

ANALYSIS OF AND RESPONSES TO PUBLIC COMMENTS
Quality Standards
Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)
(8-14-2006)

INTRODUCTION

Section 302(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1834(a)(20) to the Social Security Act, to require the Secretary to establish and implement quality standards for DMEPOS suppliers of certain items, including consumer service standards, to be applied by recognized independent accreditation organizations.

Section 1834(a)(20)(E) of the Act explicitly authorizes the Secretary to establish the quality standards by program instruction or otherwise after consultation with representatives of relevant parties. The Centers for Medicare and Medicaid Services (CMS) contractors and stakeholders formed workgroups to develop draft quality standards. On September 26, 2005, draft quality standards were posted on the CMS Web Site at <http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/> for a 60-day public comment period. We received 5,723 timely public comments in response to the September 26, 2005 draft quality standards. Some of the organizations we received electronic and hard copy letters from include durable medical equipment (DME) suppliers, providers and manufacturers; orthotic and prosthetic practitioners and providers; national trade associations, advisory committees, and advocacy groups; accreditation organizations; national and State certification, credentialing and licensure boards; physicians, pharmacists, and other health care practitioner groups and individuals; and beneficiaries. All public comments were reviewed and grouped by the same or related topics. The comments and our responses are summarized below.

A. GENERAL COMMENTS

Comment: Most commenters supported the implementation of quality standards.

Commenters stated the quality standards: a) assist in reducing the risk of fraud and abuse in the Medicare program by unscrupulous providers and suppliers; b) enhance a provider or supplier's ability to improve their service to beneficiaries and the efficiency of their operations; c) provide additional safeguards to the Medicare program and its beneficiaries; d) are a tremendous step in the right direction in promoting quality and safety for Medicare beneficiaries who depend on home medical equipment; and e) are the most potent weapon against opportunistic and unreliable "suppliers" who take advantage of Medicare beneficiaries.

Response: We appreciate the supportive comments for the establishment and implementation of quality standards for DMEPOS suppliers, which is mandated by section 1834(a)(20) of the Act.

Comment: Many commenters stated the draft quality standards are too burdensome for small suppliers.

Response: We recognized the potential burden of quality standards to small suppliers. To minimize burden, we conducted focus groups early in the development process to provide small suppliers an opportunity to share concerns regarding the impact the quality standards may have on their businesses. We have worked collaboratively with a wide range of stakeholders to ensure the quality standards are reflective of best practices for quality business and beneficiary services. Additionally, we streamlined the quality standards to reduce the burden to small suppliers and to reflect the quality services that all suppliers should be providing to their customers.

Comment: A few commenters indicated we have not adopted some of the Program Advisory and Oversight Committee (PAOC) recommendations.

Response: The statute requires us to obtain advice from the PAOC on the establishment of quality standards but does not mandate that we accept all of the recommendations made by this committee. We have met with the PAOC throughout the development process for the draft standards and received recommendations and advice. As appropriate, we have incorporated the PAOC recommendations into the final standards.

Comment: One commenter recommended for us to: 1) implement the draft quality standards, as written, as a minimum threshold standard for suppliers to participate in the Medicare program; 2) require suppliers to participate in an industry marketing standards organization aimed at developing guidelines for marketing DME; and 3) require suppliers to maintain a minimum of \$1,000,000 in comprehensive liability insurance, as opposed to the current \$300,000 standard.

Response: We believe that the final standards are appropriate minimum standards for suppliers to participate in the Medicare program and will consider revising these standards or issuing additional standards through program instructions if we determine that such changes are warranted. We believe industry marketing is an individual business decision for competitive purposes. Since there was no rationale provided for increasing the liability insurance standard, we have no basis for a revision to the current standard.

Comment: Many commenters requested stakeholders have a second opportunity to comment on the quality standards. A few commenters recommended that CMS provide its draft revisions to the quality standards to the PAOC for review and comment before adopting the standards in final form.

Response: We believe we have provided an extensive opportunity for public input on the draft quality standards. In addition to seeking the advice of the PAOC, we posted the draft quality standards on our website on September 26, 2005 for a public comment period that ended November 28, 2005. We believe that this public process provided sufficient opportunity for stakeholders to comment on the draft quality standards and do not believe that granting a second opportunity for comment on the quality standards is necessary. Additionally, PAOC members provided comments through the public comment process and these comments were considered in the final standards. As stated in response to the previous comment, we will consider revising these standards or issuing additional standards through program instructions if we determine that such changes are warranted.

Comment: Some commenters recommended that we base our quality standards on the existing standards used by the Accreditation Commission for Health Care (ACHC), Community Health Accreditation Program (CHAP), and Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Some commenters expressed that JCAHO has over 400 standards that suppliers and providers must comply to obtain accreditation and believe that the accreditation standards are inappropriate for small suppliers. Some commenters believe that the JCAHO, ACHC, and CHAP accreditation standards for DMEPOS suppliers are developed from hospital accreditation standards and are not reflective of the role and responsibilities of DMEPOS suppliers.

Response: We reviewed the existing accreditation organizations standards and believe the industry needs a set of consistent standards to be applied by accreditation organizations. Additionally, by reducing the number of standards for which suppliers must comply, we have also reduced the burden to suppliers. Many of the accreditation organizations submitted

comments through the public comment process. We considered the accreditation organizations comments during the revisions to the final standards.

