



Caring that Feels Right at Home

Via Electronic Mail

May 11, 2009

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Re: Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) Repair Labor Billing and Payment Policy

Dear Drs. Hughes, Oleck, Hoover, and Whitten:

The American Association for Homecare (AAHomecare) is writing to address the DME MACs' new policy on Medicare coverage for repair labor billing and payment of beneficiary-owned medical equipment.¹ The policy, which went into effect on April 1, 2009, limits Medicare coverage for the labor component of repairs based on the type of equipment or repair. The policy is a radical departure from, and conflicts with longstanding Medicare coverage policy for payment of repairs to beneficiary-owned equipment. Medicare beneficiaries will be adversely affected because home medical equipment providers cannot afford to perform repairs in the limited time that the DME MACs have determined to be billable. As a result, many HME providers will be unable to provide the needed items and service to Medicare beneficiaries. We request that the Medical Directors withdraw the new policy and adhere to current manual provisions which establish coverage for repairs up to the cost of replacing the equipment.

¹ Repair Labor Billing and Payment Policy, February 26, 2009, available at: <http://www.medicarenhic.com/dme/index.shtml>.

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AAHomecare is the national trade association representing the homecare community. AAHomecare represents health care providers and manufacturers that serve the medical needs of Americans who require mobility assistive technologies, sleep therapy technologies, oxygen equipment and therapy, medical supplies, inhalation drug therapy, home infusion, and other home medical equipment, therapies, services, and supplies in their homes. Our membership reflects a broad cross-section of the homecare community including national, regional, and local providers operating approximately 3,000 locations in all 50 states. AAHomecare and its members are committed to advancing the value and practice of quality health care services at home.

BACKGROUND

CMS has a longstanding policy of covering and paying for repairs that are necessary to make beneficiary-owned equipment “serviceable.”² Medicare coverage for repairs includes payment for parts and labor that are not otherwise covered by a manufacturer’s warranty. Importantly, Medicare coverage for repairs is not limited except to the extent that the repairs “exceed the cost to replace the equipment.” In that case, Medicare will not pay for the excess cost to repair the equipment if it has been in use for less than the equipment’s useful lifetime.

Specifically, the Medicare Claims Processing Manual states:

Servicing of equipment that a beneficiary is purchasing or already owns **is covered** when necessary to make the equipment serviceable. The service charge may include the use of "loaner" equipment where this is required. **If the expense for servicing exceeds the estimated expense of purchasing or renting another item** of equipment for the remaining period of medical need, **no payment can be made for the amount of the excess.**

Medicare Claims Processing Manual, 100-4, Chapter 20 § 40.1.

The Medicare Benefit Policy Manual likewise does not limit Medicare coverage for the cost to repair beneficiary-owned equipment except to the extent that the cost to repair the equipment exceeds the cost of replacing it:

Repairs to equipment which a beneficiary owns **are covered** when necessary to make the equipment serviceable. . . . **If the expense for repairs exceeds the estimated expense of purchasing or renting another item** of equipment for the remaining period of medical need, **no payment can be made for the amount of the excess.**

Medicare Benefit Policy Manual, 100-2, Chapter 15, 110.2.

² 42 C.F.R. § 414.210 (Medicare does not pay for repairs of beneficiary-owned equipment if the carrier determines the equipment will not last for the remainder of its useful lifetime based on the accumulated costs of repairing the equipment); Medicare Benefits Policy Manual, 100-2, Chapter 15 § 110.2, available at: <http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf>, last accessed on April 21, 2009; Medicare Claims Processing Manual, 100-4, Chapter 20 § 40.1, available at: <http://www.cms.hhs.gov/manuals/downloads/clm104c20.pdf>, last accessed on April 21, 2009.

The repair policy articulated under the Benefits Policy and Claims Processing manuals has been in place from the time Congress created the capped rental and purchase option payment methodologies.³ Congress included coverage for repairs to patient-owned equipment because it understood that the DME benefit would be incomplete for beneficiaries who purchased their equipment unless Medicare covered repairs during the equipment's useful life.

