



June 5, 2013

Ms. Melanie Combs-Dyer
Deputy Director, Provider Compliance Group
Office of Financial Management
Centers for Medicare and Medicaid Services
C3-09-27
7500 Security Boulevard
Baltimore, MD 21244

Re: New Proof of Delivery Policy for Durable Medical Equipment

Dear Ms. Combs-Dyer:

We are writing to make you aware of our concerns regarding the Durable Medical Equipment (DME) Medicare Administrative Contractors' (MACs) recent interpretation of the Medicare Proof of Delivery (POD) requirements. As you know, Medicare supplier standards require suppliers to deliver equipment or supplies to Medicare beneficiaries and maintain proof of delivery. The DME MACs have instructed suppliers that they must have a new proof of delivery for beneficiaries using rental equipment when the beneficiaries transition to the Medicare program following a payer change in order to qualify for Medicare payment of the item he or she is already renting.¹ However, in these situations, there is no delivery to document because the beneficiaries have the equipment in their homes and continue to be serviced by the same supplier. The DME Bulletin also states that Medicare requires Medicare-billed equipment to be new or newly refurbished when it is furnished to beneficiaries. We address this issue in a separate letter.

After carefully reviewing the applicable authorities, we believe there is no support for this new proof of delivery policy. Neither the supplier standards nor the Centers for Medicare & Medicaid Services' (CMS') interpretative guidance to the contractors require suppliers to obtain a new proof of delivery when beneficiaries switch from commercial or Medicare replacement health insurance to Medicare. Furthermore, because the beneficiary already has the equipment in his or her home, the requirement to obtain a new proof of delivery is not a practical requirement. The new policy also violates the Paperwork Reduction Act. Finally, as we

¹ NHIC DME MAC Bulletin, *Medicare Eligibility and Documentation Requirements for DMEPOS items Obtained Prior to Medicare Eligibility*, December 6, 2012, available at: http://www.medicarenhic.com/dme/medical_review/mr_bulletins/mr_bulletin_current/120612_eligi.pdf

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noted above, there is NO requirement that Medicare-billed equipment must be new or newly refurbished at the start of an initial rental.

AAHomecare is aware that CMS shares our concern with the high Medicare payment error rate for DME. This new proof of delivery policy is the most recent example of the type of retroactive policy “clarifications” that continue to drive the high error rate. Our concerns are presented in more detail below.

The Medicare Supplier Standards and CMS’ Interpretative Guidance

CMS amended the supplier standards rule in 2000 to require suppliers to maintain proof of delivery for any Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) items they furnish to Medicare beneficiaries.² The regulation does not specify the delivery methods to be used by suppliers nor does it dictate the components of the proof of delivery. It also does not state that DMEPOS providers must obtain a new proof of delivery every time a beneficiary changes payers in order to qualify for Medicare payment of the rental equipment, such as oxygen, he is already using. Shortly after publishing the final rule, CMS published contractor instructions that addressed proof of delivery. The instructions made no mention of providers needing a proof of delivery for every beneficiary payer change.³

Since then, the instructions have been revised several times, resulting in the current instructions, which also do not require suppliers to obtain a new proof of delivery when the beneficiary changes insurers.⁴ Suppliers’ primary obligations are to maintain proof of delivery for seven years and to make the proof available to contractors upon request. Most importantly, the signature date on the delivery slip **must** be the date of delivery.

The Medicare proof of delivery policy has been in place without substantive change for nearly 13 years. However, in the past several months, DME MACs have “clarified” the policy to include a requirement that providers obtain a new proof of delivery for rental equipment when a beneficiary, who is already using the equipment, qualifies for Medicare. Not only does this “clarification” conflict with the Program Integrity Manual and contractors’ previous instructions to providers, it also applies **retroactively** to claims before the date of the announcement even though the interpretation is a new policy that was not announced until November 2012. This means that any claim for a rental item where there has been a change from a commercial payer to Medicare could be vulnerable to recoupment for failure to have proof of delivery.

² Medicare Program Additional Supplier Standards, 65 Fed. Reg. 60366 at 60370 (October 11, 2000), adding 42 CFR §424.57 (c) 12.

³ Medicare Program Integrity Manual (PIM), IOM 100-8, 5.2.1; Transmittal No. R00 3PIM (November 22, 2000), available at: <http://www.cms.hhs.gov>.

⁴ PIM §§ 4.22.6.1; 4, 22.6.2, available at: <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c04.pdf>.

The New Proof of Delivery Policy Is Unworkable

The new policy also applies when the DMEPOS provider has already delivered rental equipment to a beneficiary with private insurance and documents the transaction with a proof of delivery. When the beneficiary subsequently transitions to Medicare, he or she already has the equipment in the home and the supplier has a proof of delivery. The new proof of delivery policy requires providers to ask beneficiaries to sign a **new** delivery ticket that **misrepresents** the delivery date for equipment already in the home. This practice contradicts standard business practices. In fact, to many, the practice could raise suspicions of Medicare fraud.

In the “real world,” this rule is unworkable and impractical, especially considering the frequency with which beneficiaries transition in and out of traditional Medicare and Medicare replacement policies. In effect, *all* DMEPOS providers are suddenly at risk of an overpayment when claims for rental equipment of beneficiaries who transition into Medicare are audited.

