December 31, 2018

VIA ELECTRONIC SUBMISSION

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5528-ANPRM
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-5528-ANPRM

Dear Administrator Verma:

The Medicare Rights Center (Medicare Rights) appreciates this opportunity to comment on the **Advance Notice of Proposed Rulemaking: Medicare Program; International Pricing Index Model for Medicare Part B Drugs (CMS-5528-ANPRM).** Medicare Rights is a national, nonprofit organization that works to ensure access to health care, including affordable prescription medications, 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.

We appreciate the Centers for Medicare & Medicaid Services (CMS) releasing this Advance Notice of Proposed Rulemaking (ANPRM) which contains thoughtful explorations of the causes of high drug spending in Medicare Part B drug coverage. CMS acknowledges that Medicare and its beneficiaries pay more for their drugs in general than other countries do and that the increase in Medicare drug spending over the past five years is largely due to increases in the manufacturer prices of drugs and mix of drugs for those beneficiaries who received them rather than increases in Medicare enrollment and drug utilization. We support the goal of finding mechanisms to bring down the cost of Part B medications for both Medicare beneficiaries and the Medicare program as a whole.

Health care affordability is a top issue on our national helpline each year and the high cost of prescription drug coverage is one major component of this. While Part B medications only account for a small fraction of drug spending in the US and tackling the larger system—Part D,

Medicaid, and private insurance—is imperative, it is clear that Part B medications can drive significant out-of-pocket costs for people with Medicare with life-altering conditions like cancer, end-stage renal disease, or rheumatoid arthritis. For example, Mr. B recently called the Medicare Rights Helpline. He'd just been prescribed a much-needed but very expensive Part B cancer medication. Unfortunately, he could not afford to pay the $1,000 in required cost sharing and had no available assistance to help defray this expense. Other recent callers have been unable to afford their cancer treatments or infusion therapies because of a combination of high costs and limited incomes. Circumstances like this may drive patients away from treatments and lead to more suffering and shorter lives. Reducing the out-of-pocket liabilities for people with Medicare can help increase access and regimen compliance, which in turn can improve health, economic stability, and well-being.

CMS is proposing several changes the agency sees as aiding the goal of reducing Part B program and beneficiary costs. These proposals include investigating whether the Medicare payment amount for selected Part B drugs can be phased down to more closely align with international prices; experimenting with giving private-sector vendors who would negotiate prices for drugs, take title to drugs, and compete for physician and hospital business; and testing a change to the 4.3 percent (post-sequester) drug add-on payment in the model to reflect 6 percent of historical drug costs translated into a set payment amount in order to reduce the current incentives providers have to prescribe higher-cost drugs.

CMS proposes bringing Part B prices more in line with international prices by linking Medicare prices to international prices for Part B single source drugs, biologicals, and biosimilars that encompass a high percentage of Part B drug utilization and spending. To do this, CMS would designate certain vendors to participate in Part B negotiations with manufacturers and to contract with providers to supply them with some or all Part B drugs. These vendors would have flexibility to arrange innovative delivery and inventory options. Medicare would pay such vendors an amount derived from international prices, which would be intended to lower somewhat the amount Medicare pays and also the required beneficiary cost sharing. However, though this approach would lower current prices, it does not attempt to create parity with international prices. Instead, it appears to lock American consumers into paying perpetually higher prices than comparable countries. While we support bringing down prices, which in turn reduce overall program costs, no such pricing reduction should be coupled with built-in U.S. price premiums. In addition, this proposal lacks a method to bring down prices if the international index prices go up.

CMS states that the increases in Part B drug prices have created more financial risks for providers from the current "buy and bill" system, in which providers purchase drugs and resell them to patients. To combat this increased risk, CMS proposes to eliminate buy and bill within the model and instead create a system where the physician or office does not take title to the medication but serves as a pass-through for the drug while continuing to collect cost sharing from the patient. This could potentially create a disincentive for providers to participate in the Medicare program, as it appears they would become, in essence, bill collectors for the drug vendors. We also have some concern that Qualified Medicare Beneficiary (QMB) participants

may be at heightened risk for improper billing ("balance billing") under this system. CMS must ensure that any change includes a flag on QMBs to avoid such improper billing and find ways to ensure access to participating providers.

Instead of mandating the pass-through approach, CMS should consider allowing providers to choose whether to use buy and bill or the proposed non-title approach. If CMS's approach is truly seen as risk reducing, providers would leap at the option. Provider-vendor contracts could determine how the relationship is structured instead of regulatory action, enabling providers who are comfortable with the current system to continue their practices.

CMS seeks feedback on whether or how to regulate the contractual agreements between vendors and providers, and whether the agreements should specify obligations to ensure the physical safety and integrity of the included drugs until they are administered to an included beneficiary, how drug disposition would be handled, and data sharing methods, confidentiality requirements, and potentially other requirements. We suggest CMS establish minimum standards for these agreements to best protect beneficiaries. Drug safety and consumer protections must be at the forefront of every regulation and contractual agreement.

This method of creating a new price reference system appears to show some promise in reducing the out-of-pocket expenses and programmatic costs in Medicare Part B, but it is extremely important that people with Medicare retain access to necessary medications and providers. CMS must create a method of ensuring access to medications if manufacturers choose not to participate and must be aware of this model's potential to impede access. In addition, CMS should work to identify provider specializations and geographical areas that may have providers who are especially likely to abandon the Medicare program under these proposed changes.

In addition to the Medicare drug administration payment that would still be made to physicians and hospitals, the model would pay physicians and hospitals a "drug add-on amount" that would be different from the current drug add-on amount. As with the any potential changes to the buy and bill system, CMS should work to identify which specialties may be most affected by these changes and what this might mean for beneficiary access to care.

CMS proposes that providers would continue to collect cost sharing in order to minimize the impact of this model on beneficiaries. We appreciate this proposal, as adding another biller for beneficiaries increases the burden of already complex medical payment. We also support CMS's proposal to robustly monitor the impact of this model on beneficiary cost sharing, and to undergo a coordinated effort with the Medicare Beneficiary Ombudsman. Given these proposals, we urge the agency to fulfill its 2016 commitment to establish an Alternative Payment Models Beneficiary Ombudsman. The creation of such an ombudsman would be a welcome safeguard when dealing with program changes of this magnitude.

In addition, CMS should ensure transparency by making all audit and evaluation results and incoming data public and accessible in a timely manner to permit consumers, their families, and third parties to assess the success and challenges with models, plans, and providers.

CMS also requests feedback on how to monitor and measure patient outcomes, as well as patient experiences, in a way that minimizes burden on included health care providers and beneficiaries. As with all models, this model should engage consumers early in the process to ensure that the lived experiences of people with Medicare are fully represented in model design, monitoring, and evaluation.

Finally, CMS flags potential effects on the Medicaid program. We are pleased that this model has the potential to lower costs for both Medicaid and Medicare. That potential does not negate the risks to beneficiary access outlined above. In addition, CMS must demonstrate that effects for the Medicaid program are positive and not a cost shift from Medicare to Medicaid.

Thank you again for this opportunity to comment. We look forward to working together to advance policies that truly reduce drug prices to the benefit of both beneficiary out-of-pocket expenses and also for the Medicare and Medicaid programs. To be effective, such policies cannot simply shift costs or burdens between entities and must have failsafes in place to ensure timely access to needed medicines. 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,

Joe Baker
President
Medicare Rights Center