We are concerned because the DME MAC policy significantly limits coverage for the labor component of repairs and will have a profound effect on the ability of our members to continue to furnish this Medicare-covered service. The following chart summarizes the results of an AAHomecare informal survey to determine the impact of the new policy. The survey included responses from a sample of large providers who have significant claims volume for repairs. Providers were asked to estimate the average number of allowed units of service for repair claims in the past year. While we recognize the limits of this data, we nonetheless believe that it accurately forecasts an almost fifty percent (%) reduction in coverage for labor from previous levels.

Type of Equipment	Part Being Repaired/Replaced	DME MAC Allowed UOS (One Unit of Service = 15 minutes)	Historical Average Allowed UOS	Total Claims Volume for Average Allowed UOS
Power Wheelchair	Batteries (includes cleaning and testing)	2	4	Over 5000
Power Wheelchair	Joystick (includes programming)	2	4	Over 3000
Power Wheelchair	Charger	2	3	Over 500
Power Wheelchair	Drive wheel motors (single/pair)	2/3	4/6	Over 2000
Power or Manual Wheelchair	Wheel/Tire (all types, per wheel)	1	2	Over 4000
Power or Manual Wheelchair	Armrest or armpad	1	2	Over 2500
Power Wheelchair	Shroud/cowling	2	3	Over 250
Manual Wheelchair	Anti-tipping device	1	2	Over 600

Required Time to Perform Repairs and Replacements. AAHomecare April 1, 2009.

³ Medicare Contractors Manual § 5102.2.G.2., May 1991.

1. **The new DME MAC policy on repairs for beneficiary-owned equipment is a coverage determination, not a payment determination.**

We recognize that current Medicare regulations permit the contractors to establish reasonable *payment amounts* for the labor component of repairs to beneficiary-owned equipment.⁴ Specifically, 42 C. F. R. § 414.210 states that:

Reasonable and necessary charges are those made for parts and labor not otherwise covered under a manufacturer's or supplier's warranty. Payment is made for replacement parts in a lump sum based on the carrier's consideration of the item. *The carrier establishes a reasonable fee* for labor associated with repairing, maintaining, and servicing the item.

42 C.F.R. § 414.210 (e) (1).

This provision both defines Medicare coverage for repairs to patient-owned equipment (i.e., when parts and labor are not otherwise covered by a warranty) and authorizes the contractors to establish a reasonable fee for the labor associated with repairs. Even so, § 414.210 (e)(1) cannot serve as the basis for the new repair policy because the policy does not in reality establish the “fee” for labor. Rather, it imposes a frequency limitation on coverage for this service. Consequently, we believe that the DME MACs have confused a payment determination with what is in fact a coverage determination.

For the most part, the Social Security Act (“Act”) does not list specific criteria for determining when an item or service is covered by Medicare. The Act defines broad benefit categories and authorizes the Secretary to determine when it would be “reasonable and necessary” for Medicare to pay for an item or service.⁵ The Secretary, in turn, has delegated this authority to CMS, giving it broad latitude to establish the circumstance under which an item or service is eligible for Medicare payment.

In this case, the new policy establishes limits to the units of labor *eligible for Medicare payment* based on the type of part replaced. Frequency limitations such as these are really coverage policies that specify when or how many DME items Medicare will cover, like the frequency limitations typically contained in national or local coverage determinations.⁶ The frequency limitations imposed under the new DME MAC policy likewise establish how many units of a covered service, -- i.e., labor -- are eligible for Medicare reimbursement based on the type of repair. Providers are instructed to not bill for units of service in excess of the limits in the policy. Additional units of service are not covered.

⁴ 42 C.F.R. §414.210.

⁵ See §1862, Social Security Act.

⁶ For example, the local coverage determination for glucose monitors establishes the number of test strips Medicare covers based on the beneficiary’s condition. Other local coverage determinations impose similar frequency limitations on coverage for DME items or supplies. The coverage determination for urological supplies specifies the maximum number of catheters covered by Medicare in a month depending on the beneficiary’s condition. A representative sample of LCDs is available at:

http://www.medicarenhic.com/dme/medical_review/mr_lcd_current.shtml

A *payment determination* in contrast, involves making a decision on the *methodology and the amount of reimbursement* for a Medicare-covered item or service. Congress recognized the distinction between payment and coverage policy when it eliminated the capped rental option from the DME benefit. In authorizing CMS to pay for repairs of beneficiary-owned equipment, the statutory language directs the Secretary to pay for such “service and maintenance” to beneficiary-owned equipment as he may determine to be “reasonable and necessary” and “in a payment amount” he determines to be appropriate.⁷ In short, the statutory language directs the Secretary to: 1) determine when repairs for beneficiary-owned equipment will be covered by Medicare; and 2) establish an appropriate payment amount for covered repairs.

