



Medicare Quality Standards and Beneficiary Protections for Respiratory Equipment, Power Mobility Devices (PMDs), and Other Related Durable Medical Equipment (DME) – JA1009

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Contractors Affected DME Administrative Contractors (DME MACs)

Provider Types Affected Provider types affected are all suppliers who bill DME MACs for providing respiratory equipment, PMDs and other related DME to Medicare beneficiaries.



MLN Matters® article SE1009 provides the Medicare quality standards for beneficiary protection and safeguard requirements related to respiratory therapy equipment, PMDs, and other related DME.

Beneficiary Assurances

All Medicare billed DME has beneficiary protections such as the following:

- The equipment that the beneficiary uses meets all manufacturer standards, is provided by trained professionals in the manner that is nationally recognized for safe and effective patient care and that meets their needs and therapeutic goals, and beneficiaries are provided education in order to minimize any hazard or safety risks;
- All personnel who are educating the beneficiary, or repairing their equipment, are working within the scope of their practice and their state requirements;
- Whenever the beneficiary needs assistance, someone with the right professional knowledge will be able to answer all of their questions or come out to their home, if necessary, to provide additional equipment or troubleshoot an issue with the existing

Provider Needs to Know...

equipment; and

- If there is an incident with their equipment, the supplier will be responsive in determining what caused the problem, in removing the problem and in assuring the beneficiary that the risk of the same issue occurring has been minimized.
- In order to provide these beneficiary assurances, all suppliers that provide any DME to Medicare beneficiaries must:
 - Provide only items that meet applicable Food and Drug Administration regulations and medical device effectiveness and safety standards as well as provide manufacturer copies of the features, warranties, and instructions for each type of non-custom fabricated item to the beneficiary;
 - Have equipment delivery, set-up, and beneficiary education accomplished by competent technical and professional personnel who are licensed, certified, or registered, and who are functioning within their scope of practice as required by their state standards;
 - Make repair and maintenance available on all equipment and item(s) provided;
 - Provide regular business hour and after-hour access telephone number(s) for customer service and for information about equipment repair and emergency coverage;
 - Implement a program that promotes the safe use of equipment and minimizes safety risks, infections, and hazards; and
 - Investigate any incident, injury, or infection in which DME, Prosthetic, Orthotics, and Supplies (DMEPOS) may have been a contributor, when they become aware.

Beneficiary Safeguards

- Medicare beneficiaries who use DME are assured that:
 - They are made knowledgeable about the safe use and maintenance of their equipment;
 - By complying with appropriate maintenance standards (such as not developing a secondary infection from respiratory equipment, by maintaining it according to OSHA standards), they will not acquire an equipment related complication;
 - The equipment can be used wherever the beneficiary lives (at home or in various care facilities, such as an assisted care facility or a nursing home); and
 - Their needs are consistently reevaluated by both the prescribing physician and the supplier to make certain that the equipment is being used appropriately and is meeting the intended therapeutic goals.
 - In order to provide these beneficiary safeguards, all suppliers that provide any DME to Medicare beneficiaries must:
 - Provide the appropriate information about equipment set-up features, routine use, troubleshooting, cleaning, and maintenance;
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- Provide education and any instructional material that is tailored to the beneficiary's particular needs, abilities, learning preferences, and language;
 - Provide relevant information about infection control issues related to the use of all equipment and item(s) provided;
 - Ensure that the beneficiary can use all equipment and item(s) provided safely and effectively in the settings of anticipated use; and
 - Provide follow-up services to the beneficiary, consistent with the types of equipment provided, and recommendations from the prescribing physician.

Beneficiary Safeguards for Respiratory Equipment

- Medicare beneficiaries who use respiratory equipment are assured that:
 - When they need assistance, someone with the professional knowledge will be able to come out to their home, if necessary, to provide additional equipment or troubleshoot an issue with the existing equipment;
 - All equipment is provided by trained professionals in the clinical manner that is nationally recognized for safe and effective patient care; and
 - They receive, in accordance with the *American Association for Respiratory Care Practice Guidelines*, the proper education on the safe and effective use of their equipment and treatment modality.

