May 2, 2016

The Honorable Sylvia Mathews Burwell
Secretary
Department of Health & Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Burwell and Acting Administrator Slavitt:

As national organizations, including those representing consumers, purchasers, health care professionals, and insurers, we are writing in support of the Centers Medicare and Medicaid Services' (CMS) proposed rule to test value-driven payment and delivery system models for prescription drugs covered under Medicare Part B. We believe that CMS' proposal has the potential to improve care quality and value for Medicare beneficiaries and support Medicare providers in delivering the right care at the right time. Importantly, the proposal appropriately focuses on changing prescriber behavior while ensuring that Medicare beneficiaries can maintain access to the medications that they need.

Beneficiary cost-sharing under fee-for-service (FFS) Medicare Part B is 20 percent with no out-of-pocket limit, leading some older adults and people with disabilities to face catastrophic expenses, amounting to as much as $100,000 per year.[1] Meanwhile, the median annual income for people with Medicare is less than $25,000 and one in four have less than $12,000 in savings.[2] We do not believe that it is reasonable or acceptable to expect beneficiaries to continue to pay for increasingly expensive prescription drugs without any consideration of whether their money is being well spent.

We share CMS' concern that Medicare Part B reimbursement for prescription drugs may inadvertently encourage the use of more expensive drugs. While we know that providers weigh a number of important factors in making treatment decisions, we cannot ignore research that the program's current financial incentives may encourage providers to select higher-priced treatments even if they are no more effective than lower-priced alternatives.

[1] Government Accountability Office, *Expenditures for New Drugs Concentrated among a Few Drugs, and Most Were Costly to Beneficiaries*, October 2015.
[2] G. Jacobson, C. Swoope, and T. Neuman, "Income and Assets of Medicare Beneficiaries, 2014-2030," Kaiser Family Foundation, September 2015.

We agree that CMS should explore these challenges and adapt accordingly as the health care system continues to move towards value-driven care.

We do not believe that the model's proposed changes to Medicare Part B prescription drug payment will adversely impact beneficiary access to needed care or a provider's ability to make care decisions in the best interest of their patient. Under the proposal, health care providers maintain the ability to choose the treatment that best meets the needs of individual patients— CMS' proposal merely takes steps to help ensure that treatments are chosen based on how well they work and not their price tag.

We also support CMS' proposal to test the feasibility of value-based pricing strategies that have shown promise in the private insurance market, including reference pricing, indication-specific pricing, outcomes-based risk-sharing agreements, and discounting or eliminating beneficiary coinsurance amounts. CMS also plans to develop a voluntary evidence-based clinical decision support tool for prescribers that will provide information that reflects up-to-date literature and consensus guidelines. Importantly, these strategies will only be used for prescription drugs with a strong clinical evidence base to support their use.

Recognizing the unique characteristics and needs of Medicare beneficiaries, we believe that the proposed model will ensure that these value-based pricing strategies are tested in a way that safeguards access, while encouraging providers to deliver effective, high-value care. For example, CMS' proposal establishes that beneficiary cost-sharing responsibilities will either remain unchanged or decrease, prohibits balance billing, and adds a pre-payment exceptions review for prescription drugs subject to value-based purchasing that will allow providers and beneficiaries to explain why an exception is warranted. We strongly encourage CMS to monitor beneficiary access and ensure that beneficiaries are well-informed about any impact this model will have on their benefits or care experience, as well as their rights to appeals processes.

Beyond improving the quality of care furnished to Medicare beneficiaries, the proposed model may also help to support the long-term sustainability of the Medicare program by promoting more efficient use of program funds. Last year, Medicare Part B spent $22 billion on prescription drugs—double the amount spent in 2007. This spending escalation is simply unsustainable. By removing incentives to use higher-priced medications that are no more effective than alternatives, the model creates value for both the beneficiary and the program. Further, private purchasers can use any insights gained from the model to help refine their own payment arrangements. Given Medicare Advantage plans are not subject to the demonstration, we recommend CMS work with health insurance issuers participating in Medicare Advantage (MA) to ensure that beneficiaries in both FFS and MA are treated comparably, and that CMS' Part B drug payment model demonstration does not inadvertently encourage or discourage beneficiaries from enrolling in either option.

It is also important that CMS intends to implement the demonstration in a measured and thoughtful manner. CMS notes that implementation could take several years, with the goal of making the program fully operational in two years. We believe that this timeline will provide more than enough time for CMS to obtain feedback and ensure that the proposal is implemented appropriately.

We also believe that the Part B proposal is in line with the Center for Medicare and Medicaid Innovation's (CMMI) statutory charge and authority. The ability of CMMI to independently test the effectiveness and scalability of promising new payment and delivery models to improve patient care and outcomes is critical to ensuring that policy makers and regulators have the unbiased evidence necessary to determine how to best deliver care to millions of Americans covered by public programs.

We commend CMS for requesting input on a number of important and salient questions within this proposed rule and are optimistic that the public comment process will ensure that concerns and comments raised by a variety of stakeholders are appropriately considered and addressed. We expect that the final rule issued by CMS will reflect the diversity of information gathered in the rulemaking process including public comment as well as expert opinion and scientific data. The final rule should draw on this feedback to ensure the final model is designed to drive enhanced value, and to ensure tested programs do not adversely affect beneficiary access or quality of care. We urge CMS to move forward with this demonstration, and we look forward to continuing to work with the agency to ensure that Medicare delivers the highest quality care to all beneficiaries.

Sincerely,

AARP
Aetna
AFL-CIO
Alliance for Retired Americans
American Federation of State, County and Municipal Employees
American Federation of Teachers
Blue Shield of California
California Health Advocates
Center for American Progress
Center for Elder Care and Advanced Illness, Altarum Institute
Center for Medicare Advocacy
Community Catalyst
Consumers Union
Doctors for America
Families USA
Justice in Aging
Kaiser Permanente
Lutheran Services in America
Medicare Rights Center
National Committee to Preserve Social Security and Medicare
National Education Association
National Partnership for Women & Families
National Physicians Alliance
Pacific Business Group on Health
The International Brotherhood of Boilermakers

cc: Dr. Patrick Conway
Acting Principal Deputy Administrator, Deputy Administrator for Innovation & Quality,
CMS Chief Medical Officer
Centers for Medicare & Medicaid Services

Tim Gronniger
Director of Delivery System Reform
Centers for Medicare & Medicaid Services

The Honorable Orrin Hatch
Chairman
Committee on Finance
U.S. Senate

The Honorable Ron Wyden
Ranking Member
Committee on Finance
U.S. Senate

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives

The Honorable Kevin Brady
Chairman
Committee on Ways and Means
U.S. House of Representatives

The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives

The Honorable Sander Levin
Ranking Member
Committee on Ways and Means
U.S. House of Representatives