CMS addressed coverage for repairs through issuances in the Benefit Policy and Claims Processing Manuals. CMS addressed the reimbursement methodology and payment amount for the labor component of repairs in a program transmittal which establishes statewide fee schedules for one unit of labor in a repair.⁸ Importantly, the transmittal established both the *payment methodology (fee schedules)* and the *payment amount (state-by-state payment ceilings)* for repairs such that any additional action by the DME MACs with respect to establishing *reimbursement* for labor is unnecessary.⁹

The DME MACs should not be misled by the premise that frequency limitations for DME items are based on a patient’s clinical condition. Medicare carriers make coverage decisions in many contexts in the course of administering Medicare benefits. When contractors deny a claim for a “same or similar” item, such as a manual wheelchair, they are imposing a frequency limitation on coverage for that item. Stated another way, Medicare covers only one manual wheelchair per beneficiary at a time. Same or similar denials inherently are frequency limitations imposed on a covered item or service; they establish parameters on the scope of Medicare coverage for a type of item or service. In actuality, however, beneficiaries do have to meet threshold clinical criteria before Medicare covers repairs to their equipment because Medicare will not cover repairs if the equipment is no longer medically necessary for the beneficiary’s condition. It is also worth noting that, for many years, at least one Durable Medical Equipment Regional Carrier (DMERC) maintained a local medical review policy on coverage for repairs of patient-owned equipment.¹⁰

⁷ Section 5101(a) of the Deficit Reduction Act, PL 109-171 (2005). The statute states:

Maintenance and servicing.—After the supplier transfers title to the item under clause (ii) or in the case of a power-driven wheelchair for which a purchase agreement has been entered into under clause (iii), *maintenance and servicing payments* shall, if *the Secretary determines such payments are reasonable and necessary*, be made (for parts and labor not covered by the supplier’s or manufacturer’s warranty, as determined by the Secretary to be appropriate for the particular type of durable medical equipment), and such payments shall be *in an amount determined to be appropriate by the Secretary*.

⁸ Medicare One Time Notification Manual, 100-20, CR6297, December 31, 2008, available at: <http://www.cms.hhs.gov/transmittals/downloads/R421OTN.pdf>

⁹ CR6297 does not establish frequency limits for a covered unit of service.

¹⁰ The policy conformed to the repair policy specified in Medicare Carriers Manual §2100.4 which is nearly identical to the policy in the benefits policy and claims processing manuals today. *See* Local Medical Review Policies (LMRPs) § 14.12 Repairs, Supplier Manual, DMERC Region A, 1993, available at: http://www.medicarenhic.com/dme/medical_review/mr_lcds/mr_lcd_archived/SM_Repairs_1993-10-01.pdf

Congress included coverage for repairs of patient-owned equipment under the DME benefit to ensure that beneficiaries who own their equipment can continue to use it effectively. In creating this benefit, Congress directed CMS to specify when repairs are covered by Medicare, and to set payment rates for repairs. CMS implemented Congress' direction through instructions in the Benefit Policy and Claims Processing Manuals and via a program transmittal establishing fee schedules and payment rates for one unit of labor associated with repairs. CMS chose to develop the payment amounts itself, although it could have delegated this function to the DME MACs.

In contrast, the DME MAC policy neither creates the payment methodology nor sets the payment amount for a unit of service. The policy limits the units of service that Medicare covers based on the type of part replaced. Although the policy impacts reimbursement, it is not a payment policy because it impacts payment only indirectly, as a consequence of reducing coverage.

