March 7, 2016

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

Dear Acting Administrator Slavitt:

As patients, providers and advocates trying to protect the millions of Medicare beneficiaries that are diagnosed with cancer every year, we are writing to express serious concerns over the Centers for Medicare and Medicaid Services' (CMS) Part B Drug Payment Demo discussed in a transmittal to Medicare contractors earlier this month. Based on preliminary information that was released, we strongly urge you to withdraw any consideration of implementing this initiative. We are deeply concerned this risky, unproven experiment to Medicare Part B drug payments will jeopardize the health of millions of Medicare patients with cancer.

Medicare beneficiaries make up 60% of the 14 million Americans living with cancer, and the elderly are 10 times more likely to get cancer than the younger population[1]. Medicare beneficiaries with cancer face a life or death struggle to access curative treatment options that will cure their disease or extend their life. Patients must sometimes adjust the courses of treatment because of changes in their clinical status or goals of care. CMS should not create additional barriers to providing the necessary care.

The proposed experiment to be implemented by the Center for Medicare & Medicaid Innovation (CMMI) appears simply to focus on Medicare drug spending rather than on patients and the quality of medical care they receive. Any CMMI experiment that forces these vulnerable Medicare patients to abandon treatments that are working and improving their quality of life is misguided and ill-conceived. We strongly oppose any effort to rush through a cost-cutting program that will affect patients' access to life-saving Medicare Part B covered drugs.

In the posting of the CMS transmittal to contractors, CMS expressed concern that the 6 percent add-on to average sales price (ASP), the basis for Medicare Part B drug reimbursement, may create incentives for use of higher priced drugs. CMS' supposition fails to acknowledge providers' prescribing decisions depend on a variety of factors, including clinical considerations that may influence a provider's choice among therapeutic alternatives, especially as it relates to cancer. Further, there is no evidence that the payment changes contemplated by the CMS experiment will improve quality of care or even reduce spending. In fact, a project by UnitedHealthcare implemented within community oncology practices designed to eliminate any "incentive" proved the exact opposite to the CMS assumption. According to the study, "eliminating existing financial chemotherapy drug incentives paradoxically increased the use of chemotherapy." The spending on drugs increased by 179 percent.[2]

[1] http://www.allhealth.org/briefingmaterials/CancerandMedicareChartbookFinalfulldocumentMarch11-1412.pdf
[2] Journal of Oncology Practice: Changing Physician Incentives for Affordable, Quality Cancer Care: Results of an Episode Payment Model. Available at: http://jop.ascopubs.org/content/10/5/322.full

CMS must understand the actual Part B reimbursement rate before implementing fundamental changes that may have serious consequences for patients and providers. The ASP methodology currently includes a customary distributor prompt pay discount which reduces Part B reimbursement to approximately ASP plus 4 percent. Furthermore, Medicare applied the Budget Control Act of 2011 mandatory 2 percent sequester cuts to Part B drugs in such a way that the actual payment set by Medicare, after the prompt pay inclusion, is equivalent to approximately ASP plus 2.3 percent. It is imperative CMS understands and evaluates this current reimbursement rate and its outcome – especially as practices continue to close or consolidate with large health-systems, increasing costs for both patients and Medicare – and engage multiple stakeholders before implementing any initiative that would further reduce reimbursement rates.

In an era of hospital acquisitions and consolidation in the oncology space, drastic changes in reimbursement could further push oncology care into the more expensive hospital outpatient setting. Since 2005, there has been a 30% swing of oncology care from the lower cost physician setting to the higher cost hospital outpatient department.[3] A Moran study from 2013 showed, that not only was chemotherapy administration 42%-67% higher in the hospital outpatient department (HOPD) setting, the drug spend was between 25%-47% higher in an HOPD than in the physician office setting.[4] Just last week, a study released by the Health Care Cost Institute, confirmed that increased medical provider consolidation with hospitals and/or health systems results in increased spending on outpatient prescription drug-based cancer treatment. Specifically, that study found that "a one percent increase in the proportion of medical providers affiliated with hospitals and/or health systems is associated with a 34 percent increase in average annual spending per person and a 23 percent increase in the average per person price of treatment."[5]

Policies and experiments that drive patients to a higher cost setting creates access issues and increased costs for patients and the Medicare program.

Lastly, while information is scarce on the Medicare Part B Drug Model, we have great concern over how CMMI plans to manage this experiment with the Oncology Care Model (OCM) that CMMI plans to roll out this spring. CMMI has spent years and countless dollars developing the OCM in which they partnered with oncologists and other stakeholders to develop a model designed to manage the quality and costs of cancer treatment (the majority of which are not attributable to drugs). The posted mandatory experiment, on the other hand, had no physician or patient input and appears to be hastily conceived compared with the OCM.