Comment: Some commenters believe the quality standards establish a fine line between the responsibilities of a DMEPOS supplier, physicians, and other health professionals. They believe the responsibilities of a DMEPOS supplier are substantially expanded in some respects.

Response: We revised language throughout the standards to clarify the role of the supplier. The supplier's role is to provide quality products and associated services to consumers. The quality standards incorporates requirements for the supplier to coordinate and collaborate with the prescribing physician and other healthcare team members, as appropriate for the types of items it provides. We believe the supplier provides expertise of the item, its function, and appropriate usefulness for beneficiaries that many prescribing physicians may not have. The CMS promotes the collaboration between the supplier and the prescribing physician to optimize the care and services to the beneficiary for which items and services are provided.

Comment: Many commenters believe the draft standards are too detailed, specific, and overly prescriptive. They believe the quality standards should provide guidance on providing care to patients. They believe that full compliance with the draft quality standards will be extremely burdensome and costly for suppliers to comply with and for CMS contractors to implement and enforce. Many commenters recommend that CMS streamline the draft quality standards by eliminating detailed product standards for specific DMEPOS items.

Response: We streamlined the standards to eliminate some of the specificity and redundancy reducing the document from 109 pages to 14 pages. Additionally, we deleted some of the product specific standards and consolidated others resulting in a general product specific standard and three specific product standards instead of fifteen. We disagree that the standards

should provide guidance on how to care for patients. The physician is accountable for the medical care of the patient. The DMEPOS supplier is accountable for providing expertise on the items and associated services.

Comment: Some commenters believe that CMS' implementation of the draft standards in the retail pharmacy setting could significantly reduce access that Medicare beneficiaries currently have to diabetic testing items and services. They commented that the draft quality standards are not applicable to the type of practice or the business model of community retail pharmacy.

Response: Section 1834(a)(20) of the Social Security Act requires all suppliers of DMEPOS to comply with the quality standards in order to receive Medicare Part B payments and to retain a supplier billing number. The law does not provide for any exemptions. The standards are mandated for all suppliers and pharmacies are one type of supplier.

Comment: Many commenters expressed that while the Secretary has been accorded the flexibility to establish the standards "by program instruction or otherwise," there is nothing that relieves the Secretary of his obligation to comply with substantive standards of the Administrative Procedure Act.

Response: Section 1834(a)(20)(E) of the Act explicitly authorizes the Secretary to establish the DMEPOS quality standards by program instruction or otherwise after consultation with representatives of relevant parties. We consulted with the Program Advisory and Oversight Committee (PAOC), whose responsibility is to provide CMS with advice on quality standards. After consulting with the PAOC and a wide range of stakeholders, we determined that it was in the best interest of the industry and beneficiaries to publish the DMEPOS quality standards through program instructions to facilitate the opportunity for suppliers to participate in the

Medicare DMEPOS Competitive Bidding Program. Additionally, we conducted focus groups to understand the impact of the quality standards, posted draft quality standards on the CMS Web Site for a 60-day public comment process and held an open door forum to explain the draft quality standards. We expect future revisions to the standards after the Medicare Competitive Bidding Program is implemented. We believe that publication of the standards through program instructions provide greater flexibility for changes to the standards as technology and services change. Additionally, the final quality standards were cleared using administrative procedures before publication on the CMS Web site.

Comment: A commenter recommended adding a standard regarding a supplier's obligations and processes to attempt to collect co-payment and deductible amounts for Medicare covered products and supplies.

Response: The quality standards are not the appropriate vehicle to specify supplier collection processes. The State Debt Collection laws provide requirements related to these issues.

B. SUPPLIER BUSINESS QUALITY STANDARDS

Note: The new title for this section is Business Services.

Administration

Comment: Some commenters expressed concern that the CMS-855S form does not allow for "similar" equipment or supplies that may be provided as part of a higher standard of care. Commenters provided an example such as the Food and Drug Administration (FDA) approved devices which may become part of a supplier's inventory and which are considered part of the same "family" of devices (such as bone growth or electrical stimulation). They stated the supplier should be able to provide items that are not listed on the CMS 855S, but that fall

within the same product category during a designated 855 “amendment period.” Commenters further stated that often patients present themselves with a prescription for an item that may need to be special ordered. A few commenters recommended that suppliers not be limited only to products and services on the CMS 855S as doing so hurts beneficiary access to goods. A commenter recommended CMS make it easy to update the 855S for new lines and services.

Response: We deleted this standard. Further guidance on this issue will be provided through the DMEPOS supplier enrollment and accreditation processes as needed.

Comment: Most commenters support the standard for suppliers to provide only FDA approved products and packaging that are either directly procured from the manufacturer or a distributor whose sole source of product is directly from the manufacturer. Some commenters believe it is acceptable and reasonable to require specific classes of medical equipment that have FDA approval, but it is not reasonable to mandate that the equipment should meet voluntary standards such as standards required by the International Organization for Standardization (ISO) Quality Systems. Most commenters recommended that suppliers be required to obtain a statement from the manufacturer certifying that they have met applicable regulatory standards. Some commenters recommended the standard to apply only to FDA Class II and III medical devices.

