Ratings for Plans that are Appropriately Managing Utilization of High-cost Drugs. Medicare Rights strongly opposes this change. The appeals process is an essential safety valve, allowing access to prescription medications that are not on the plan's formulary, or are subject to high cost sharing, when formulary or lower cost alternatives are not appropriate for a beneficiary's unique medical needs. To ensure that Part D enrollees can successfully navigate the appeals process, we continue to strongly encourage CMS to improve information at the point of sale and to streamline the appeals process.

Access to information about the reason for a plan denial—provided at the pharmacy counter—would eliminate significant beneficiary confusion and limit delays in accessing needed medications. Armed with information about why a prescription drug was refused at the pharmacy counter, Part D enrollees and their providers would be better equipped to determine the best course of action for the beneficiary’s health. Along these same lines, we strongly support allowing the pharmacy counter refusal to serve as the coverage determination. This would remove a burdensome step for beneficiaries and their prescribers, by explicitly stating why the drug is not covered and by expediting the appeals process for those who need it.

We also continue to support CMS efforts to thoroughly evaluate how audits, civil money penalties, and sanctions impact Star Ratings.⁷ This work is important, as any disconnect between audit scores and the Star Ratings system can be a source of confusion for people with Medicare and professionals seeking to evaluate and compare health plan quality.

We strongly urge CMS to ensure that the Star Rating system does not camouflage or minimize plan behaviors that put Medicare enrollees at risk, even if those behaviors are consistent with other plan goals or objectives. People may be less likely to appeal to the IRE if their denial is understandable, based in accurate interpretations of Medicare law, and well explained. Indeed, the number of appellants who are successful at the IRE indicates continued and pervasive failures at the plan appeal level. CMS should accurately signal these failures through Star Ratings, providing beneficiaries with a clear tool that helps them fully evaluate and compare health plans. Of particular concern is the repeated finding of the same serious deficiencies in audit scores while Star Ratings continue to rise.

Further, we urge CMS to establish a cost-sharing exception and appeal process for drugs included on the specialty tier. The issue remains exceptionally important for beneficiaries with conditions that have limited treatment options (i.e., when all of the therapeutic options fall under the specialty tier and its equivalent higher cost-share for beneficiaries). For all other plan formulary tiers, beneficiaries may file an exception for a drug to be placed on a lower cost-sharing tier, provided that the medication is the only therapy available for their disease. Specialty tier drugs are the sole exception to this, despite the fact that these drugs often having the most burdensome cost-sharing requirements. We encourage CMS to reconsider this policy and implement an exception and appeal process for the specialty drug tier as soon as practicable.

Transparency. HHS asks what steps can be taken to improve price transparency so that consumers can seek value when choosing and using their benefits. Removing incentives to hide pricing and requiring transparency at all levels would be a good step toward removing some of the worst excesses and cost shifting. However, this cannot be used as an excuse to increase the responsibility of beneficiaries for controlling drug spending and costs. Most beneficiaries are not medical experts and cannot be expected or required to understand which drugs are appropriate for their conditions; many have difficulty correctly interpreting even simple displays of Medicare health plan information.⁸

⁷ Medicare Rights Center. “Re: Enhancements to the Star Ratings for 2018 and Beyond” (November 2016), <https://www.medicarerights.org/pdf/112916-comments-enhancements-star-ratings-2018.pdf>.

⁸ O’Brien, Ellen and Jack Hoadley; The Commonwealth Fund. “Medicare Advantage: Options for Standardizing Benefits and Info to Improve Consumer Choice” (April 2008),

Value-Based Arrangements and Price Reporting. HHS asks what benefits would accrue to Medicare beneficiaries by allowing manufacturers to exclude from statutory price reporting program discounts, rebates, or price guarantees included in value-based arrangements. The complex interactions that increase or decrease drug prices must be thoroughly explored and studied before any changes are made that may increase the burden on beneficiaries. As with many proposals in this Blueprint, this proposal appears not to address the fundamental issue: high, unaffordable, drug prices.

