COALITION OF

Wound Care Manufacturers

February 19, 2016

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1653-NC
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted electronically to: www.regulations.gov

Re: (CMS 1653-NC) Medicare Program; Request for Information Regarding the Awarding and the Administration of Medicare Administrative Contractor Contracts

Dear Acting Administrator Slavitt:

The Coalition of Wound Care Manufacturers ("Coalition") is pleased to be submitting our comments to CMS' request for information regarding the Awarding and the Administration of Medicare Administrative Contractor Contracts (CMS 1653 – NC). The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds and often interacts with the MACs and PDAC. Therefore we have a vested interest not only in providing you information but to ensure that financial interests do not interfere with the accuracy of coverage, coding and payment as well as the provision of appropriate medical care and claims processing.

Over the years our members have had many issues with the MACs/PDAC in which there has been no accountability or transparency and at times when the contractors have exceeded their statutory authority. While this request for information focuses on the MACs – the Coalition respectfully requests that the PDAC be held to the same standards and that this request be extended to include the PDAC. Our reasons for this request are as follows:

The MACs also hire subcontractors to do work for them—the criteria for hiring the subcontractors should be as transparent as that for the MACs themselves. Specifically, the Coalition has expressed its concerns to the Pricing Data Analysis and Coding contractor (PDAC) and to CMS itself on operations issues. There have been circumstances in which the PDAC has made decisions with no standard in place, they have exceeded their statutory authority, and have made inappropriate remarks to manufacturers who have met with them. As such, we believe that there should be metrics established on such items as:

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- Outreach to stakeholders for feedback in improvement in operations. There should be advisory committees established for this purpose. The metric should not be solely technology based for obtaining the contract but also a high priority in verbal communication in outreach to outside stakeholders on quality improvement.
- Greater accessibility to PDAC staff for answering questions and obtaining information.
- Technology so that electronic submissions of coding verification applications can be accommodated
- Training process for PDAC staff for each function. (i.e. provider outreach, review staff, etc.) [Suggestion that additional training be provided to PDAC staff on the processes {coding initial assignment, coding re-verification, coding reconsideration, etc}]
    - How often are they trained? Does the training include cross-functional training? Are all staff trained on each product category of DMEPOS? Is there specific training for "specialists" on each product category?
    - What plans does the PDAC have to conduct webinar/training to review these processes with the public?
- The processes that the PDAC puts in place for its coding verification process and any work done with stakeholders to improve this process. The processes should be transparent and clearly written, posted on the website and the customer service staff who answers the phones should be knowledgeable about the processes. The Coalition has been on record to suggest that the PDAC coding verification process must be improved using the following recommendations:
    - Clarify elements of the coding verification processes: initial and reconsideration
- Proper Notice and Comment of All Coding Changes: All revisions, deletions, consolidations and changes to code criteria of HCPCS codes announced by the PDAC must first be published on the DME MAC websites and supplier publications in draft form with reasonable time for public comment before any HCPCS coding change becomes final and effective.
- Coding Errors: Coding errors brought to PDAC's attention (assuming PDAC agrees) must be corrected within 30 days of receipt of the applicant's letter to PDAC. This would include PDAC mailing a corrected letter to the applicant, correcting the coding error on the website, and alerting other payers to this issue. Corrections of coding errors and statutorily-directed revisions should be exempt from the notice and comment provisions recommended above.
- Greater Access to the PDAC: PDAC officials should meet with coding verification applicants to discuss the product(s) at issue. In addition, key PDAC decision makers should be required to keep periodic office hours at CMS central in Baltimore, Maryland in order to permit small businesses and manufacturers to more easily engage the PDAC in coding verification discussions.
- Pediatric Coding: CMS should develop a mechanism for coding verifications for pediatric products or otherwise work with Medicaid programs to eliminate the requirements for obtaining PDAC code verification. (PDAC currently declines to conduct coding verification for pediatric products yet some of the Medicaid programs require listing by the PDAC for product coverage.)
- Coverage Information Separate from Coding: Consistent with our recommended standard for separate consideration of coverage and coding for new and revised codes, the PDAC should never use coverage information in the code verification process.

We believe the PDAC also needs to be held accountable for their actions, there should be more transparency and there should be meaningful and measureable standards published and publically available by which they are measured in order to maintain their contract. Many of the metrics provided above are also applicable to the MAC.