Response: We revised the standard to require only items that meet applicable FDA regulations and medical device safety and effectiveness standards. For additional item specific standards, the general product specific service standards require the supplier to comply with CMS regulations, policies, contractor policies, and articles for equipment and items. Additionally, the quality standards require the supplier to comply with Medicare coverage policies. We added a standard for the supplier to obtain copies of the features, warranties, and

instructions from the manufacturer. We disagree with the recommendation to apply the standard only to Class II and III medical devices. For example, mechanical walkers are Class I medical devices. A mechanical walker is a four-legged device with a metal frame intended for medical purposes to provide moderate weight support while walking. Disabled persons who lack strength, good balance, or endurance use this device. The device is also exempt from the current FDA good manufacturing practice regulations with the exception of standards regarding general standards concerning records and complaint files. Medicare beneficiaries are at high risk for falls and injuries when provided with a mechanical walker that is not at the correct height for the beneficiary and made of poor quality material that is not sturdy enough to support the beneficiary's weight. Devices made of poor quality and durability poses a safety risk for Medicare beneficiaries. Therefore, Class I devices are included in this standard.

Comment: Most commenters expressed concern regarding the standard requiring a supplier to maintain business hours at its location for a minimum of 40 hours per week. They stated the standard assumes that all supplier models include a business location that is appropriate for beneficiaries to visit. They believe this standard does not allow flexibility for the different models of service delivery such as stock show rooms, retail outlets, small independently owned suppliers that provide one type of product, and mail order suppliers. A few commenters recommended that suppliers be allowed to be open at least 20-25 hours per week. They believe this will allow beneficiaries ample time to get to locations if necessary and allow suppliers the ability to be out in the field and visit doctor offices, patient homes and other referral making locations.

Response: We agree with the concern and deleted the standard. Suppliers are required to maintain posted business hours for beneficiary access at its physical location as required in 42 CFR 424.57 (c)(8).

Comment: Many commenters expressed concern related to the standard requiring staff availability for telephone customer service during posted business hours and after-hours emergency service. Many physician commenters stated that physicians have satellite offices, which are only sporadically staffed one or two days per week. They report that most physicians are required to maintain 24-hour access with their office, and/or hospital affiliation. They report that most if not all responsible physicians have pagers and cell phones which allows them easy access to their patients regardless of their physical location. Physician commenters believe telephone-recording devices, which leaves an emergency number or where a physician or his staff may retrieve messages on a regular basis should be sufficient. Many community pharmacies commented that they would not have staff available to provide telephone customer service after hours. They recommended that if acceptable, some chain pharmacies could refer after-hours calls to a nearby 24-hour location for assistance. Commenters believe that manufacturers generally maintain these 24-hour 7-day a week services because they are likely to be the best source of information on technical aspects of their equipment.

Response: We revised the standard to require the supplier to provide the beneficiary with information and telephone numbers for customer service assistance regarding regular business hours, after-hours access, item repair, and emergency coverage.

Comment: Many commenters believe delivery by mail or courier service can be effectively managed using telephone and other forms of electronic communication in conjunction with patient education materials. Supplemental education materials may include

written and, if needed, electronic (CD-ROM, DVD, VCR tape, etc.) forms. Some commenters shared that where a health care professional separately provides beneficiary education or the beneficiary is a long-time user with a chronic condition, an item can safely be provided via mail order. Some commenters support the standard that mail order should not be used for initial delivery to beneficiaries. Some commenters reported that with the rapid advances in medical and communication technology, mail order might migrate to other home technologies in the near future.

Response: We revised the standard to require the mail order delivery supplier to verify that the beneficiary has received training and education on the use of items at the time of initial mail order delivery of items. This standard has been moved to the General Product Specific Service Standards.

Comment: A few commenters state that referencing “911” in the emergency service standards is an inappropriate level of specificity. A commenter recommends that the reference to “911” in the emergency response standard be placed in the section addressing patients’ rights and responsibilities.

Response: We deleted the reference to 911.

Comment: Some commenters expressed concern that maintaining a list of all equipment and supplies would be burdensome. A few commenters requested clarification as to the purpose of requiring suppliers maintain a list of all equipment and supplies including how they are provided to the beneficiary. A commenter requested that retail items be excluded from this standard.

Response: We revised the language to require the supplier to implement and maintain a plan for identifying, monitoring, and reporting (where indicated) equipment and item failure,

repair, and preventive maintenance, for equipment and items provided to beneficiaries. This standard has been included in the section “Product Safety.”

Comment: Most commenters expressed concern related to the standard to provide the beneficiary with a toll free number. They believe while many large corporations have toll free national numbers, the standard for local physicians, pharmacists, and small suppliers is unnecessary. Commenters recommended that the standard for physicians and pharmacy suppliers should state the suppliers have a local telephone number and permanent address in a local telephone directory. Commenters stated that if a supplier maintains a 24/7 helpline for its patients, that helpline should be allowed to serve the needs of all operating divisions or subsidiaries regardless of whether or not they have or are required to have separate supplier numbers. Only products where a malfunction would be life threatening or life endangering should require emergency after hours support.

Response: We deleted the standard requiring a toll free number. The supplier is required to provide the beneficiary with information and telephone numbers for customer service assistance regarding regular business hours, after-hours access, item repair, and emergency coverage.

Comment: Some commenters believe the notification of change in ownership standard is burdensome and duplicative. Some commenters stated that an immediate notice of change is impractical and conflicts with the 30-day timeframe. A few commenters recommended specific language revisions to the notification standard as follows: “Provide written notice to the NSC and its accreditation organization regarding ownership changes within statutory timeframes and if a change occurs.”

Response: We revised this standard to require suppliers to comply with the Medicare disclosure of ownership and control information standards at 42 CFR 420.201 through 420.206. We deleted the requirement to notify CMS, NSC, and the accreditation organizations.

