August 10, 2012

Karen Jackson
Director
Medicare Contractor Management Group
Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard, Mail Stop C3-09-27
Baltimore, MD 21244

Re: Recent Durable Medical Equipment (DME) Medicare Administrative Contractor (DME MAC) Bulletin on Refills of DME Supplies

Dear Ms. Jackson:

We are writing to express our concerns about a bulletin the four DME MACs published on June 8, 2012.[1] Specifically, the bulletin states that "non-consumable" DME supplies cannot be refilled unless the beneficiary confirms, and the supplier documents, that the supply item to be refilled is "non-functional." While the policy would apply to all non-consumable medical supplies, the DME MAC bulletin specifically references supplies for CPAP and RAD devices. According to the contractors, this policy is retroactive to August 2, 2011.

This new rule is inconsistent with current Medicare guidelines for refills of ongoing DME supplies. It is also contrary to the local coverage determinations (LCDs) for DME items that require so-called non-consumable supplies. Finally, contractors cannot issue new rules and apply them retroactively as the DME MACs have done in this case. AAHomecare has exhausted its efforts to address this issue directly with the DME MACs; consequently, we request that CMS instruct the contractors to rescind the policy.

I. BACKGROUND

Under longstanding Medicare rules, providers cannot automatically ship refills of DME supplies, even when the beneficiary has authorized automatic refills. Instead, Medicare requires providers to confirm the need for more supplies before refilling the items.[2] Recently, the Centers for Medicare

[1] http://www.medicarenhic.com/dme/medical_review/mr_bulletins/mr_bulletin_current/060812_refill.pdf
[2] *See*, *e.g.*, CMS Claims Processing Manual (CPM), Chapter 20.200, MCM, IOM 100-4 § 20.200, available at: http://cms.gov

and Medicaid Services (CMS) revised the Program Integrity Manual (PIM) to include specific timelines for confirming a request for a refill: 1) the supplier may not contact a beneficiary sooner than 14 calendar days before the shipping date of the supplies; 2) the supplier must document that the beneficiary requested the refill; and 3) the supplier cannot ship the refill more than 10 calendar days before the beneficiary's current supplies are expected to run out.[3]

Subsequently, the DME MACs issued a bulletin in August 2011 expanding those requirements by also requiring providers to document the quantity of supplies beneficiaries had remaining.[4] Around this time, the contractors also revised some LCDs to reflect the new time frames for documenting beneficiaries' need for supplies.[5] Notably, the revision for the CPAP LCD did not include any special rules for refills of "non-consumable" DME supplies other than those specified in the PIM.[6] On June 8, 2012, the DME MACs adopted a new standard for coverage of refills of non-consumable supplies. Under the new rule, these supplies must be "nonfunctional" before Medicare will pay for a refill.[7] The DME MACs explicitly applied this standard to coverage of CPAP and RAD supplies, but the policy also applies to any number of non-disposable DME supplies.

II. THE NEW RULE IS ARBITRARY, VAGUE AND UNWORKABLE

The DME MACs are unable to articulate any rationale to support this arbitrary new rule or explain how it applies or why it is retroactive. Providers do not even know which non-consumable supplies are affected by the rule, and the DME MACs have been unable, or unwilling, to respond to providers' questions about the rule. First, the term "non-consumable" is confusing. Presumably, the term refers to supplies that are not disposable so they can be used more than once but that are not durable in the nature of DME. These supplies are typically soft goods such as masks or tubing that would be used with respiratory equipment or enteral and infusion pumps.

Using respiratory supplies as an example, one contractor was unable to identify the non-consumable CPAP supplies that would be subject to the rule. During an Ask-The-Contractor (ACT) call shortly after the policy was announced, providers asked whether CPAP masks or cushions were consumable or non-consumable. Under the current CPAP LCD, Medicare covers one mask every three months (HCPCS A7027) and two cushions a month (HCPCS A7028 and A7029). These items are all non-disposable and can be used more than once, so ostensibly they should fall within the non-consumable category and be affected in the same way by the rule.

The answer, however, surprised providers. The contractor stated that a mask was non-consumable, but cushions were more than likely consumable but did not offer a conclusive answer or any

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[3] Medicare Program Integrity Manual, (PIM), IOM 100-8 § 5.2.6 available at: http://cms.gov.

[4] http://www.medicarenhic.com/dme/medical_review/mr_bulletins/mr_bulletin_current/080511_refill.pdf. We note that this bulletin announced a policy that exceeds the instructions established in the PIM for documenting refills of DME supplies because it adds an interpretive gloss to the PIM instructions by requiring providers to ascertain the quantity of supplies a beneficiary has remaining before shipping the refill.

[5] http://www.medicarenhic.com/dme/medical_review/mr_lcds/mr_lcd_current/L11528_2011-10-01_PA_2011-02.pdf

[6] *Id*.

[7] http://www.medicarenhic.com/dme/medical_review/mr_bulletins/mr_bulletin_current/060812_refill.pdf

rationale for the distinction, leaving providers to guess what items fall within the parameters of the rule.[8] Providers were even more surprised to learn that contractors have declined providers' requests that they publish a list of the DME supply items subject to the new rules. Apparently, the contractors plan on making this determination case-by-case. Thus, it is highly likely that providers with branches in multiple MAC jurisdictions will be subjected to conflicting MAC interpretations about whether a DME supply item is consumable or non-consumable.

