HEALTHCARE LEADERSHIP COUNCIL

STATEMENT FOR THE RECORD

House Energy and Commerce Committee
Subcommittee on Health:

The Obama Administration's Medicare Drug Experiment: The Patient and Doctor Perspective

May 17, 2016

Dear Chairman Pitts and Ranking Member Green:

The Healthcare Leadership Council (HLC) appreciates the opportunity to submit a statement for the record regarding the hearing entitled, "The Obama Administration's Medicare Drug Experiment: The Patient and Doctor Perspective." We applaud the subcommittee for focusing on the implementation of the Center for Medicare and Medicaid Innovation's (CMMI) Part B Drug Payment Model demonstration and the impact on patient access and the quality of care for beneficiaries.

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century health system that makes affordable, high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, biotech firms, health product distributors, pharmacies, post acute care providers, and information technology companies – advocate measures to increase the quality and efficiency of healthcare through a patient-centered approach (attached is a list of our members).

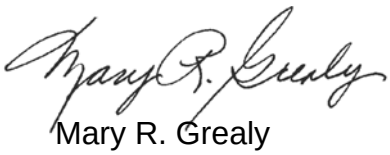
Please find attached comments that HLC provided to Acting CMS Administrator Slavitt in response to the proposed rule. In our comments, we emphasize that CMMI was created under the Affordable Care Act (ACA) to selectively test new payment and delivery models in the Medicare and Medicaid programs. In order to protect beneficiaries and avoid treatment disruptions, the ACA requires CMMI to perform extensive analysis in the selection and expansion of its demonstrations. The statute ensures that a demonstration may only be expanded on a nationwide basis after CMMI

can establish that the demonstration (1) improves or maintains the quality of care while (2) reducing spending. We feel that it is critically important for CMMI to adhere to this process before expanding any demonstration to ensure that improved patient access and quality of care are the defining characteristics of any demonstration being advanced.

On behalf of HLC, I applaud you for your bipartisan work to support meaningful healthcare reforms and ensure that they are implemented effectively. As you know, HLC has been supportive of the concept of testing a variety of healthcare delivery strategies to determine best approaches to possible systemic reform, but has some concerns related to the scope of CMMI's operations and statutory authority.

We stand ready to assist and support your efforts.

Sincerely,



Mary R. Grealy
President

Attachments

May 9, 2016

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

RE: CMS-1670-P, Part B Drug Payment Model, Proposed Rule

Dear Acting Administrator Slavitt:

The Healthcare Leadership Council (HLC), a coalition of chief executives from all sectors of the healthcare industry, appreciates the opportunity to comment on the Center for Medicare and Medicaid Innovation's (CMMI) demonstration and the impact on patient access and the quality of care for beneficiaries. CMMI was created under the Affordable Care Act (ACA) to selectively test new payment and delivery models in the Medicare and Medicaid programs. Since its inception, CMMI has administered new, innovative models that aim to enhance beneficiary care, improve health outcomes, and provide assistance to populations with special health needs. In order to protect beneficiaries and avoid treatment disruptions, the ACA requires CMMI to perform extensive analysis in the selection and expansion of its demonstrations. The statute ensures that a demonstration may only be expanded on a nationwide basis after CMMI can establish that the demonstration (1) improves or maintains the quality of care while (2) reducing spending. We feel that it is critically important for CMMI to adhere to this process before expanding any demonstration to ensure that improved patient access and quality of care are the defining characteristics of any demonstration being advanced.

<u>Transparency</u>
As you know, HLC has been supportive of the concept of testing a variety of healthcare delivery strategies to determine best approaches to possible systemic reform, and to allow a mechanism for faster nationwide adoption of those approaches that improve value. We believe that efforts to move all health care stakeholders—including payers, manufacturers, and providers—towards a system grounded in value over volume will ultimately improve patient outcomes and reduce costs, and thus appreciate the work

CMMI has taken on to achieve these goals. We do, however, believe that some of these efforts by CMMI have moved beyond the intended scope established by Congress, and have done so in a way that could impede patient access to and the delivery of quality care. Furthermore, as CMMI contemplates additional payment and delivery system reforms, there is a critical need for transparent, comprehensive collaboration with stakeholders throughout the demonstration process.

Effective communication is particularly important in that all healthcare stakeholders are already adjusting to rapidly evolving payment and coverage rules under the ACA, and soon, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). CMMI, however, has generally provided a limited opportunity for stakeholder input before launching new payment demonstrations. For example, with the recently announced Medicare Part B Payment Model, stakeholders did not have the opportunity to discuss potential opportunities and challenges with the Agency's proposed construct, including potential impact that the demonstration's reimbursement changes could have on patient access or the spillover effect on the Medicare program.

We would also recommend enhanced efforts to share the lessons learned and best practices from completed demonstration projects and to do so in a timely manner. Especially during this critical time of innovation in healthcare delivery, more information about both successful and unsuccessful CMMI pilots could help to inform private sector efforts to improve value and enhance the patient experience.

Burdensome or Misaligned Incentives

We also suggest that CMS consider the challenges involved in participating in many of the demonstrations and whether there are properly aligned incentives for participation. We have heard from many of our members that they choose not to participate in demonstration projects because the participation requirements are onerous, incentives are not appropriately aligned, or data from CMS is insufficient to make educated decisions about participation. CMMI pilots should allow participants the flexibility to determine the tools that will promote innovation while ensuring regulatory consistency and a level playing field between federal programs such as fee-for-service and Medicare Advantage.

For example, the proposed rule on Revised Benchmark Rebasing Methodology did not allow enough lead time for providers to adjust their strategies for assuming risk. As a result, providers were locked into a term which precluded assuming risk in the timeframe necessary to qualify as an alternative payment model (APM) under the MACRA rule. In another example, the Comprehensive Primary Care Plus (CPC+) payment model does not provide adequate incentives or flexibility for payer participation. Thus, participation in the first round (Comprehensive Primary Care Initiative) has been tepid, and it is unclear with the CPC+ whether this will change because the model remains largely unaltered.

Scope

In addition to potential patient access and treatment disruption concerns, several recent CMMI demonstrations also raise questions about the large scope and required participation of these demonstrations. Under the 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 after careful assessment of its impact on quality of care, patient access, and spending. We are, therefore, concerned that the scope of the Part B Payment Model appears to conflict with the narrow, targeted "demonstrations" that CMMI is required to administer under the ACA. Of particular concern is the lack of data to verify that patients will not lose access to live-saving drugs for diseases like cancer.

HLC appreciates the opportunity to provide input on issues related to the scope of CMMI's operations and statutory authority. If you have any questions, please feel free to contact Tina Grande at 202-449-3443**.**

Sincerely,

Mary R. Grealy
President