ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

May 9, 2016

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1670-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: CMS -1670-P -Medicare Program; Part B Drug Payment Model

Submitted electronically: http://www.regulations.gov

Dear Acting Administrator Slavitt:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we are pleased to submit the following comments in response to the proposed Part B Drug Payment Model. The Alliance is a nonprofit multidisciplinary trade association of health care professional and patient organizations whose mission is to promote quality care and access to products and services for people with wounds through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. These comments were written with the advice of Alliance clinical specialty societies and organizations that not only possess expert knowledge in complex chronic wounds, but also in wound care research. Many of our members utilize skin substitutes (now known as cellular and/or tissue based products for wounds [CTPs]) in their practices as an adjunctive therapy when treating a patient with a chronic non-healing wound. CTPs are subjected to this proposed rule when provided in a physician office and have a published ASP rate. As such, we have a vested interest in this proposal and our ability to continue to prescribe and apply these products without losing money in doing so. A list of our members can be found at www.woundcarestakeholders.org.

As clinicians, the Alliance believes in evidence based medicine and in the notion that when appropriate quality care is provided there are better outcomes and lower costs to any health care program. However, we disagree with a broad sweeping change to the payment methodology for drugs and biologics especially since there is no evidence to support the change. This proposed rule seems to solely focus on costs rather than on the complexities of patient care and a patients continued access to drugs and biologicals as well as quality of care. As a result, we are concerned that the proposed rule could limit patient-physician options and hinder the ability to foster the treatments best suited to addressing individual needs. Any disruptions to care can create negative results and could lead to serious adverse outcomes for patients nationwide. The drive to control costs should not jeopardize the health status of Medicare beneficiaries.

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Transparency

The Alliance has consistently commented that transparency in CMS's actions is necessary. In this case, CMS has continued to disregard transparency by issuing a regulation in which CMS has proposed a change in the Part B Drugs and Biologicals payment methodology without providing data or evidence which:

1. Shows how the proposed methodology will save costs and improve quality of care and how CMS plans to assess access and quality during the "test" period,
2. Explains how CMS determined that ASP +2.5% plus the flat fee will address saving costs and improve quality as opposed to ASP+5% or any other variable,
3. Validates that that the ASP + 6% is the reason for the growth in Part B spending for separately payable drugs and biologics or
4. Provides specific details on the design, evaluation or implementation of this program other than to say that it will be done in a sub-regulatory fashion.

Furthermore, CMMI is statutorily required to ensure that its initiatives target deficits in care. CMS has not identified what deficits in care are being addressed in this proposed rule. CMMI is also required to assess the models impact on quality of care, patient access and spending **before** it can expand the scope and duration of a model. Yet, no where in the proposal has CMS assessed the impact on quality of care, access or spending AND this regulation is proposed to be implemented nationwide not on a limited scope in order for CMS to test the model proposed.

Moreover, it is our opinion that being transparent also means working with and communicating with a wide range of stakeholders throughout the process. Based on the concerns raised by Members of Congress and other clinical organizations we know that stakeholder involvement was minimal at best.

Meaningful Comment

CMS has proposed to implement Phase 1 of the regulation by August 1, 2016. With a minimum of a 60 day implementation period from publication (as stated in the proposed regulation) AND comments being due on May 9, 2016, CMS will have about 30 days to consider all stakeholder comments and, based on the comments, issue a final rule. This timeframe establishes that CMS will not have sufficient time to review in a meaningful way the comments that are being submitted to them by interested and affected stakeholders.

Similarly, CMS proposes to roll out Phase 2 on January 1, 2017 without providing enough details on the design, evaluation or implementation for stakeholders to provide meaningful comment. In describing Phase 2, CMS has stated that following publication of a final rule that it would provide information on specific value based purchasing tools through a sub regulatory process. In doing so, CMS will post a notice on their website, provide 30 days for comments and a 45 day period for implementation. Not only is this timeframe simply insufficient for such a sweeping change in which complex models are being proposed and developed, it is inappropriate for CMS to roll out such a complex system using sub-regulatory guidance.

Conclusion

We urge you to withdraw this proposed rule, engage patient and professional societies, to develop a program which is substantiated in data and evidence and is more limited in scope (such as a pilot program) in order to achieve a proposal that is best for patient care in a cost-sensitive environment. We furthermore urge CMS to go through a formal rulemaking process for Phase 2 instead of a sub-regulatory process – which is insufficient due to the complexity of the models being developed.

On behalf of the Alliance of Wound Care Stakeholders, we appreciate the opportunity to submit these comments. If you have any questions or would like further information, please do not hesitate to contact me.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director