The Coalition does not support the awarding of the MACs or PDAC in a financial manner. Rather we believe that information should be requested on how the contractors should be measured in order to keep their contract. While CMS desires to provide the contractors with incentives to reward them for exceptional performance – it is unclear what measures the contractors have to meet currently – nor what measures would meet exceptional performance as that term has not been defined in this notice. The Coalition and its members have often commented about the lack of transparency in the MAC and PDAC processes and the fact that these contractors are not held accountable for their actions. We have often tried over the years to find information on the CMS website regarding the performance measures of its contractors and have not been able to find such information. So we would like to have CMS provide the standards by which the contractors are measured, a report card on how they did in meeting these standards and provide a definition of what exceptional performance means. CMS should publish this information on its website for the public to be able to review. The measures by which a contractor should be evaluated should be meaningful - such as accuracy in claims processing, accurate and timely information being provided to stakeholders, or ensuring that medical coverage policies are evidenced based and based on current clinical practice - and not based on the number of phone calls the call center receives or a survey on the website. Furthermore contractor performance should not be tied to monetary requirements or incentives. This will prevent problems such as those related to the RAC.

Finally, CMS needs to ensure that the MACs - and the PDAC - are actually doing their job in a transparent way and are not exceeding the scope of their authority, developing policies by reaching out to appropriate stakeholders, and not comingling coverage, coding or payment – which unfortunately occurs often and will only increase if there are financial incentives being provided to them.

In the request for information, CMS has requested input on 6 specific questions regarding incentives being provided to the MACs for exceptional performance and transparency. The MACs should already be providing transparency and as such should not be rewarded for doing what we believe they are already obligated to do. As for exceptional performance incentives – we believe this bar will be very difficult to reach as the bar should already be set very high given the nature of the work the contractors are expected to perform and the population that they are serving.

Our specific comments in addressing the questions posed are as follows:

Concerns or suggestions related to development of a potential "award term" strategy and plan

The Coalition does not believe that CMS should develop a financial incentive for the MACs or PDAC. The current contract seems to be more focused on saving money rather than performance. While all of us are in the position of trying to save money for the Medicare system, the contractors should be focusing on creating clinically appropriate policies and, accordingly, processing claims in an accurate, fair and responsible manner. Anything less not only impacts our members, but the patients who are being treated with their products.

Suggestions for incentivizing and rewarding exceptional MAC performance

It is difficult to provide suggestions for incentivizing and rewarding exceptional performance. Our members have not seen evidence of exceptional performance and do not know what CMS's definition of exceptional performance is. We also do not have a metric to compare what is currently being measured but based on what our members have observed, the metrics are based on cost savings and meaningless standards (the number of calls received in a call center). It is our opinion that contractors would have to go above and beyond meaningful and measureable standards (which are published and available to the public on the CMS website) in order to be rewarded. If a contractor does succeed to go above and beyond the meaningful and measurable published standards their reward should be an extension of their contract. However, if they fall short of their performance standards – they should be penalized. In either case there should not be a financial reward.

Contractors already have guidelines in place that they are required to adhere to when they have been awarded their contract. Yet we consistently see the following:

* Lack of accountability (contractors develop and release policies which are flawed. They sometimes even acknowledge that they are flawed and yet the recourse available is onerous on the stakeholder and usually nonproductive)
* Lack of clinical expertise (contractor review of clinical evidence is myopic and often completely inaccurate. They do not follow the premise of evidence based medicine, disregard clinician subject matter experts and often cite commercial payer coverage policies as basis for an LCD)
* Lack of transparency to decision making and operational processes.
* Poor medical review of individual cases (contractors often review wrong diagnosis, applying wrong LCD criteria, etc. This only clogs an already burdened appeals process).
*Disregard of appropriate processes

When MACs conduct themselves in a way that is not meeting basic performance standards – it negatively impacts not only clinicians and others in the industry but Medicare beneficiaries. Currently, Currently, there are many functions that MACs are expected to meet – claims processing, establishing establishing local coverage determinations, educating the industry (clinicians, manufacturers and suppliers) etc. There should be high standards already in place for their knowledge and performance of these tasks. And, yet, daily questions are answered inaccurately and inconsistently, LCDs are issued

with clinically inaccurate information and claims are processed incorrectly.

If CMS believes that it needs to reward the MACs for doing what they should be contractually obligated to do, CMS needs to be transparent in what their contractors are currently being held accountable for and how they are judged. Then CMS should work with stakeholders to develop are more meaningful list of quality metrics – similar to how the physician community is being judged on their performance.

