ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

August 29, 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 Alliance of Wound Care Stakeholders ("Alliance"), we are pleased to submit the following comments in response to the proposed Changes to the Medicare Appeals process. The Alliance is a nonprofit multidisciplinary trade association of physician medical specialty societies and clinical associations 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. All of our members have at one time or another appealed a Medicare contractor claims decision. We have long recognized that the appeals process is backlogged and there are fundamental problems with the way the appeals process is administered. As such, we have a vested interest in this policy. A list of our members can be found at www.woundcarestakeholders.org.

GENERAL COMMENTS

We appreciate CMS' attention to the crisis surrounding the current Medicare appeals process, and understand the challenge in balancing Medicare beneficiaries' needs for health care services, timely and accurately processing of claims, and protecting the Medicare Trust Fund. We value the opportunity to provide input on these issues and on Medicare's proposed actions to remedy them.

Our comments below address specific proposed language set forth in the proposed rule. We do believe that some of the suggested procedural and administrative refinements will help address unnecessary confusion and delays in the appeals process. However, the overarching issues that are the foundation of the staggering backlog at the Administrative Law Judge (ALJ) level are not

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identified or addressed in either the proposed rule or in other actions currently proposed by CMS to resolve the backlog and fix the appeals process.

In order to resolve the Medicare appeals process crisis that has resulted in an untenable ALJ backlog, it is necessary to review all potential causes of this situation. In the HHS Primer: The Medicare Appeals Process, released in June 2016 as part of its communication strategy preceding release of this proposed rule, CMS identifies four primary areas of the increase in appeal volume:

1) Increases in the number of beneficiaries;
2) Updates and changes to Medicare and Medicaid coverage and payment rules;
3) Growth in appeals from State Medicaid Agencies; and
4) National implementation of the Medicare Fee-for-Service Recovery Audit Program."

We concur that each of these areas play a role in the volume increase. However, the main cause is the flaws in the MAC (Medicare Administrative Contractor), Qualified Independent Contractor (QIC) and Recovery Audit Contractor (RAC) medical review processes and the collection of overpayments by RACs before all levels of appeal are exhausted. These flaws contribute significantly to the to the backlog. Evidence supports that Medicare contractor appeal denials are frequently either clinically inaccurate or are erroneous in applying NCD and LCD criteria. These inaccuracies include, but are not limited to, review of a wrong diagnosis, failure to review or acknowledge submitted medical records, and application of criteria irrelevant to the case. Further, upon review of MAC and QIC denials, it is clear that Medicare contractor reviewers are often stymied either by the lack of current clinical knowledge of the diagnosis or of the services under review, or by LCD criteria that are ambiguous, open to varied interpretation, and sometimes based on outdated medical knowledge. Our members have experienced these issues first hand.

The Alliance recommends that any proposed remedies to the Medicare appeals backlog include evaluation of Contractor appeal decisions. We also recommend that any Medicare appeal improvement initiative must include a thorough, unbiased, knowledgeable evaluation of Medicare contractor appeal decisions, and implementation of robust contractor oversight. Erroneous contractor decisions clog the appeals systems at all levels and expend unnecessary resources for all stakeholders including CMS and providers.

SPECIFIC COMMENTS

Precedential Final Decisions of the Secretary

While we understand the underlying rationale for this proposed rule is to limit inconsistent appeal decisions, we have deep concerns about the actual ramifications of this proposal. We strongly believe that Medicare contractors, including MACs and QICs, are not equipped to appropriately apply "precedential" decisions. Indeed, we raise significant concerns about many contractors' inaccurate application of LCD and NCD criteria. The potential for inaccurate decisions is exacerbated by the added responsibility of interpreting precedential decisions.

We believe the implementation of precedential decisions has a strong likelihood, through shortsighted application of these decisions by contractors, of restricting access to services and equipment that are

medically necessary for Medicare beneficiaries and to which they are entitled by law. We understand that parties have a right to challenge precedential decisions in federal court. However, the time and resources needed to appeal to federal court poses a significant burden for appellants and therefore effectively removes access to rightful coverage.

We have concerns that the Departmental Appeals Board's (DAB) decisions are made without direct hearing with the appellant. The Alliance is concerned that CMS has failed to establish safeguards to protect appellants from broad application of case authority that is either flawed or not factually applicable to certain appeals.

As such the Alliance recommends the following:

- Create a process to review and reject case precedent when it is no longer applicable.
- Develop a process for advocates and beneficiaries to challenge case precedent after it is published.
- Require all providers and Medicare contractors to attend education and training sessions on the proper use of precedential cases. CMS should also be required to provide its contractors with a summary of each case precedent and summarize how it may be applied to any future appeals.

Attorney Adjudicators

The Alliance supports the addition of attorney adjudicators to issue decisions in cases where there is no oral hearing, dismissals when the appellant withdraws the request for an ALJ hearing, and demands for information that can only be provided by CMS or its contractors, and to conduct QIC and Independent Review Entity (IRE) dismissals. We believe this solution allows for swifter resolution of cases without impeding beneficiary access to an ALJ when appropriate. However, the Alliance would like to recommend that CMS establish timelines – which need to be adhered to – for each stage of the appeal, including a timeline for attorney adjudicators' decisions on whether or not to reassign an appeal to an ALJ. We would also like to recommend that the attorney adjudicators have some experience in Medicare coverage and payment denials as well as appeals. These attorney adjudicators must be properly trained. As such, we further recommend that attorney adjudicators be required to stay current on coverage, coding and payment criteria by obtaining continuing education in these areas. These recommendations will help to ensure that attorney adjudicators make sound decisions.

Overpayment Collection Prohibited Until All Level of Appeals are Exhausted

The Alliance has long been concerned with the RAC denying a claim and recouping an overpayment prior to the adjudication of that denial. This incentivizes the RAC to deny claims – which we believe is the primary source of the appeals backlog – rather than providers – as CMS has claimed in this proposal. The appeal process should be fully exhausted before a RAC can recoup money from the provider. As such, the Alliance urges CMS to prohibit contractors from recouping overpayments until the appeal process is fully exhausted.

Conclusion

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