



CMS ISSUES FINAL STANDARDS FOR SUPPLIERS OF DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES

Executive Summary

Action: *On August 14, 2006, the Centers for Medicare & Medicaid Services (“CMS”) issued quality standards that suppliers of durable medical equipment, prosthetics, orthotics, and supplies (“DMEPOS”) must meet in order to receive Medicare reimbursement.*

Impact: *These standards require DME suppliers to implement specific business and product management practices designed to protect Medicare beneficiaries who receive equipment, items, or services from the suppliers.*

Effective Date: *Immediately.*

Introduction

On August 14, 2006, the Centers for Medicare & Medicaid Services (“CMS”) issued quality standards for suppliers of durable medical equipment, prosthetics, orthotics, and supplies (“DMEPOS”). The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 required CMS to issue such quality standards which suppliers must abide by in order to receive Medicare reimbursement.

At 14 pages in length, the final standards, fortunately, are significantly less onerous than the 104-page draft CMS issued on September 26, 2005. The final standards set forth the requirements DMEPOS suppliers must now meet with regard to business services and product specific services.

On August 16, 2006, CMS also published a notice inviting accreditation organizations to apply for deeming authority in order to apply the standards to DMEPOS suppliers and grant accreditation.

Business Services

The quality standards contain rules governing how DMEPOS suppliers must operate certain business services. These requirements pertain to suppliers' administration, financial management, human resource management, consumer services, performance management, product safety, and information management.

Administration

The section on administration requires suppliers to run their business so that they can obtain and provide quality equipment and services to beneficiaries. To comply with the standards, DMEPOS suppliers must designate one or more individuals who perform leadership functions. Leadership positions may be different based on the supplier's structure, and examples of leadership positions include owners, chief executive officers, or governing bodies. In addition, suppliers must: (1) have a physical location; and (2) display all licenses, certificates, and permits necessary to operate their business in an area accessible to customers and patients. Suppliers may only provide items that meet applicable Food and Drug Administration ("FDA") regulations, and medical device safety and effectiveness standards. When conducting business services, suppliers must also comply with Medicare coverage, claims processing, and payment policies. Suppliers are also required to establish business practices designed to prevent and control fraud, waste, and abuse, and to designate at least one person in a leadership position to address compliance issues.

Financial Management

Suppliers must also implement financial management practices that ensure accurate billing and accounting to beneficiaries and the Medicare program. This includes maintaining complete, current, and accurate financial records. Suppliers must also manage revenue and expenses on an ongoing basis as they relate to beneficiaries' services.

Human Resource Management

The CMS standards provide rules for human resource management as well. DMEPOS suppliers must implement policies that specify the qualifications, training, experience, and continuing education required of its personnel, and must provide such policies to accreditation organizations and government officials upon request. Personnel must be able to deliver and set up equipment and items and, in addition, must be able to train beneficiaries on how to utilize DMEPOS.

Consumer Services

CMS' consumer service standards are intended to promote effective relationships among beneficiaries and suppliers. DMEPOS suppliers must provide beneficiaries with clear instructions on how to use and maintain products, and their potential hazards. Suppliers

must inform beneficiaries: (1) when their products will arrive; (2) verify that beneficiaries have, in fact, received the equipment, item, and/or services; and (3) provide contact information for customer service assistance. If necessary, suppliers must also provide information on how to purchase and rent supplies. In the event a supplier is unable to furnish a beneficiary's device, it must promptly notify the physician who prescribed the item. Should a beneficiary file a complaint, a supplier is also required to notify the beneficiary using oral, telephone, email, fax, or letter format within 5 days of receipt of the complaint that his or her complaint has been received and that an investigation is underway. Within 14 days, the supplier must provide the beneficiary with the written results of its investigation.

Performance Management

The quality standards also set forth performance management rules. DMEPOS suppliers must establish a performance management plan that measures the outcomes of consumer services, billing practices, and adverse events (such as a product that causes an injury, etc.). At a minimum, the CMS standards require suppliers to measure the: (1) beneficiaries' satisfaction with and complaints about products and services; (2) response time to beneficiaries' concerns; (3) impact of business practices on beneficiaries' access to products and information; (4) frequency of billing and coding errors (such as the number of Medicare claims denied, errors the supplier finds in its own records after it has been notified of a claims denial, etc.); and (5) adverse events to beneficiaries due to inadequate or malfunctioning equipment, items, or services.

