COALITION OF

Wound Care Manufacturers

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:

The Coalition of Wound Care Manufacturers ("Coalition") is submitting the following comments in response to the proposed Part B Drug Payment Model. The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of chronic wounds including cellular and/or tissue based products for wounds (CTPs) that will be impacted by the proposed methodology changes. As such we have a particular interest in this proposed rule and are writing to express our concerns over the proposal and request that CMS withdraw it.

According to CMS, the rationale for creating this new payment methodology is the significant growth in Part B payments for separately payable drugs (and biologics). CMS further states that they seek to "test whether the alternative payment designs will lead to spending our dollars more wisely for drugs paid under Part B while preserving or enhancing the quality of care provided to Medicare beneficiaries."

Health care delivery is moving towards a system by which better quality care is provided with lower costs to the over all Medicare program. The Coalition agrees with this approach – providing the most appropriate care with better outcomes can result in lower costs. But, nationally testing a new payment model under the guise of a demonstration without providing any data/evidence to support the new methodology or any information to substantiate the claims being made by CMS, specifically that quality will be enhanced and spending will be reduced, is disconcerting and contrary to the notion of transparency. There is no evidence that the proposed changes will improve quality of care or even

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reduce spending.

CMS has not provided any evidence or data as to why the proposed methodology was used as opposed to any other nor did they work with a wide range of stakeholders when creating this proposal. The Coalition recommends that CMS should meet with a wide range of stakeholders to develop alternative models that can achieve the goal of the proposed demonstration without increasing risk or decreasing access for patients.

The Coalition respectfully requests that CMS withdraw this proposal for the following reasons:

- CMS has not explained or provided data to show that the proposed methodology will save costs and improve quality of care. In fact, it is the Coalitions' opinion that this proposal will simply shift care settings.
- CMS has not provided any data for the proposed methodology of ASP + 2.5% + $16.80 over any other methodology nor has CMS provided evidence that the ASP + 6% is the reason for the growth in Part B spending for separately payable drugs and biologics.
- The Budget Control Act of 2011 created a mandatory 2 % sequestration to Part B drugs and biologicals. Nowhere in this proposal has CMS considered the impact of sequestration on this new methodology. The reality is that the real proposed methodology – due to sequestration – is really ASP + 0.86% + $16.53 rather than ASP + 2.5% + $16.80. As a result, access to some part B products will become a financial liability which will impact patient access to these products
- As mentioned previously, the new payment methodology being rolled out in the guise of a demonstration is misleading. This proposal goes well beyond a true demonstration project as this demonstration would apply nationally and is changing the entire payment methodology for separately payable part B drugs and biologicals. A true demonstration would be limited in size and scope.
- With respect to Phase II of the proposed rule, Value Based Purchasing, CMS has not provided the level of detail and specificity regarding how CMS will develop Phase II nor how it will be implemented. CMS discusses a sub-regulatory process for this Phase - which is completely inappropriate for the size, depth and scope of the changes being proposed. As such it is difficult not only to make meaningful comments on phase II, but the brief time frame CMS has created to submit comments, review the comments, issue a final rule and implement the regulation precludes meaningful review by CMS of any comments submitted.

CONCLUSION

The Coalition appreciates the opportunity to provide our comments. Based on the above reasons, we respectfully request that CMS withdraw this proposal. We hope that CMS will work with stakeholders to craft a more appropriate and well-balanced policy. If you

need more information or have any questions, please do not hesitate to contact me.

Sincerely,

Karen S. Ravitz, JD
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Coalition of Wound Care Manufacturers
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