Indication-Based Payments. HHS asks if it could be appropriate to implement indication-based pricing in Medicare, such as by charging higher coinsurance for off-label usage than for on-label usage. People with Medicare must be protected and assured access to the therapies their providers prescribe for them. We oppose policies that would inhibit this access, including those that would increase beneficiary OOP costs. Studies have demonstrated that increased out-of-pocket spending can disproportionately burden people with high health needs and reduce utilization of necessary, clinically-important treatments— leading to worse health outcomes and higher program costs.⁹

Medicare Part B has a long-standing policy of providing coverage and payment for off-label therapies, so long as certain criteria are met. Accordingly, increasing out-of-pocket spending for certain indications—such as those associated with off-label usage—poses an extreme risk of permitting, or advancing, discrimination against beneficiaries with certain diseases and conditions, while driving down compliance for treating those indications. This is especially concerning for expensive or hard-to-treat disorders or diseases, as well as for those with few drug options or a reliance on off-label access. Options to lower out-of-pocket spending for certain indications would be more appropriate, but care must be taken that it does not lead to discrimination.

In addition, indication-based pricing raises privacy concerns for patients. To correctly bill Medicare, pharmacists would need information about the indication for which a beneficiary utilizes a drug. This is information that pharmacists do not currently have, and beneficiaries may not wish to share.

Long-term Financing Models. Long-term financing models are being proposed to help states, insurers, and consumers pay for high-cost treatments by spreading payments over multiple years. HHS asks if the state, insurer, drug manufacturer, or other entity bear the risk of receiving future payments. While finding ways of dealing with expensive new treatments is vital to ensuring such treatments are available for beneficiaries who need them, it is important that any new financing model not increase the net burden on beneficiaries.

Moving Drugs from Part B to Part D. We are concerned that the proposal to shift some Part B drugs to Part D would lead to higher OOP costs for beneficiaries, depending on the individual's coverage and combination of drugs, among other factors. For example, in many cases, particularly for high-cost specialty medications, the 20% patient cost sharing for therapies in Part B is lower than the 25% to 33% cost sharing for therapies on the Part D specialty tier. Depending on the mix of drugs a beneficiary takes, they could also be pushed into the coverage gap sooner if they are paying for more drugs under Part D. And nearly eight million beneficiaries don't

http://www.commonwealthfund.org/~media/Files/Publications/Issue%20Brief/2008/Apr/Medicare%20Advantage%20%20Options%20for%20Standardizing%20Benefits%20and%20Information%20to%20Improve%20Consumer%20Choice/O'Brien_Medicare_Advantage_options_1117_ib%20pdf.pdf

⁹ Paez, Kathryn Anne and Lan Zhao, et al; Health Affairs. "Rising Out-Of-Pocket Spending for Chronic Conditions: A Ten-Year Trend" (January/February 2009), <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.28.1.15>.

have Part D coverage, meaning they would lose coverage for the drugs that shifted from Part B to Part D.¹⁰ Overall, analyses conducted by CMS and other stakeholders have found that shifting some drugs from Part B to Part D would lead to increased out-of-pocket costs for at least some beneficiaries.¹¹

In addition, certain drugs, often very expensive drugs for devastating conditions, require careful handling and transportation, such as refrigeration. The average patient may be unable to safely handle and transport such fragile medications or may be anxious about their ability to do so. We cannot support any model that would transfer the risk of drug handling to beneficiaries who may face challenges maintaining the drug's safety and efficacy.

Rather than jeopardize beneficiary access to care, we encourage HHS to explore alternative reforms to Part B. Medicare Rights regularly hears from older adults and people with disabilities who are unable to afford the 20% coinsurance for costly Part B medications. Most often, these are individuals who are among the 14% of people with Medicare who lack adequate supplemental coverage. Part B medications, commonly used to treat cancer, macular degeneration, anemia, and arthritis, tend to be very expensive. According to a recent analysis, some beneficiaries spend as much as \$107,000 per year on Part B medications, and in 2015 the Medicare program spent \$22 billion on these prescription drugs.¹² And the current Part B prescription drug reimbursement model can create a perverse incentive to prescribe higher cost medications.