Comment: Many commenters support the idea that suppliers should have compliance plans. Some commenters believe that many small suppliers, including small independent pharmacies and small mail order suppliers, do not have the resources to meet the additional compliance plan standards set forth in the draft quality standards. Commenters support the designation of a compliance officer, but believe that this individual should not be an owner of the DME Company. Commenters suggested compliance officers focus initially on areas of greatest risk.

Response: The intent of the standard was not for suppliers to add additional staff or increase burden. We deleted aspects of the standard that could be potentially burdensome for small suppliers. We revised the standard to focus on preventing fraud, waste, and abuse.

Financial Management

Comment: Many commenters support the need for minimum financial standards. They stated the financial management standards are normal financial practices and should not be difficult for providers to embrace. Some commenters stated the cornerstone of financial planning and reporting is Generally Accepted Accounting Principles (GAAP). Some commenters stated that businesses file income tax returns with the internal revenue service, which provides additional accountability. Commenters shared that for operating budgets, most companies project financial performance for the calendar year in some manner. Commenters stated that based on their current balance sheets and operating structures, good providers will continually project their financial position throughout the year, paying particular attention to the

projected capital structure of the business under different scenarios in order to evaluate opportunity and risk. Some commenters believe that the companies that are the strongest in the DMEPOS industry run their businesses by spending cash from revenue to buy more equipment and care for more patients. They believe growth through increased patient base is the only way to keep these businesses growing and surviving, as the revenue per item or service is constantly decreasing and costs are going up. They believe the best, safest way to fund this growth is out of cash flow (if possible), which does not always create an attractive financial statement while growing. Pharmacy commenters shared that retail items are provided on a “cash and carry” basis and delivery is not required. If delivery is required, it is often because the pharmacy provides the service for convenience of the patient.

Response: We appreciate the supportive comments for financial standards. We believe that to ensure beneficiary access to quality suppliers, equipment, items and services, suppliers should demonstrate financial viability of their businesses.

Comment: Some commenters stated that financial reporting should not be a part of quality standards and should be deleted. They believe that public companies are bound by certain reporting standards in the draft standards and this could potentially conflict with the Securities Exchange Commission (SEC) standards. Some commenters believe that much of the information listed in the draft standards would be considered proprietary. Some commenters perceived the term “audited” to mean that the financial statements should be monitored by an independent and external accounting personnel.

Response: We disagree with the deletion of financial standards. Financial accountability of a supplier’s business ensures beneficiary access to items and services with minimal disruption of beneficiary services. We agree with the public reporting issues and deleted the standard for

GAAP. We deleted the requirement for data sheets, which could be perceived as proprietary information. We deleted the requirement for audited financials. We revised the standard to require suppliers to implement financial management practices that ensure accurate accounting and billing to beneficiaries and the Medicare program.

Comment: Most commenters objected to the standard for notification to CMS and accreditation organizations of potential adverse financial operations. They expressed concerns about the use of this information and its impact on the supplier's ability to stay in the Medicare program.

Response: The intent of the draft standard was to have supplier's notify CMS early during financial difficulties involving the supplier's potential delayed payment to manufacturers and reimbursement issues from the Medicare program. Many times these issues could be resolved before the supplier filed bankruptcy. However, we understand the concerns and have deleted the notification requirement.

Human Resource Management

Comment: Most commenters expressed support of the human resource management standards. Many commenters believe that defined job descriptions, employee policies, chains of command, and disciplinary guidelines are the cornerstones of a good human resources program. They commented that performing due diligence and checking references and licenses on potential employees mitigates a substantial amount of risk for the providers and suppliers. Some commenters believe that spending money on training employees through internal and external programs generates great returns in raising the quality of standards of practice for the beneficiary. Many commenters believe that DMEPOS suppliers provide important professional and educational services and must do more than "drop ship" products.

Response: We revised the standard to reduce the specificity and references to other federal regulations and laws and clarify language.

Comment: Most commenters believe that the standard for criminal background checks is burdensome and the associated costs could amount to thousands of dollars for just one individual. A few commenters indicated the State of Florida requires criminal background checks on all employees who have direct patient care contact. Commenters indicated the standard to have a criminal background check on a warehouse manager, customer representative or other ancillary employee is expensive and unnecessary, as they do not have direct contact with the beneficiary in their home. A commenter suggested it should be sufficient for a supplier to check employees against the Office of Inspector General (OIG) exclusion list to fulfill the background check requirement.

Response: We believe the State and local laws are sufficient to address this issue and deleted this standard. We will continue to monitor the OIG exclusion lists.

Comment: Many commenters reported there are no professional licensure or credentialing standards applicable for certain categories of personnel. For instance, delivery techs are an important part of a supplier's service team, but there are no licensure standards applicable to this personnel class. One commenter recommended revising the standard to state, "The supplier shall ensure that personnel are employed and assigned responsibilities commensurate with their education and experience."

Response: We revised the language to clarify that technical personnel shall be competent to deliver, set-up equipment, items, and train beneficiaries. We added a requirement that the supplier shall maintain copies or other verification of licenses, registrations, certifications, and competency assessments for personnel who provide beneficiary services.

Comment: A few commenters stated the standard for documentation of annual verification of licensure is inappropriate in some cases as not all licenses require annual renewal nor do all States require annual renewal.

