COALITION OF

Wound Care Manufacturers

August 22, 2016

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Office of Medicare Hearing and Appeals
Department of Health and Human Services
Attention: HHS-2015-49
5201 Leesburg Pike, Suite 1300
Falls Church, VA 22041

Submitted Electronically to www.regulations.gov

Re: CMS-Medicare Program; Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures; Proposed Rule

Dear Acting Administrator Slavitt,

On behalf of the Coalition of Wound Care Manufacturers ("Coalition"), I am pleased to submit the following comments in response to the proposed rule regarding Medicare Appeals Process. The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds. This proposed regulation is of particular interest and concern to us since it impacts our members who also bill Medicare as well as they want to support their customers who are providers and suppliers. We have concerns that the number of claims for adjudication have reached an unprecedented level. We believe that the backlog is staggering and something needs to be done to fix this problem since the administrative delays, financial burden, and high frequency of improper denials create significant hardships for both providers and suppliers.

While the Coalition appreciates the efforts made by CMS to address the incredible backlog, the main causes of this backlog have not been addressed in this proposed rule. The Agency must have improvement on claims review and the initial determination process as focal points. Until CMS addresses flaws in the Medicare Administrative Contractor (MAC), Qualified Independent Contractor (QIC) and Recovery Audit Contractor (RAC) medical review processes as well as the RAC's ability to collect overpayments prior to the exhaustion of all levels of appeal, the backlog that CMS is seeking to address will not be significantly impacted.

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We and our customers have found that Medicare contractor appeal denials are often clinically inaccurate. Furthermore, Medicare contractors often apply National Coverage Determinations (NCD) and Local Coverage Determination (LCD) criteria erroneously when denying an appeal. Based on these decisions, it is clear that Medicare contractor reviewers are often stymied by either a lack of current clinical knowledge of the diagnosis or of the services under review, or by NCD/LCD criteria that are ambiguous, open to varied interpretation, and sometimes based on outdated medical knowledge.

A number of data elements point to a flawed Medicare Contractor review. Six out of ten coverage denials were overturned through the appeals process in 1 quarter. This suggests that CMS should be looking to improve the claims review and initial determinations process. Data from the May 2016 GAO Report: *Medicare Fee-For-Service Opportunities Remain to Improve Appeals Process* displays the appeal denial percentages at the 3 levels of appeal by service category. Using DMEPOS as a discussion example, the 2014 data reveals the following:

Level 1 denial fully reversed:	26.5%
Level 2 denial fully reversed:	9.1%
Level 3 (ALJ) denial fully reversed:	55.4%

The high rate of reversal at the Administrative Law Judge (ALJ) or third level as demonstrated above is consistent over years and across categories. This longstanding discrepancy calls into question the accuracy of initial appeal decisions and, as noted by the Senate Finance Committee in April 2015, raises concerns that beneficiaries and providers are facing undue burden at the front end of the appeals process. While it is acknowledged that ALJs have somewhat more latitude than contractors, we believe this trend is illustrative of an underlying problem with the quality of review at the first two levels of appeal. This is the area CMS needs to address in order for any meaningful change to take place in the appeals backlog.

In June 2016, HHS issued the HHS Primer: *The Medicare Appeals Process.* In this primer, HHS takes the position that some providers may believe that routinely appealing denials is "good business practice." While we cannot speak to every provider's situation, we strongly object to the general characterization that a supplier's decision to routinely appeal erroneous denials is done because it is "good business practice" – rather it is a "necessary business practice" forced upon suppliers who serve Medicare beneficiaries in good faith. The provider's cost in time and resources to appeal erroneous denials is significant. The HHS primer refers to the "low risk and potentially high reward with pursuing appeals regardless of their merit." "Merit" of those claims cannot be broadly called into question since many are overturned at the ALJ level. We believe any evaluation of claims "merit" must include review of the validity of contractor denials as well as the provider appeals.

This mindset CMS has in its belief that the backlog is due to suppliers or providers simply because it is a good business practice is troubling as it makes HHS seem out of touch with the harmful consequences of erroneous claims review on providers, especially small and mid-size providers. The notion that appealing Medicare denials is "low risk" – when providers are waiting years for final claims adjudication through the appeals process – is extremely disturbing in its lack of understanding of the significant financial impact of this flawed process. Many providers choose to serve Medicare beneficiaries in spite of the risks of the appeals process. We question the implication, absent evidence to the contrary, that providers are in some way responsible for the appeals backlog simply because they repeatedly appeal claims that were wrongfully denied by Medicare contractors.

Concerns regarding Medicare contractor review and the overwhelmingly high denial rates are further illustrated by Sherman versus Burwell, a recent legal case in which a federal judge has granted a motion for certification of a nationwide class to challenge the high denial rates by Medicare contractors at the first two levels of appeal. While the eventual outcome of the case remains to be seen, these proceedings shine a light on the ongoing experiences that point to flawed contractor review.

As such, the Coalition recommends that CMS do the following:

- Develop additional proposals to address and minimize improper denials that are caused by broad audits and burdensome contractor reviews.
- Prohibit contractors from collecting provider overpayments until all levels of the appeal process have been exhausted.
- Ensure that there is mandatory education and training for all providers and Medicare contractors
- Create a process for advocates and beneficiaries to challenge case precedent after it is published
- Ensure that any attorney adjudicator has experience in Medicare coverage, coding and payment.
- Ensure that attorney adjudicators receives continuing education annually so they stay current on Medicare law – including training on Medicare coding, coverage and payment criteria.

Conclusion

The Coalition appreciates the opportunity to provide our comments. If you need further information or have any questions, please do not hesitate to contact me.

Sincerely,

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