Specific metrics or evaluation criteria that would be valuable in measuring the level and quality of the service provided by a MAC

As stated numerous times in our comments - the metrics should never take cost into consideration – this would only drive the MAC to deny claims. The metrics should include both operational and clinical parameters. However it should be left up to the clinicians to provide those parameters. The operational parameters could include (but are not limited to):

Operational:

- Public disclosure of any medical director or senior officer responsible for coverage, coding or payment decisions of any financial interest to ensure no conflict of interest in their decision making
- Transparent list of the qualifications for a medical director
- Medical Director or high level staff that has experience in evaluation of studies – and in particular wound care studies
- Transparency in MAC operational processes
- Adhering to CMS regulations in terms of notice and comment requirements
- Number of Claims denied
- Number of Claims appealed
- Number of claim denials overturned on appeal – including the level of appeal where it was overturned.
- Appropriate stakeholder engagement and involvement in policy
- Customer service skills
- Accessibility to providers – through more than the IVR
- Open Grievance process
- Time to address and resolve issues (for example – there have been times when providers raise an issue with the MAC - which the MAC agrees is a problem. The MAC should take it upon themselves to correct the issue and not make the provider go through an unfamiliar, onerous process to address it.)

These should be reported for each MAC and penalties should apply if they are not met.

Specific metrics or evaluation criteria that would be valuable in measuring the level and quality of the MAC's relationships (including education and outreach) with providers

Currently, the criteria that CMS seems to be using are meaningless. The number of phone calls

answered or provider satisfaction with a MAC website is not satisfactory. The MAC can answer 1000 calls but give out misinformation in 999 of their responses. So the metrics need to be meaningful and go directly to the performance of the MAC.

The Coalition suggests the following metrics to evaluate the level and quality of MAC relationships:

- Transparency of decision making
- The accuracy of information being provided to clinicians or others that call into the hotlines or customer service
- Issues that have been addressed – the resolution and the time to get to resolution
- The accuracy and topics of the Training sessions – both internal and external
- Consistency in messaging and response to questions
- The type and number of Education sessions and the questions answered accurately during those sessions
- Accessibility to the hotline
- Glaring issues raised on chat sessions addressed in a timely manner
- A grievance process outside of the MAC so stakeholders can report shortcomings or issues with contractor performance
- A list of staff and the policy areas they are responsible for should be provided.

What types or kinds of information should be published for public release regarding MAC quality and level of service and performance*?*

As Medicare is publishing all information regarding physician quality in their physician compare website – it is only fitting that in the interest of government transparency, **all** MAC information regarding quality, level of service and performance should be available publicly, including award fees. Examples of the type of information that should be made available to the public include, but are not limited to:

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- The accuracy of the information provided
- The consistency in messaging and the response to questions
- The number of prepayment audits provided by product category;
- The accuracy of claim processing;
- The number of appeals at each level;
- The error rate;
- The overturn rates on pre and post payment audits;
- The number of claim denials in claim processing;
- The number of claims denied in pre and post-payment audits;
- The overturn rates on reopening ;
- The MAC goals and achievement rates.
- Issues addressed and the time it takes to resolve the issue
- Meaningful provider satisfaction ratings (not just for the website)
- The number and type of training sessions – both internal to their staff and external to the public

- ❖ The number of time there is clinically inaccurate information contained in an LCD

<u>Which types of metrics or information should be made available for public release if CMS was to publish the results or the evaluation of a MACs performance</u>

As stated above-as Medicare is publishing all information regarding physician quality in their physician compare website – it is only fitting that in the interest of government transparency, **all** MAC information regarding quality, level of service and performance – whether clinical or operational- should be made publicly available.

<u>Advantages and disadvantages of the last two MAC consolidations</u>

The Coalition has several concerns with the consolidation of MACs. There should be clear and transparent information provided regarding the transition and why the medical director that is chosen to chosen to be medical director was chosen. We also would like to ensure that there is transparency when transparency when policies are combined that they are not issued without affording the public the opportunity to comment on the policy and that the least restrictive policy is operationalized. Finally, Finally, when the MACs are consolidated, access to the medical directors and other policy staff becomes becomes even more important and should be required for all stakeholders.

<u>Conclusion</u>

To summarize, the Coalition would like to request that both the MACs and the PDAC be held to measureable and meaningful performance measures. We do not support rewarding MACs for their performance financially but it is possible that we could supports a contract award extension if the contractor performs exceptionally but request that the metrics to meet exceptional performance are published. We do believe that more transparency is necessary not only from the MACs but from CMS as well. The standards or measures for which the MACs are being held accountable should be published and a report card on how they are doing should be made available to the public.

On behalf of the Coalition of Wound Care Manufacturers, I 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,

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Coalition of Wound Care Manufacturers
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