The New Proof of Delivery Policy Constitutes an Unapproved Paperwork Burden Under The PRA

Under the Paperwork Reduction Act (PRA), agencies are required to justify the public burdens associated with a collection of information. The purpose of the PRA is to ensure that agencies give careful thought to the necessity and costs of imposing documentation requirements on the public. The law requires agencies to submit a proposed collection of information for the approval of the Office of Management and Budget (OMB). Prior to their submission to OMB, the agency is required to give 60-days’ notice in the Federal Register and solicit public comment on the burdens associated with the information collection. Specifically, agencies must solicit public comments on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency's estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

A supplier’s obligation to have a proof of delivery is a paperwork requirement associated with the supplier standards rule. As such, CMS’ proof of delivery policy is subject to the requirements of the PRA. Since 2000, when the requirement to obtain and maintain proof of delivery became a supplier standard, CMS has consistently acknowledged the fact that it must have OMB approval of the paperwork burden.⁵

⁵ See RULES and REGULATIONS DEPARTMENT OF HEALTH AND HUMAN SERVICES Health Care Financing Administration 42 CFR Part 424 Medicare Program; Additional Supplier Standards. Wednesday, October 11, 2000 65 FR 60366-0; PROPOSED RULES DEPARTMENT OF HEALTH AND HUMAN SERVICES Centers for Medicare & Medicaid Services 42 CFR Parts 405, 410, 411, 414, 418, 424, 484, and 486 Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005 Thursday, August 5, 2004 69 FR 47488-01; PROPOSED RULES DEPARTMENT OF HEALTH AND HUMAN SERVICES Centers for Medicare & Medicaid Services 42 CFR Part 424 Medicare Program; Establishing Additional Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Enrollment Safeguards Friday, January 25, 2008 73 FR 4503-01; and

CMS complied with its obligations under the PRA by soliciting public comments on the burdens related to proof of delivery and other collection of information requirements under the supplier standards.⁶

CMS' position has been that the requirement to obtain a proof of delivery is exempt from the PRA because suppliers are only collecting information they would otherwise collect during the course of a regular business transaction. The following excerpt captures the essence of the reasoning underlying the Agency's argument:

Section 424.57(c)(12) states that a supplier, "*Must be responsible for the delivery of Medicare-covered items to beneficiaries and maintain proof of delivery.*" In addition, the supplier must, "Document that it or another qualified party has at an appropriate time, provided beneficiaries with information and instructions on how to use the Medicare-covered items safely and effectively."

This standard imposes reporting and recordkeeping requirements. The burden associated with this section is the time and effort required to: Document the delivery of the Medicare-covered item; document the provision of information or instructions to the beneficiary by the supplier itself or another qualified party; maintain the documentation of delivery of the Medicare-covered items and the necessary information and instructions. ***The burden associated with these requirements is subject to the PRA. However, we believe it is exempt under 5 CFR 1320.3(b)(2) to the extent that the time, effort, and financial resources necessary to comply with collection of information that would be incurred by persons in the normal course of their activities.***⁷

73 Fed. Reg. 4503-at 4510 (Emphasis supplied).

CMS argues that the government does not impose paperwork burdens by requiring suppliers to have a proof of delivery because this activity is already part of suppliers' business practices. This argument may have been credible in the past, but it is not credible today in light of the DME MACs' new proof of delivery policy. As we noted above, the policy is unworkable and contradicts standard business practices. No rational businessperson would waste time and money to obtain a proof of delivery already in the supplier's files. Taking the new policy to its logical extreme, no rational business person would ask a customer to sign a proof of delivery with a recent date of delivery for an item that was delivered (and documented) in the past; nor would a rational business person retrieve equipment from a beneficiary's home, drive around the block and "redeliver" it as some DME MACs have suggested that suppliers

RULES and REGULATIONS DEPARTMENT OF HEALTH AND HUMAN SERVICES Centers for Medicare & Medicaid Services 42 CFR Part 424 Medicare Program; Establishing Additional Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Enrollment Safeguards Friday, August 27, 2010 75 FR 52629-0 (addressing the application of the PRA requirements to the standard for POD under the supplier standards rule).

⁶ *Ibid.*

⁷ 73 FR 4503-01.

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do in order to comply with the new policy. On the contrary, the policy is so removed from what reasonable people would consider "common sense" that it exemplifies precisely the type of paperwork burden Congress intended to regulate under the PRA. If CMS wishes to implement a new proof of delivery policy like the one the MACs have articulated, then it must publish a notice soliciting public comments on the new policy and submit it to OMB for its approval under the PRA.

Conclusion

AAHomecare requests that CMS instruct the DME MACs to rescind the new proof of delivery policy because it is not supported by regulation or CMS manual instructions. The Medicare proof of delivery rules have not in the past, and currently do not, require providers to obtain a new proof of delivery when beneficiaries change insurers. Consequently, there is no authority to support the DME MACs' position that a new proof of delivery is required when a beneficiary changes payers. The policy is unworkable and contradicts to standard business practices. Finally, it constitutes a mandatory collection of information that has not undergone public comment and OMB approval as required by the PRA.

We appreciate your consideration of this important issue. We would like the opportunity to discuss this issue with you in more detail. I will call you next week to determine a mutually convenient time for a conference call.

Sincerely,

A handwritten signature in black ink, appearing to read "Jay Witter IV". The signature is stylized and cursive, with a large initial "J" and "W".

Jay Witter IV
Vice President of Government Affairs