Because of these issues, Medicare Rights supported a previously proposed CMS initiative to test value-based payment strategies for prescription drugs covered under Medicare Part B. By testing a variety of reimbursement methods and value-based purchasing innovations already in use in the private insurance market, the proposed test would have promoted utilization of the most clinically effective medications—not the most costly. This test would have explored multiple strategies to encourage the use of high-value medications, especially those that eliminate or lower beneficiary cost sharing and promote the adoption of evidence-based clinical decision support tools.

HHS should return to the idea of testing multiple strategies to better understand the effects and repercussions of any one change to the Part B program. Barring such sweeping testing, extensive research into which drugs moving from Part B to Part D would save beneficiaries money without curtailing access to care must be a priority. The effect of such a move on people with Medicare supplemental plans must be included in any such research.

HHS also asks if Part B drugs sold by manufacturers offering lower prices to OECD nations be subject to negotiation by Part D plans. Rather than a piecemeal approach, Medicare Rights supports broad negotiation of

¹⁰Kaiser Family Foundation. "Medicare Prescription Drug Plans: Enrollment" (March 2014 data), <https://www.kff.org/medicare/state-indicator/medicare-rx-drug-coverage/?currentTimeframe=0&selectedDistributions=beneficiaries-in-employer-plans-taking-retiree-drug-subsidies--beneficiaries-with-other-prescription-drug-coverage--beneficiaries-with-no-known-creditable-drug-coverage&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>.

¹¹ Brow, Matt and Richard Kane. "Avalere Analysis Highlights Complexities of Transitioning Medicare Part B Drugs into Part D" (May 21, 2018), <http://avalere.com/expertise/life-sciences/insights/avalere-analysis-highlights-complexities-of-transitioning-medicare-part-b-d>.

¹² GAO. "Medicare Part B: Expenditures for New Drugs concentrated among a Few Drugs, and Most Were Costly for Beneficiaries" (October 23, 2015), <https://www.gao.gov/products/GAO-16-12>.

prices by the Medicare program. We do not expect such negotiation to end the problem of high drug prices, but it would likely prove more effective at reducing drug costs for beneficiaries and the Medicare program than the current plan-by-plan negotiation scheme. Access to medications must be the priority, but “access” is not real if the drug is not affordable, and Part D plan negotiation is demonstrably ineffective at reducing drug pricing and keeping prescriptions affordable.

International Pricing Disparity. HHS asks for ways to reduce the pricing disparity and share the burden for incentivizing new drug development more equally between the U.S. and other developed countries. Basic economic theory reveals that increasing drug costs in other countries will do nothing to decrease drug costs in the U.S.; it would only serve to drive up manufacturer profits.

If the Administration is truly interested in legislative solutions to high drug prices, requesting that Congress lift any restrictions on Medicare’s ability to negotiate drug prices is an obvious first step. It is also important that the Administration not curtail future Congressional action by including language in trade negotiations that would limit Medicare’s ability to address high drug prices.

Site Neutrality for Physician Administered Drugs. HHS asks what effect a site neutral payment policy for drug administration procedures would have on the location of the practice of medicine, and how this might impact the organization of health care systems and competition for health care services, particularly for cancer care. This issue must be studied closely before any changes are made that could affect beneficiary access to care.

Site Neutrality between Inpatient and Outpatient Settings. As with the questions about site neutrality for physician administered drugs, it is vital that HHS closely study these issues before making changes that could affect beneficiary access to needed treatments.

Accuracy of National Spending Data. HHS asks if average Part D rebate amounts should be reported separately for small molecule drugs, biologics, and high-cost drugs. We support increasing transparency around rebates and all aspects of drug pricing. We do not expect such transparency to dramatically improve drug spending, but the current system’s opacity has proven ineffective at controlling costs.