2. The DME MACs are bound by coverage provisions in Medicare program interpretive manuals.

The new repair policy departs from the Benefit Policy and Claims Processing Manuals' instructions on coverage and payment for repairs. Although not part of a national coverage determination, these manual instructions nonetheless define when Medicare coverage of repairs to patient-owned equipment is "reasonable and necessary." As we noted above, before Medicare covers repairs to patient-owned equipment a beneficiary must show: 1) a continuing medical need for the equipment; 2) the repairs are for parts and labor not covered under a manufacturer's warranty; and 3) the repair costs (or depending on the type of equipment, the accumulated repair cost) will not exceed the estimated cost of replacing the equipment. A plain reading of the coverage provisions in the manuals shows that there are no limits on the units of service that Medicare covers for repairs, provided that all coverage criteria are met.

The Medicare Program Integrity Manual (PIM) addresses coverage provisions in interpretive manuals such as the repair policy under the Benefits Policy and Claims Processing Manuals. The PIM distinguishes these types of coverage provisions from national coverage determinations, stating that coverage provisions in interpretive manuals are "instructions that are used to further define when and under what circumstances services are covered or not covered."¹¹ Coverage policies in manuals are no less applicable to the contractors than are national coverage determinations or other CMS instructions published in manuals or program transmittals.

The PIM instructs contractors to revise their local coverage determinations (LCDs) within 90 days of a new or revised coverage provision in an interpretive manual in order to ensure consistency between LCDs and CMS manuals.¹² Because Medicare interpretive manuals supersede and control contractor issuances, contractors are not required to solicit comments when they revise LCDs to conform to coverage provisions in interpretive manuals. The PIM describes these revisions to LCDs as "Non-discretionary Coverage/Payment/Coding Updates" and exempts them from the requirement for notice and comment.¹³ Implicit in these instructions is that contractors may not revise coverage policies in ways that conflict with coverage provisions in interpretive manuals.

¹¹ PIM, 100-8 § 13.1.2.

¹² PIM, 100-8 § 13.4C

¹³ PIM, 100-8, § 13.7.3

The Benefit Policy and Claims Processing Manuals are interpretive manuals that are binding on the contractors. As we interpret the PIM, the DME MACs cannot unilaterally create a new coverage policy for repairs by imposing limits on units of service where none existed before. Accordingly, we request that the DME MACs withdraw the new repair policy and adhere to the policy specified in the manual.

3. Revisions to local coverage policies require notice and an opportunity for interested parties to comment on the public record.

In light of the analysis above, there are no grounds on which to base the frequency limitations in the DME MACs' new repair policy. We note however that, even assuming, but not conceding, that the DME MACs can revise the repair policy in order to impose frequency limits, the policy is nonetheless procedurally defective and must be withdrawn. While the DME MACs have authority to issue coverage determinations, they are bound to follow all applicable statutes and rules when doing so.

The Act and its implementing regulations establish the procedural requirements that the Secretary and its contractors must follow when issuing new or revised coverage policies. The PIM provides further guidance to Medicare contractors developing and implementing changes to existing coverage policies. Contractors must publish proposed local coverage determinations and solicit public comments when the new policy would restrict existing coverage for an item or service.

The PIM states:

Contractors shall provide for both a comment period and notice period in the following situations:

- All new LCDs
- Revised LCDs that restrict existing LCDs
- Revised LCDs that make a substantive correction
- LCDs that require a comment and notice period

PIM, 100-8 § 13.7.2

In this case, the repair policy is a new coverage determination that reduces Medicare coverage for the labor component of repairs to nearly half of what it was before the policy went into effect. Consequently, the DME MACs were required to publish a draft policy and solicit public comments on the draft before implementing the policy. Providers should have the opportunity to comment on the scope of labor associated with equipment repairs. In order to competently perform repairs, providers must engage in a number of tasks that require technical skill and training and that are unaccounted for under the new policy. These include (list is not exhaustive):

- Intake/Needs Assessment/Pre-evaluation:
 - Field incoming call and troubleshoot problem/issue
 - Review rental/sale, warranty information and repair history
 - Verify beneficiary demographic information and eligibility and coverage requirements

- Evaluation/Safety Check
 - Clean, disinfect and disassemble equipment
 - Document equipment condition
 - On-site service/repair or prepare specifications and order parts
- Funding and Procurement
 - Documentation collection
 - Purchase, receive and conduct quality assurance on manufacturer parts
- Service/Repair/Delivery
 - Perform required service and repair(s)
 - Re-assemble equipment/components/seating
 - Fitting and adjustment
 - Beneficiary/caregiver training and education

Even if the DME MACs had the authority to depart from the coverage provisions in the Medicare manuals (which we contest), the policy would nonetheless be procedurally flawed because it was issued without any opportunity for public comments.