The DME MACs have also been reluctant to say what constitutes "non-functional" in the context of this new policy. Although these supply items may be non-disposable, they must nevertheless be refilled regularly. This is why the LCDs contain schedules for how frequently these supplies should be replaced. These products usually serve as the interface between a device and the patient using it. In many cases, they are literally the link between the equipment and the person and are the means for delivering the therapy administered by the device. LCD frequency limits for refilling DME supplies are based on the understanding that these items are indispensable to achieving effective treatment with a device. Consequently, it is possible for a supply item to remain "functional" but nonetheless be ineffective, and beneficiaries may not be able to make this distinction. Tubing or masks that have not been properly maintained may seem to be functional, but, in fact, they are not delivering effective therapy. In the case of respiratory supplies, moreover, tubing and masks can be agents for infection when they are not properly maintained and replaced regularly.[9]

Even assuming, without conceding, that the DME MACs have the discretion to issue a new policy that is inconsistent with existing CMS guidance and the applicable LCDs without prior notice to providers as the DME MACs have done in this case, the policy is unworkable given the inability of providers to determine how the DME MACs intend to apply and enforce the policy. Finally, we note that providers are and have been aware of the rules that prohibit "auto-shipping" of refills of DME supplies. These rules adequately address program integrity issues relating to auto-shipping of supply refills and should be enforced accordingly. Concerns pertaining to auto-shipping, if any, should not be a basis for the DME MACs' improper expansion of the PIM instruction for refills of DME supplies.

III. THE DME MAC CONTRACTORS SHOULD NOT BE PERMITTED TO APPLY NEW RULES RETROACTIVELY

Although the new rule for non-consumable DME supplies was published on June 8, 2012, the DME MACs have told suppliers that the rule is retroactive to August 2, 2011. Their rationale is that in July 2011 CMS published new manual provisions on timeframes for documenting requests for refills. Consequently, the rule announced in the June 8, 2012, bulletin "relates back" to the publication date of the manual provisions. Presumably, the basis for this conclusion is that each of these rules

[8] Transcript of ACT call available at: http://www.medicarenhic.com.

[9] Horowitz S, Horowitz A, Chun C, *Sleep And Breathing: Care Of Cpap Equipment A Factor In Compliance And Hygiene,* available at: http://www.journalsleep.org/PDF/AbstractBook2009.pdf (Study suggesting that there are high counts of bacterial and fungal flora on CPAP interfaces, despite routine washing, with the older interfaces, more contaminated and resistant to cleaning.)

concerns documentation for refills and supplies. Our understanding is that "relating back" or "to relate back" is a term of art for a legal doctrine that is completely inapplicable in this context. In situations where government agents impose new obligations on providers, enforcement must be prospective, not retroactive as the DME MACs contend.

The doctrine of "relation back" is a legal construct that deems an action taken today as having occurred at some point in the past. The doctrine applies in the context of litigation to establish whether an amended pleading "relates back" to the original pleading to determine if a statute of limitation applies to the new pleading. Whether the doctrine applies involves what can be a tedious and arcane analysis of specific facts and circumstances which have been the subject of much controversy among lawyers and judges.[10]

The rule announced in the June 8 bulletin cannot relate back to any earlier time period. To allow this would be unfair and contrary to applicable law and regulation, which require public notice before new rules are enforced. In this case, the June 8 bulletin announced specific new requirements that are in addition to those contained in the documentation provisions of the PIM. The bulletin contains explicit documentation rules for a subset of DME supplies that relate to the manual provisions only in the most general way, *i.e*., each concerns documentation for ongoing DME supplies. Moreover, the DME MAC bulletin identifies a new category of DME supplies, non-consumable supplies; establishes "non-functional" as the new standard for determining whether a supply item is reimbursable by Medicare; and places a new documentation burden on providers that is in addition to what the PIM provisions require.

Under these circumstances, it simply is not credible to say that the June 8 bulletin relates back to the 2011 manual revision or even to suggest that the latter is a mere "clarification" of the former. Given the specificity and level of detail that the bulletin requires, we just do not see how any provider can produce documentation from 2011 that is consistent with the rules announced in the DME MAC bulletin.

The Medicare statute, the Administrative Procedure Act, and longstanding CMS policy all require at least 60 days-notice before a new rule or policy takes effect, absent extenuating circumstances affecting public welfare. Those circumstances are not present here. Even assuming, without conceding, that the DME MAC's new documentation rules are not arbitrary, vague and unworkable, it would be patently unfair to enforce the rule retroactively.

IV. CONCLUSION

We hope that you share our concerns regarding the arbitrary nature of the DME MACs' actions in issuing this policy without prior notice to providers and in announcing their intent to enforce it retroactively. It is not an exaggeration to say that lowering the DME error rate will be an impossible goal as long as the DME MACs are able to undermine established procedural and substantive rules *ad hoc*. Moreover, the new rule is vague and unworkable, leaving suppliers to guess at how the rule

[10] For example, a quick search on Westlaw indicates that there are at least 143 United States Supreme Court cases where "relation back" was an issue.

applies to specific DME supply items. We request that CMS instruct the DME MACs to withdraw the bulletin and to refrain from enforcing it retroactively.

We very much appreciate your consideration of the issues we raise in this letter. Please feel free to contact me if you have any questions. We would like to arrange a conference call to discuss this matter further. I will be contacting you soon to arrange a time to review this issue.

Sincerely,

Walter J. Gorski
Vice President of Government Affairs