Response: We acknowledge that not all applicable licenses or States require annual renewal. We revised this standard to remove the term “annual.” However, suppliers remain required to maintain copies or other verification of licenses, registrations, certifications, and competency assessments for personnel who provide beneficiary services.

Comment: A few commenters expressed concern with the standard requiring the creation of an assessment program. These commenters indicated the standard places an undue burden on suppliers as well as highlighting that the standard is redundant of the standard to maintain documentation of verification of licensure.

Response: We revised the standard to require suppliers to maintain copies or other verifications of competence. Supplier’s technical staff may not be required to maintain a license. Therefore, the supplier would ensure the technical staff is competent to perform the assigned responsibilities related to delivery and set-up of equipment and items, and training of beneficiaries.

Comment: Most commenters indicated the Centers for Disease Control (CDC) and the Occupational Safety and Health Administration (OSHA) do not identify medical equipment suppliers at high risk for tuberculosis exposure. A few commenters recommended that requiring suppliers to maintain current documentation regarding the results of employees’ tuberculosis screening and Hepatitis B vaccination be limited to those employees who have direct patient contact.

Response: After further consideration of the industry and other State laws required of the supplier related to infection control, we deleted this standard.

Comment: A few commenters recommended revising the standard for a valid driver's license to state, "The supplier shall ensure that all drivers who deliver DMEPOS as part of Medicare Part B services to beneficiaries have a valid driver's license."

Response: After further consideration of State laws, we deleted this standard.

Comment: A few commenters stated that requiring suppliers to ensure personnel are employed and assigned responsibilities commensurate with their education and experience is too specific a standard. A few additional commenters recommended that the bullets listed under this standard be eliminated.

Response: We deleted this standard.

Beneficiary Services

Note: The new title for this section is Consumer Services.

Comment: A few commenters recommended changing the title of this section to "Supplier Provision of Services to Beneficiaries." They stated the new title is more reflective of the information in the standard.

Response: We agree the information is more reflective of beneficiary services. We changed the heading to Consumer Services.

Comment: Many commenters suggested deleting the reference to documentation of physician's orders since suppliers are familiar with the Medicare Program Integrity Manual instructions. They stated that CMS has internal processes for monitoring the supplier's compliance with documentation.

Response: We deleted this standard.

Comment: Many commenters believe it is impossible to provide a guaranteed estimate delivery time. They recommended revising the standard to state, “For DME suppliers, there are estimates for the time needed to ship items (estimated duration from the time supplier receives an order to the item an order is shipped) and these are disclosed to the beneficiary.”

Response: We agree the term “guaranteed” should be deleted. We revised the standard to require suppliers to provide beneficiaries with information about expected time frames for receipt of delivered items.

Comment: Many commenters believe the standard for coordination of services enhances communication and benefits the beneficiary by ensuring they receive the most appropriate equipment based on their clinical condition and need of items. Some commenters believe the standard creates the impression that it is the sole responsibility of the DME supplier to consult with the physician to coordinate care. They believe the standard should be deleted. Some commenters believe the information suppliers are required to obtain by this standard is not necessary for every beneficiary receiving a DMEPOS item. Additional commenters believe the information required by the standard is excessive.

Response: We disagree with deleting the standard. We acknowledge that it is not the sole responsibility of the supplier to ensure that services are coordinated with the prescribing physician and their healthcare team. The supplier’s role is to participate in the coordination of care, as part of the healthcare team, to provide item expertise and knowledge of the medical devices. The supplier should be aware of any pertinent beneficiary information that may influence the products or services provided. We deleted the list of examples provided in the draft standard and incorporated the expectation of coordinated services into the general product-specific service standard.

Comment: A few commenters believe the supplier's role is to only provide medically necessary equipment pursuant to a physician's order. Some commenters believe the supplier should not be required to consult with the physician or other health care professional. Some commenters believe that in certain limited circumstances, such as the provision of custom fitted prosthetics or orthotics, the supplier may be or employ a professional clinician. However, for most DMEPOS items, this is not necessarily the case. Some commenters reported that providers that properly fill a doctor's order should not be required to evaluate the appropriateness of the equipment for the beneficiary or communicate with the physician regarding outcomes.

Response: The supplier and its staff are experts in the equipment, devices and items provided to beneficiaries and are critical to the coordination of services to promote positive health outcomes for beneficiaries. Certain medical items impose certain risks of health and safety to a beneficiary, and it is often necessary for suppliers to communicate with the prescribing physician and/or healthcare team members to ensure the most appropriate items and services. We revised the standard to require the supplier to consult with the prescribing physician as needed, to confirm the order and to recommend any necessary changes or refinements or additional evaluations to the prescribed items and services.

Comment: Some commenters believe the draft standards assign the principal responsibility for training patients on the use of all DMEPOS to the supplier, even where others are currently providing or have already provided such training. A few commenters specifically recommend to state, "The supplier shall ensure that education and training is, or has been, provided to the beneficiary on how to use Medicare covered items safely and effectively. Evidence that the beneficiary has received adequate education and training shall be documented in the beneficiary's records."

Response: We acknowledge that often a beneficiary receives training in a clinical setting and in such a case, re-education is not necessary. We revised the standard to require only that suppliers verify that the beneficiary and/or caregiver has received training and instructions related to the use and maintenance of equipment. When a supplier provides the training and instructions, they are required to document such training and instructions in the beneficiary record or file. We believe this is a generic business service expectation that can feasibly be met by all suppliers. Additionally, educating a beneficiary on the equipment, functions, and purposes of medical items empowers beneficiaries and caregivers to make better choices related to items and promote compliance with health regime.

