May 9, 2016

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Proposed Medicare Part B Payment Model (CMS-1670-P)

Dear Mr. Slavitt:

The Physicians Advocacy Institute (“PAI”) appreciates the opportunity to voice its concerns relating to the Centers for Medicare and Medicaid Services’ (CMS) proposal to restructure the way that Medicare reimburses physicians and other health care providers for administering Medicare Part B drugs.

PAI is a 501(c)(6) advocacy organization that was established to advocate for fair and transparent payment policies and contractual practices by payers in order to sustain the profession of medicine for the benefit of patients. PAI is committed to advancing policies that protect the ability of patients to receive the best possible care in the most appropriate clinical setting. This is particularly important for Medicare beneficiaries, who often suffer from complex health care conditions and for whom the most effective course of treatment varies considerably from patient to patient.

PAI’s Board of Directors is comprised of CEOs and former CEOs from nine state medical associations: California, Connecticut, Georgia, Nebraska, New York, North Carolina, South Carolina, Tennessee, and Texas, and a physician member from Kentucky.

PAI is deeply concerned that the Part B reimbursement “demonstration” initiative would disrupt longstanding patient-physician relationships and in many instances create barriers to Medicare beneficiaries receiving the most clinically effective treatments for their conditions. The policy would have a disproportionately negative impact on patients suffering from illnesses that are life threatening or disabling and often require complicated treatment regimens, including cancer, macular degeneration and rheumatoid arthritis.

The reimbursement cuts for many Part B drugs embodied in the proposed reimbursement formula would make it extremely difficult for many physician specialists to continue to treat these conditions with the most effective therapies for their patients. This would force these patients to seek treatment in other settings, which would in many cases disrupt continuity of care.
PAI feels strongly that the proposed policy – as well any other sweeping payment reforms tested by the Center for Medicare and Medicaid Innovation (CMMI) – should be fully vetted among stakeholders in order to ensure Medicare beneficiaries are sufficiently protected. For these reasons, PAI respectfully urges CMS to withdraw the proposed Part B Payment Model.

I. The Initiative will create access issues for the most vulnerable Medicare patients

Our nation’s physicians see firsthand how Medicare beneficiaries face significant complexities in their care and treatment options. It is important that Medicare beneficiaries retain access to their physician of choice and receive treatment in the most appropriate, accessible setting for themselves and their caregivers.

The reimbursement cuts in the proposed initiative will limit Medicare patients’ ability to continue to receive care from their chosen physicians, especially patients who receive care in rural settings or from physicians who practice in solo or small group practice settings. Unlike other medications, Part B drugs are purchased by physicians and hospitals and then administered in the physician office or hospital outpatient department setting. Physician practices generally pay a higher price for these drugs because they lack the ability to negotiate for volume purchasing. Small and independent physician practices are forced to frequently purchase Part B drugs above Medicare’s “average” sales price. These physicians have already struggled with reimbursement cuts tied to sequestration, and under Phase I of the initiative, many physicians will simply be unable to purchase costly Part B drugs with the additional proposed cuts of ASP + 0.86% (plus a small flat fee). As a result, the initiative may displace many patients from their current physicians and result in potentially harmful access issues.

II. The Initiative raises serious statutory authority and procedural concerns

Under the Affordable Care Act (ACA), CMMI was charged with implementing payment and delivery demonstrations in a targeted, patient-centered and transparent way that accounts for the unique needs of beneficiaries. CMMI is statutorily required to ensure that its initiatives target “deficits in care,” and can only expand the scope and duration of a demonstration – including on a nationwide basis – after CMS establishes that the demonstration (1) improves or maintains the quality of care while (2) reducing spending. PAI therefore has serious concerns about CMS’ proposal to launch the Model on a nationwide basis and include the “majority” of Part B drugs. First, PAI questions what “deficits in care” the initiative aims to address, given the historic success of the Part B program in ensuring patient access to their most clinically appropriate treatments. Second, the scope of the initiative appears to conflict with the narrow, targeted demonstrations that CMMI is statutorily directed to administer under the ACA.

CMMI must carefully consider how its demonstrations impact Medicare beneficiaries’ access to care and treatment decisions before expanding any of its initiatives. PAI previously joined with the Average Sales Price (ASP) Coalition in a letter to CMS asserting that vulnerable Medicare patients should not face mandatory participation in an initiative that appears to represent an overreach of CMS’ demonstration authority. Even more concerning, CMS did not undertake any preliminary evaluations on smaller patient/physician populations before proposing to subject Medicare beneficiaries across the nation to these new and untested payment structures. For these reasons, the Part B Payment Initiative does not comply with the beneficiary protections included in the ACA.
III. There are significant implementation issues with CMS’ proposed “Value Based Purchasing” tools (Phase II)

The “value-based purchasing” tools that CMS proposes to test in Phase II of the initiative also raise serious concerns. Under the ACA, CMMI is prohibited from testing Phase II of the initiative unless and until it fully evaluates the Phase I reimbursement cuts and determines that these cuts do not adversely affect beneficiaries’ quality of care.

PAI believes CMS’ proposal to test “value-based purchasing” tools in Phase II is premature as there has been insufficient consultation with stakeholders about how its proposed “value-based purchasing tools” would impact beneficiaries’ access to the most appropriate drug therapies for their conditions. We believe CMS would be exceeding its statutory authority if it proceeds to implement this expanded phase of the initiative in January 2017, or any time before it has performed the extensive analysis and evaluation of the Phase I reimbursement cuts.

For the above reasons, PAI urges CMS to withdraw the Part B Payment Model.

Thank you for your consideration.

Sincerely,

[Signature]

Robert W. Seligson, MBA, MA
President, Physicians Advocacy Institute
Executive Vice President/CEO, North Carolina Medical Society