Create Incentives to Lower List Prices

Fiduciary Duty for Pharmacy Benefit Managers (PBMs). HHS asks if PBM rebates and fees based on the percentage of the list price create an incentive to favor higher list prices (and the potential for higher rebates) rather than lower prices.¹³ Research demonstrates that some PBM arrangements can encourage higher list

¹³ Since the release of this RFI, Secretary Azar has stated that the proposal to make Pharmacy Benefit Managers fiduciaries was “meant more directionally than any type of incorporation or suggestion of state law-type financial fiduciary obligation.” Despite this apparent shift, we will address the questions as written. Wilkerson, John; Inside Health Policy. “Azar Backpedals On Trump’s Plan To Make PBMs Act As Fiduciaries” (June 14, 2018), <https://insidehealthpolicy.com/daily-news/azar-backpedals-trump%E2%80%99s-plan-make-pbms-act-fiduciaries>.

prices,¹⁴ while other reports point to the potential for these arrangements to bring down net spending on some drugs.¹⁵

As we note throughout our comments, more transparency and accountability in drug pricing could help address costs. However, focusing these aims solely on PBM arrangements ignores the fundamental problem that manufacturer drug prices are unreasonably high and must come down. The “middle man” problem may be increasing costs, but it is not the root cause.

Similarly, while a fiduciary status for PBMs may serve to eliminate some of the existing excesses, drug pricing can often be a complex system that benefits one set of beneficiaries while burdening another. As such, we appreciate that HHS also asks what unintended consequences for beneficiary out-of-pocket spending and Federal health program spending could result from these changes. To avoid and minimize adverse impacts, we recommend that CMS extensively model and carefully test any significant changes before a national rollout.

Rebates in Medicare Part D. HHS asks what CMS should consider doing to restrict or reduce the use of rebates in Part D. We recommend that rebates and other discounts that encourage manufacturers to inflate list prices not be incentivized. High list prices raise costs for people who have not yet met their deductibles; people with coinsurance requiring payment of a percentage of nominal drug prices; and people without health insurance. However, we note that rebates are a symptom and not a driver of the fundamental problem of high drug prices.

Incentives to Lower or Not Increase List Prices. HHS asks if manufacturers of drugs who have increased their prices over a particular lookback period or have not provided a discount should be included in the protected classes. While we support policies that encourage manufacturers to keep drug pricing under control, we cannot support efforts to do so that would jeopardize beneficiary access to needed drugs. By excluding these drugs from the protected classes, HHS would be doing just that.

Exclusion of Certain Payments, Rebates, or Discounts from the Determination of Average Manufacturer Price and Best Price. HHS asks about the effect of excluding payments received from, and rebates or discounts provided to, PBMs from the determination of Average Manufacturer Price on list prices, price increases over time, and public and private payers. Again, while rebates, discounts, and PBMs may have some effect on drug costs, this does not address the underlying issue: prescription drug prices are too high. These high prices cause high costs for the Medicare program and for beneficiaries.

Copay Discount Cards. HHS asks if the use of manufacturer copay cards helps lower consumer costs, or if it drives increases in manufacturer list price, and if the use of copay cards incents manufacturers and PBMs to work together in driving up list prices by limiting the transparency around the true cost of the drug. The lack of transparency in drug pricing incentivizes all parties involved to engage in complex cost shifting as there is no risk of exposure to public pressure. While we support heightened transparency, we caution that it must not be used

¹⁴Campbell, Holly; PhRMA. “New Analysis: More than half of patients’ out-of-pocket spending for brand name medicines is based on full list price” (March 29, 2017), <https://catalyst.phrma.org/new-analysis-more-than-half-of-patients-out-of-pocket-spending-for-brand-medicines-is-based-on-full-list-price>.

¹⁵QuintilesIMS Institute. “Medicine Use and Spending in the U.S. – A Review of 2016 and Outlook to 2021” (April 19, 2018), <https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022>.

as an excuse to increase beneficiary responsibility for drug spending. Further, we reiterate that if they are to be effective, efforts to address high prescription drug costs must not be limited to marginal incentives—like rebates and discount cards. Rather, they must also focus on the underlying issue that drives prescription drug spending—high prices.