The PIM also explicitly requires that contractors support their coverage decisions by publishing the factual evidence that they relied on in making a determination.¹⁴ The DME MACs imposed frequency limits on Medicare coverage for labor without any consultation with providers. As a result, the new policy grossly underestimates the time involved in making a repair. These limits are arbitrary and do not consider the time it takes to repair equipment can vary from product to product based on factors that are outside a provider's control. Further, by characterizing the policy as a "payment policy," providers lose the opportunity to appeal claims denied on the basis of the policy.

We are at a loss to explain the rationale for reducing by half the units of service covered for repairs, except to speculate that perhaps the contractors expect a growing volume of claims (and thus increased costs to the program) as more beneficiaries assume ownership of their equipment.¹⁵ At a minimum, it would have been prudent for the contractors to solicit comments on the services that are inherent in the repair of various items of DME so as to avoid establishing unnecessary restrictions on appropriate coverage. As it now stands, the policy must be

¹⁴ PIM, 100-8 § 13.7.1.

¹⁵ To the extent that the repair policy is in any way intended to control costs, we remind you that coverage determinations must not be based on considerations of costs. The standard for determining coverage under § 1862 of the Act is whether of an item or service would be "reasonable and necessary." The statutory language does not include costs as factor to be considered in making a coverage determination. Moreover, each time CMS has attempted to include costs factors in coverage decisions, it has been forced to withdraw the proposals. *See* Criteria and Procedures for Making Medical Service Coverage Decisions that Relate to Health Care Technology, 54 Fed. Reg. 4302 (to be codified at 42 C. F. R. pts. 400 & 405 (proposed June 30, 1989) (The rule would have allowed the Medicare program to consider "cost-effectiveness" when making a determination that an item or service was reasonable and necessary); Notice, Procedures for Making National Coverage Decisions, 64 Fed. Reg. 22619 (April 27, 1999) (Announcing that CMS would not finalize the 1989 proposed rule); Notice of Intent, Criteria for Making Coverage Decisions, 65 Fed. Reg. 31124 (to be codified at 42 C. F. R. pt. 405) (May 16, 2000) (Stating that national coverage determinations would be based on an assessment of an item's "medical benefit" and "added value"); Revised Process for Making Medicare National Coverage Determinations, 68 Fed. Reg. 55634 (September 26, 2003) (Stating that, contrary to the 2000 notice of intent, CMS would not use rulemaking to identify the criteria it would it would apply in making coverage determinations).

withdrawn and published as draft policy and the public should be allowed to comment on the changes.

CONCLUSION

The new DME MAC policy on repairs is a coverage determination that imposes frequency limits on coverage for the labor component of repairs for Medicare beneficiaries. It is different from a payment policy because it does not establish either the payment methodology for repair claims or the payment amount applicable to repairs. While it is true that the policy affects reimbursement for repairs, it does so only indirectly by reducing coverage for the labor component of repairs from previous levels.

Importantly, to the extent the policy imposes frequency limitations on coverage where none existed before, the new policy conflicts with the coverage provision on repairs articulated under the Medicare Benefit Policy and Claims Processing Manuals. These manuals stipulate that Medicare will not cover the cost of repairs when they exceed the cost of replacing the equipment, but do not otherwise restrict coverage for the labor necessary to perform the repair. The DME MACs are bound by the coverage provisions in the manuals and cannot unilaterally depart from them. Consequently, we request that the DME MACs withdraw the policy and adhere to the repair policy specified under the manuals.

Alternatively, assuming without conceding, that the DME MACs have authority to depart from the coverage provisions in the Benefit Policy and Claims Processing Manuals, the DME MACs must withdraw the policy and issue a proposed policy with an appropriate comment period.

We are available to discuss this issue in further detail. If you have any questions, please contact me, Alexandra Bennewith, Senior Manager, Government Affairs at (703) 535-1891 or alexb@aahomecare.org or Walter Gorski, Vice President, Government Affairs at (703) 535-1894.

Sincerely,

Tyler J. Wilson



President and Chief Executive Officer
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