Comment: Many commenters believe education is important to assure the intended patient outcomes and supports the need of education and training of every item of DMEPOS. They indicated that the supplier is responsible for educating the beneficiary and/or caregiver(s) regarding the function of the technology and its care and maintenance. However, in some situations, it is the role and responsibility of another health care provider to educate and train the beneficiary regarding the safe and effective use of the technology to maximize function while adapting to physical deficits. One commenter provided the following example: Beneficiaries in an inpatient rehab setting will receive comprehensive education by a physical or occupational therapist regarding the use of the prescribed mobility assistive equipment in performing activities of daily living (ADL) and instrumental activities living (IAL). In fact, performing this role is outside the scope of practice of the supplier. Engaging in these activities would violate the code of ethics and standards of practice of the industry and profession.

Response: The scenario appears to demonstrate a close relationship between training beneficiaries on how to operate equipment and devices and how operating equipment and

devices assist in the accomplishment of mobility related activities of daily living. On the surface, this appears to be a duplication of services. We do believe situations exist where suppliers provide the equipment, especially complex medical devices, and practitioners provide assessment and evaluation of the beneficiary to ensure the device is appropriate to meet the physical limitations of the beneficiary. In addition, regarding DME in general, the supplier may determine it is necessary to recommend the use of somewhat different equipment in the home than equipment used in the institutional setting. The prescribing physician would order the consultative evaluation by the practitioner. We included complex rehabilitation and assistive technology in the product-specific standard for manual wheelchairs and power mobility devices.

Performance Management

Comment: Many commenters expressed concern that client outcomes in relation to equipment are the responsibility of the provider and not the supplier.

Response: The standards recognize the suppliers as a member of the healthcare team for the provision of medical devices and items. We revised the standard to require the supplier to implement a performance management plan that measures the outcomes of consumer services, billing practices and adverse events.

Comment: Many commenters expressed support for suppliers to measure their performance, but believe the draft standards are overly prescriptive. Commenters stated for a supplier to be successful in the market place, there must be constant evaluation of service performance, staff performance and the meeting of organizational goals. Each supplier, however, may have their own methods or business models as to how they evaluate criteria. Some commenters appreciate the function of quality improvement programs in encouraging healthcare providers to continuously upgrade their performance. They recognize a data-driven

process to improve supplier performance and support the draft quality standards as currently conceived. Some commenters state the list of reported percentages, as indicated in the draft document, is overly burdensome and does not yield results that will improve the supplier.

Response: We deleted the list of example indicators. We revised the standard to require minimal categories of measures related to consumer services, billing practices and adverse events. Suppliers could develop specific indicators in measuring their performance.

Comment: Many commenters suggested the trends analysis required by the draft standards might require small suppliers to invest in costly software to identify and analyze trends. Some commenters believe the data collection and time that necessitates adding personnel and or new software to meet the suggested performance standards could be burdensome. Commenters believe consideration should be given to the fact that small businesses may meet these standards at varying levels. For this reason, these standards must not dictate the particular measures. Some commenters state that many suppliers track complaints, product warranties, and response to their customers within an appropriate time frame. While they agree that a performance management process is worthwhile, the draft standards should be streamlined to allow the supplier to identify and track its own performance measures. Some commenters believe many of the performance standards do not appear to be easily adaptable or applicable to retail pharmacy situations. They believe the standards would impose additional standards for retailers that the current fee structure does not adequately support.

Response: The draft standards identified indicators as examples that could be used to measure the supplier's performance. The intent was never for suppliers to monitor all of the indicators. We reduced the prescriptiveness of the standard and revised it to require minimal categories of measures that are related to consumer services, billing practices and adverse events.

Suppliers could then develop specific indicators related to the specific equipment and items provided. Consumer service is an indicator that applies to all service oriented businesses.

Comment: Many commenters supported the standard for beneficiary satisfaction surveys. They believe patient satisfaction measurement is part of knowing how your business is operating. Some commenters believe quarterly beneficiary surveys and documentation of responses is excessive. They reported survey return is historically poor and yearly surveys should be sufficient. Additionally, they believe quarterly customer satisfaction surveys would be very costly to conduct and prepare in the unlikely event a customer would request that information. Pharmacy commenters stated that because of the close relationship many customers have with retail pharmacies, the customers typically call the pharmacy/pharmacist if there is an issue with items provided. They believe retailers are very customer service oriented and take care of any problem that may arise.

Response: Section 1834(a)(20) of the Act requires the quality standards to include consumer service standards. We acknowledge that quarterly customer satisfaction surveys may be burdensome to both large and small suppliers. We reduced the prescriptiveness of the standard and revised it to require minimal categories of measures that are related to consumer services, billing practices, and adverse events. We believe this provides more flexibility for suppliers to develop indicators applicable to their products and services. The supplier has flexibility in developing methods to collect and analyze this data.

Comment: Many commenters expressed concern about the indicator that suppliers respond to beneficiaries within 60 minutes of inquiry. They believe this places a significant burden on existing resources. They believe response to beneficiaries within 60 minutes is only

appropriate if the patient states it is an emergency or if a patient is an existing oxygen or ventilator customer.

Response: We deleted the 60-minute requirement.

Equipment Safety

Note: The title of this section is changed to Product Safety.