Product Safety

Suppliers must implement programs promoting the safe use of products, monitor the safety of their equipment, and investigate any incident in which a product may have contributed to an adverse event. If a product may have contributed to a beneficiary's hospitalization or death, the supplier must initiate an investigation within 24 hours after becoming aware of the incident. For other occurrences, suppliers must open an investigation within 72 hours after being made aware of the incident. A supplier must also have a contingency plan that allows it to respond to emergencies and disasters, or implement arrangements with other suppliers in the event that it cannot service its customers as a result of an emergency or disaster.

Information Management

The last section of the business services standards concerns information management. DMEPOS suppliers must maintain accurate, accessible, confidential, and secure beneficiary records in accordance with the Health Insurance Portability and Accountability Act ("HIPAA") privacy and security standards and applicable state laws.

General Product-Specific Service Standards

The second major section of the CMS standards includes requirements for general product-specific service standards. These standards address supplier preparation, delivery and setup of equipment, as well as training and instruction of beneficiaries and caregivers, and follow-up services. This section also contains appendices that set forth additional standards for specific products.

Preparation

Preparation procedures are designed to ensure that products and services meet Medicare rules and beneficiaries' needs. DMEPOS suppliers must consult with prescribing physicians to confirm orders and recommend changes or refinements to any item or service. Suppliers are also required to incorporate any such changes in the beneficiary's record.

Delivery and Setup

Suppliers must also follow certain equipment delivery and setup rules, as they are responsible for delivering and setting up all equipment and items in a timely manner, performing any necessary adjustments to the equipment or items, and providing or arranging for loaner equipment during any repair period.

Training and Instruction to the Beneficiary and Caregiver

The standards include specific training and instruction procedures suppliers need to provide to beneficiaries concerning the setup and use of their equipment. Suppliers must also advise beneficiaries, and caregivers, about possible safety hazards and infection control issues associated with the equipment's use. Such training and instruction must occur when a beneficiary first receives his or her equipment, and must be documented in the beneficiary's record.

Follow-Up Services

Lastly, suppliers must provide follow-up services to the beneficiary, consistent with the types of equipment, items, and services provided and recommendations made by prescribing physicians and other healthcare practitioners.

Appendices with Additional

Product Specific Standards

The CMS standards also contain appendices with supplemental standards applicable to specific products.

Appendix A provides additional requirements for respiratory equipment and services. In addition to the general standards, suppliers must provide respiratory services 24 hours a day, 7 days a week, as needed by beneficiaries. Suppliers are also required to follow certain rules prescribed in the American Association for Respiratory Care Practice

Guidelines concerning equipment delivery and setup, and beneficiary training and instruction.

Appendix B includes supplemental standards for manual wheelchairs and power mobility devices. Suppliers must employ at least one qualified Rehabilitation Technology Supplier (“RTS”) per location or be certified as a RTS, and each RTS must have at least one trained technician available to service each location appropriately depending on the size and scope of its business. The RTS, in coordination with the prescribing physician, must conduct face-to-face evaluations of the beneficiary; provide the beneficiary with appropriate equipment for trial and simulation when necessary; maintain all information obtained during the assessment in the beneficiary’s record; and implement procedures for assembly and setup of equipment. If beneficiaries are evaluated for wheelchairs or other mobility devices at the supplier’s facility, the supplier must provide a clean, safe, and private room for such purposes and a maintenance shop in close proximity.

Appendix C addresses custom fabricated and/or custom-made orthotics, prosthetics, and therapeutic shoes and inserts. Suppliers of custom-made items must provide diagnosis specific clinical examinations; assess items for safety; and ensure that the manufacturer’s guidelines are followed prior to fitting or delivery; and collect appropriate pre-treatment photographic documentation as appropriate for the item.

Suppliers also need to ensure that the implementation plan is consistent with the prescribing physician’s orders. In addition, the standards require suppliers to establish goals and expected outcomes for beneficiaries and to communicate with beneficiaries, and their physicians, regarding the recommended treatment plan. Suppliers must also provide instructions to the beneficiary and/or caregiver regarding the care and maintenance of the equipment; how to inspect and monitor for complications; and provide necessary supplies to attach, maintain, and clean the devices. Finally, suppliers must also provide follow-up care consistent with the items or services provided, inform the beneficiary or caregiver of the procedures for repairing, replacing, or adjusting the device; and advise the beneficiary to make an appointment with the prescribing physician, as appropriate.

Conclusion

Because of the new quality standards described above, suppliers will need to devote the necessary time and resources to ensure that they meet the new requirements. Suppliers should make certain that they comply with all applicable standards and should conduct self-assessments to determine whether their present practices are in concert with the new rules. Suppliers should also designate at least one individual whose job it is to address compliance concerns and establish organizational practices that promote ongoing compliance with the standards.