The current Part B reimbursement methodology was designed to recognize the additional costs and complexity associated with acquiring, handling, maintaining and delivering Part B medicines. Evidence suggests that the current Part B drug payment system has been successful in ensuring patient access while moderating the cost of these services for the Medicare program, as Part B expenditures remain relatively stable[6] and Part B drugs account for just 3% of total program costs.[7]

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[3] The Moran Company: Results of Analyses for Chemotherapy Administration Utilization and Chemotherapy Drug Utilization, 2005-2011 for Medicare Fee-for-Service Beneficiaries; May 29, 2013.
[4] The Moran Company: Cost Differences in Cancer Care Across Settings; August 2013
[5] Health Care Cost institute: The Impact of Provider Consolidation on Outpatient Prescription Drug-based Cancer Care Spending; February 25, 2016.
[6] 2015 Medicare Trustees Report.

We believe that any true demonstration project should be voluntary, small scale, centered on the quality and value of medical care provided to patients, and account for the unique needs of Medicare beneficiaries, through an open, deliberative process that involves all members of the affected communities – most importantly patients. In fact, under the law, the CMMI is required to ensure that any payment and service delivery reform model it tests addresses a defined patient population with "deficits in care." It is unclear what deficits in care CMS is attempting to address in the Medicare Part B Drug Model, given its broad scope potentially involving a range of Part B providers and "most Part B drugs."

In closing, we are seeking your commitment not to jeopardize the health and safety of Medicare patients, especially vulnerable seniors, who rely on Medicare Part B drugs. We urge you to permanently withdraw the Part B Drug Payment Model from consideration.

Sincerely,

Alabama Cancer Congress
American Society of Clinical Oncology
Association of Community Cancer Centers (ACCC)
Association of Northern California Oncologists
Cancer Support Community
CancerCare
Caregiver Action Network
Community Hematology Oncology Consortium
Community Oncology Alliance
Connecticut Oncology Association
Cutaneous Lymphoma Foundation
Delaware Society for Clinical Oncology
Denali (Alaska) Oncology Group
Florida Society of Clinical Oncology
Georgia Society of Clinical Oncology
Hawaii Society of Clinical Oncology
Idaho Society of Clinical Society
Illinois Medical Oncology Society
Indiana Oncology Society
ION Solutions
Iowa Oncology Society
Kansas Society of Clinical Oncology
Kentucky Association of Medical Oncology
Kidney Cancer Association
Louisiana Oncology Society
Maryland/D.C. Society of Clinical Oncology
Massachusetts Society of Clinical Oncologists
Medical Oncology Association of Southern California
Medical Oncology Society of New Jersey

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[7] Medicare Payment Advisory Commission, "Medicare Drug Spending;" presentation at September 2015 public meeting; available at: http://www.medpac.gov/documents/september-2015-meeting-presentation-medicare-drug-spending.pdf?sfvrsn=0.

Michigan Society of Hematology and Oncology
Midwest Oncology Practice Society
Minnesota Society of Clinical Oncology
Mississippi Oncology Society
Missouri Oncology Society
Montana State Oncology Society
National Patient Advocacy Foundation
Nebraska Oncology Society
Nevada Oncology Society
North Carolina Oncology Association
Northern New England Clinical Oncology Society
Ohio Hematology Oncology Society
Oklahoma Society of Clinical Oncology
Oncology Nursing Society
Oncology Society of New Jersey
Oregon Society of Medical Oncology
Pennsylvania Society of Oncology & Hematology
Premier Oncology Hematology Management Society (POHMS)
Puerto Rico Association of Hematology and Medical Oncology
RetireSafe
Rocky Mountain (Colorado) Oncology Society
Society of Utah Medical Oncologists
South Carolina Oncology Society
Southern Oncology Association of Practices
Tennessee Oncology Practice Society
Texas Society of Clinical Oncology
The Arizona Clinical Oncology Society
The US Oncology Network
Upstate New York Society of Medical Oncology and Hematology
Virginia Association of Hematologists & Oncologists
Washington State Medical Oncology Society
West Virginia Oncology Society
Wisconsin Association of Hematology and Oncology

cc: Patrick Conway, MD, MSc
Acting Principal Deputy Administrator, Deputy Administrator for Innovation & Quality,
CMS Chief Medical Officer, CMS

Tim Gronniger
Director of Delivery System Reform, CMS