Comment: Many commenters expressed concern over requiring suppliers to maintain a current, accurate inventory of equipment. Some commenters recommended the standard simply require compliance with applicable state and federal regulations. A few commenters indicated the FDA does not require suppliers to maintain batch numbers. Some commenters recommended tracking serial and model numbers. They believe with computer technology many suppliers are able to function with far smaller inventories or no inventory at all by relying on the just in time shipping capabilities of their wholesalers. They believe the standard must not interfere with the adoption of supply line efficiencies.

Response: We deleted this standard. The requirement for inventory is addressed at 42 CFR 424.57(c)(4).

Comment: Many commenters expressed concern over requiring suppliers to implement and maintain a system for tracking and monitoring the history of all equipment and items. Some commenters stated the standard is overly burdensome and not feasible for small suppliers.

Response: We revised the standard to require the supplier to implement and maintain a plan for identifying, monitoring, and reporting (where indicated) equipment and item failure, repair, and preventive maintenance, for equipment and items provided to beneficiaries.

Comment: Many commenters expressed concern over requiring suppliers to conduct an environmental safety evaluation of the beneficiary's home. A few commenters indicated that the

provider might obtain information necessary for home assessments through sources other than an onsite visit. An interview with the patient, their family (if necessary), and a competent medical history should be sufficient for many DMEPOS suppliers to obviate the standard for a home visit.

Response: We agree. After further consideration of the impact of this standard to different models of suppliers, we have deleted the standard from the standards.

Comment: A few commenters reported that enteral nutrition solutions are prepared and prepackaged by the manufacturer. The supplier is not involved in the preparation of the solutions.

Response: We agree and deleted this standard.

Beneficiary Rights

Note: This section has been consolidated under the new title Consumer Services.

Comment: Many commenters endorse the standards for complaints. Some commenters indicated the existing DMEPOS supplier standards already require a written complaint resolution protocol, including records of complaints and their resolution. They believe this standard should be deleted or modified.

Response: We agree that 42 CFR 424.57(c)(19) requires a complaint resolution process. However, the quality standards provide specific requirements that focus on the outcome of the process.

Information Management

Comment: Many commenters indicated that standards two through eight should be deleted in lieu of the fact that a supplier must already comply with the Health Insurance Portability and Accountability Act (HIPAA) standards, which call for administrative, physical,

and technical standards. They believe the additional standards may cause conflict with the HIPAA standards.

Response: We deleted standards two through eight.

C. SUPPLIER PRODUCT-SPECIFIC SERVICE REQUIREMENTS

INSPECTION AND PREPARATION

Note: The term “inspection” is deleted from the standards.

Intake

Comment: Some commenters expressed concern related to the term “written prescription.” They indicated that in this technological driven age, faxed orders, as well as digital orders with verifiable electronic signatures should also be acceptable.

Response: We revised the standard to state, “Comply with CMS regulations, policies, and Medicare contractor policies and articles.”

Service Plan

Comment: Many commenters indicated that clarification is needed relative to the service plan, which appears to be the medical equipment provider’s responsibility. They reported that physicians are reluctant to provide this information to retailers under HIPAA. A few commenters believe that while suppliers get to know their patients over a period of time and establish a relationship with that patient, any notable changes in the patient’s condition should be reported to the physician, called to 911 and/or the patient’s choice of contact for an emergency.

Response: We agree the use of the term “service plan” caused confusion with the term “care plan.” We deleted the term and changed the heading to “Beneficiary Record.” These standards incorporate requirements for the supplier to coordinate and collaborate with the

prescribing physician and other healthcare team members, as appropriate for the types of items it provides. We believe the supplier provides expertise of the equipment and items, their functions, and appropriate usefulness for beneficiaries that many prescribing physicians may not have. Therefore, this information is pertinent to the beneficiary's record and the supplier's items and services provided.

Equipment Management

Comment: Some commenters believe the Equipment Management standards are duplicative of the Equipment and Safety standards and should be eliminated or revised.

Response: We agree and deleted this section.

Delivery and Set-up

Comment: Several commenters believe the standard "Assess and reassess parameters for the specific equipment and/or any physician guidelines" should be removed because it is the responsibility of the health care provider.

Response: We agree and deleted the standard.

Condition of the Home

Comment: Most commenters believe it is unrealistic for a supplier to inspect an individual's home for safety and environmental concerns. Some commenters offered alternative language to state, "The supplier shall have established guidelines for delivery personnel for specific instances in which the delivery personnel should not leave the equipment due to potential safety risks (e.g., electrical hazard). The guidelines should include a script for explaining to the beneficiary why the equipment cannot be left, a protocol that will relay an

urgent message of the specifics of the non-delivery back to responsible supplier management, and a notification to the prescribing physician regarding the inability to provide the equipment.”

Response: We agree that the in the home standard raises many issues beyond the supplier’s control. We deleted the standard.

Training/Instruction to Beneficiary and Caregiver

Comment: A few commenters believe suppliers should not be required to additionally supplement written, video, or electronic formatted training with oral instructions and recommend deleting the phrase “supplemented with oral instructions.”

Response: We agree and revised the language. Additionally, we believe some standards under this section are duplicative of others and deleted them accordingly.

Follow-up

Comment: A few commenters believe communicating with the treating physician or clinical team regarding outcomes of monitoring, maintenance, and operation of all equipment provided to the beneficiary should be the exception rather than the rule. Some commenters believe the services described are exclusively or nearly exclusively clinical services that are not provided by suppliers or reimbursed under the DMEPOS benefit.