Note: Such standards ensure beneficiaries have the information they need to be an active participant in their care.

- In order to provide these beneficiary safeguards, all suppliers that provide any respiratory equipment to Medicare beneficiaries must:
 - Provide respiratory services 24 hours a day, 7 days a week, as required;
 - Comply with the current version of the *American Association for Respiratory Care Practice Guidelines for Oxygen Therapy in the Home or Extended Care Facility; Long Term Invasive Mechanical Ventilation in the Home; and Intermittent Positive Pressure Breathing*; and
 - Provide training to the beneficiary consistent with the current version of the *American Association for Respiratory Care Practice Guidelines* (<http://www.rcjournal.com/cpqs/index.cfm>).

Beneficiary Safeguards for Any Power Mobility Devices

- PMDs include power wheelchairs and power operated vehicles and accessories. Complex Rehabilitative Wheelchairs are: 1) Group 2 power wheelchairs with power options; and 2) Group 3 and higher power and manual wheelchairs that can accommodate rehabilitative accessories and features (for example, tilt in space).
 - Medicare beneficiaries who use manual wheelchairs, PMDs, and complex rehabilitative wheelchairs and assistive technology are assured that they receive the wheelchair that best meets their needs based on a complete physical and environmental assessment.
 - All suppliers that provide any Manual Wheelchairs, PMDs, and Complex Rehabilitative
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Wheelchairs and Assistive Technology must verify that seating, positioning, and specialty assistive technology have been evaluated.

Beneficiary Safeguards for any Complex Rehabilitative Wheelchairs and Assistive Technology

- Medicare beneficiaries who use complex rehabilitative wheelchairs and assistive technology are assured that:
 - Anyone evaluating them has the training and experience to handle all of the technology and understands their very complex needs;
 - Their privacy will be maintained, and that they will be treated with respect;
 - The equipment they receive can always be repaired, modified, and maintained (one of the most important aspects of providing safe and therapeutic complex rehabilitation);
 - Everyone associated with the equipment is always actively participating in assessing, and with providing the optimal care and equipment that they require;
 - The equipment will be reliable and will work for the beneficiary without worry; and
 - Beneficiaries receive the equipment at their convenience, in a prompt manner, and according to both the prescribing physician's recommendations and the beneficiaries assessed needs.
- All suppliers that provide any Complex Rehabilitative Wheelchairs and Assistive Technology must:
 - At each of their locations, employ (as a W-2 employee) at least one qualified individual as a Rehabilitative Technology Supplier (RTS), who is either a Certified RTS or an Assistive Technology Professional;
 - Have at least one or more *trained technicians* available to service each location, who is identified by the following:
 - Factory trained by manufacturers of the products supplied by the company;
 - Experienced in the field of Rehabilitative Technology, (e.g., on the job training, familiarity with rehabilitative clients, products and services);
 - Completed at least 10 hours annually of continuing education specific to Rehabilitative Technology; and
 - Able to program and repair sophisticated electronics associated with power wheelchairs, alternative drive controls, and power seating systems;
 - Provide the beneficiary private, clean, and safe rooms appropriate for fittings and evaluations;
 - Maintain a repair shop located in the facility (or in close proximity, or easily accessible from another of the supplier's locations), as well as an area appropriate for product assembly and modification;
 - Ensure that the RTS coordinates services with the prescribing physician to conduct face-to-face evaluations of the beneficiary in an appropriate setting and include

input from other members of the health care team (i.e., Physical Therapist, Occupational Therapist, etc.);

- Provide the beneficiary with appropriate equipment for trial and simulation, when necessary; and
 - Implement procedures for assembly and set-up of equipment as well as a process to verify that the final product meets the specifications of the original product recommendation approved by the prescribing physician.
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Background N/A

Operational N/A
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Reference The related MLN Matters® article can be found at
Materials <http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE1009.pdf> on the CMS
 website.