Reduce Patient Out-of-Pocket Spending

Part D End-of-Year Statement on Drug Price Changes and Rebates. HHS asks what additional information could be given to beneficiaries about the rate of change in negotiated price over the course of the benefit year, and how best to distribute that information. We support beneficiaries receiving information in many formats, though it is likely that the most effective method of communication would be through a trusted provider, including a clinician or pharmacist. It is essential that beneficiaries not be overwhelmed with information, in particular with information that they are unable to effectively use or easily understand. It is even more essential that beneficiaries not be held solely responsible for controlling drug spending through shopping. Patients are generally not in a position to argue with providers about the appropriateness of any given prescription. Because patients are not usually medical experts, we cannot demand that they exercise expertise in prescribing.

Federal Preemption of Contracted Pharmacy Gag Clause Laws. HHS asks whether pharmacy gag clauses serve any purpose other than to require beneficiaries pay higher out-of-pocket costs, and also asks what other communication barriers between pharmacists and beneficiaries may be impeding lower drug prices, out-of-pocket costs, and spending. Elimination of pharmacy gag clauses could potentially cause slight price increases or cost shifting if PBMs or plans perceive them as necessary to support their overall pricing scheme. However, we cannot support the lack of transparency that goes along with pharmacy gag rules or clauses, and therefore support their elimination.

When someone is not fully aware of how their health coverage works, there is a potential information-flow problem. For example, if a Medicare beneficiary does not know to ask if a comparable drug may be less costly, they are unlikely to ask, and unlikely to be told. Pharmacists and prescribers should be encouraged, but not required, to relay information to beneficiaries that may help them better manage their drug costs, as well as to look into alternatives when drug prices are unusually high, or when the beneficiary expresses concern.

HHS also asks if pharmacists should be required to ask if beneficiaries would like information about lower-cost alternatives. As mentioned above, pharmacists should be encouraged to ask beneficiaries if they would like information and to proactively seek alternatives in the beneficiaries' plan formulary. However, there must be guardrails in place to prevent inappropriate marketing, and communication should be designed to avoid beneficiary confusion.

In addition, HHS asks what strategies might be most effective in providing price information to consumers at the point of sale. As we stated above, pharmacists should be encouraged to explore lower-cost alternatives, and all providers should be encouraged to discuss Part D appeals, tiering exception requests, and formulary exception requests, especially when they are aware of high drug costs for a particular patient.

Inform Medicare Beneficiaries with Medicare Part B and Part D about Cost-sharing and Lower-cost Alternatives. HHS asks about new ways to inform prescribers and pharmacists, when prescribing or dispensing a new

prescription, about the formulary options, expected cost-sharing, and lower-cost alternatives specific to individual patients and how these tools could reduce out-of-pocket spending for people with Medicare. Identifying drugs that may have a lower cost for beneficiaries can help providers guide patients toward more affordable drugs. We support equipping beneficiaries with the information and tools they need to best manage their health care needs. However, we are concerned that requirements to adopt certain systems may erode beneficiary access to prescribed medications. That is, while this effort could help beneficiaries who are unaware of lower-cost alternatives, it could also create a situation in which a beneficiary does not know to ask for help, and providers do not investigate other options because they were unaware of the beneficiary's concerns.

Thank you again for this opportunity to share our comments. Medicare Rights supports efforts to improve the affordability of prescription drugs for people with Medicare, including through increased transparency and strengthened beneficiary protections. We look forward to working together to achieve these shared goals. For additional information, please contact Lindsey Copeland, Federal Policy Director at LCopeland@medicarerights.org or 202-637-0961 and Julie Carter, Senior Federal Policy Associate at JCarter@medicarerights.org or 202-637-0962.

Sincerely,

A handwritten signature in black ink, appearing to read "Joe Baker". The signature is fluid and cursive, with the first name "Joe" being more prominent than the last name "Baker".

Joe Baker
President
Medicare Rights Center