Response: Follow-up services by suppliers are not clinical in nature but rather focus on consumer services. Follow-up services may relate to the types of items provided that pose a high or moderate risk to patient safety. We clarified the standard to read, “The supplier shall provide follow-up services to the beneficiary, consistent with the types of equipment, items and service(s) provided, and recommendations from the prescribing physician or healthcare team members.”

Appendix B: Oxygen and Oxygen Equipment

Comment: Many commenters and the American Association for Respiratory Care (AARC) recommend the inclusion of the following Clinical Practice Guidelines for oxygen and oxygen equipment: 1) Long Term Invasive Mechanical Ventilation in the Home, 2) Oxygen Therapy in the Home or Extended Care Facility, 3) Providing Patient and Caregiver Training, and 4) Suctioning of the Patient in the Home.

Response: We appreciate the support and recommendations of the AARC and are requiring compliance with these guidelines under the new Appendix A, “Respiratory Equipment, Supplies, and Services.”

Comment: The AARC recommends “qualified personnel” be defined as “either a licensed or credentialed respiratory therapist or other licensed health care practitioner who are qualified in accordance with applicable state laws.”

Response: We have stated under the Human Resource Management section, “Professional personnel shall be licensed, certified, or registered and function within their scope of practice as required by the State standard, under which the professional is licensed.”

Comment: Some commenters recommend the adoption of the AAHomecare Clinical Respiratory Standards for providers of respiratory equipment and inhalation drug therapies.

Response: We appreciate the submission of the AAHomecare Clinical Respiratory Standards. We have chosen to require compliance with the AARC guidelines related to delivery, set-up, and training/instruction.

Appendix C: Home Invasive Mechanical Ventilation Therapy

Note: This standard has been incorporated into the new Appendix A, “Respiratory Equipment, Supplies, and Services.”

Appendix D: Noninvasive Continuous Positive Airway Pressure (CPAP and Bi-level Positive Airway Pressure)

Note: This standard has been incorporated into the new Appendix A, “Respiratory Equipment, Supplies, and Services.”

Appendix E: Intermittent Positive Pressure Breathing (IPPB)

Note: This standard has been incorporated into the new Appendix A, “Respiratory Equipment, Supplies, and Services.”

Appendix F: Power Wheelchairs

Comment: Many commenters recommended providing quality standards that are appropriate for Rehab Technology Companies. Several commenters recommended standards for Complex Rehab and Assistive Technology.

Response: We accepted these recommendations and consolidated them into a new product specific standard, Appendix B, “Manual Wheelchairs, Power Mobility Devices, including Complex Rehab and Assistive Technology.”

Appendix G: Manual Wheelchairs

Note: This standard has been incorporated into the new Appendix B, “Manual Wheelchairs, Power Mobility Devices, including Complex Rehab and Assistive Technology.”

Appendix H: Diabetic Equipment and Supplies

Comment: Many commenters confused the training and instructions required of suppliers on equipment and items with the training and education standards for diabetes self-management training services for treating physicians and treating qualified nonphysician practitioners.

Response: We deleted this standard. The General Product Specific Service Standard incorporates the supplier’s role for diabetic equipment and supplies.

Appendix I: Customized Orthotics and Prosthetics

Comment: Many commenters believe the standard excluded practitioners other than orthotists and prosthetists from providing orthotic and prosthetic items and services. Recommended standards were submitted to ensure the inclusion of services provided by various practitioner groups.

Response: We reviewed the submitted standards and accepted language that is consistent with Medicare laws, regulations, policies, and role of the supplier. Additionally, we did not find a substantive difference in the two sets of standards and combined them into one document, Appendix C, Custom Fabricated, Custom Fitted, Custom-Made Orthotics, Prosthetic Devices, Somatic, Ocular and Facial Prosthetics, and Therapeutic Shoes and Inserts.

Comment: Commenters recommended definitions for custom fabricated, custom fitted high, custom fitted low, ocular prosthetics, facial prosthetics, and somatic prosthetics.

Response: We did not accept the recommendations for custom fabricated, custom fitted high, and custom fitted low. These terms are not consistent with Medicare law and regulations. We accepted the recommended definitions for ocular prosthetics, facial prosthetics, and somatic prosthetics with few modifications.

Appendix J: Enteral Nutrition

Comment: Some commenters shared that the enteral nutrition supplier plays a service-oriented role in the care of patients in skilled nursing facilities and home health agencies. A few commenters indicated that for patients who do not have home health services, the clinical monitoring of the patient should be the responsibility of the prescribing physician.

Response: We deleted this standard. We believe the general product specific service standard captures the role and responsibility of the enteral nutrition supplier.

Appendix K: Electric and Manual Hospital Beds

Comment: One commenter stated the expectation to provide more than a cursory evaluation of the electric outlet for an electric bed would be unrealistic.

Response: After consideration of burden, we deleted this standard. We believe the general product specific service standard captures the role and responsibility of a supplier that provides hospital beds.

Appendix L: Support Surfaces

Comment: Many commenters believe the requirement for a wound care nurse is unwarranted. They believe qualified, trained technical support persons can quite ably perform the prescribed duties.

Response: We agree and deleted this standard. We believe the general product specific service standard captures the role and responsibility of the supplier that provides support surfaces.

Appendix M: Walkers, Canes, and Crutches

Comment: Many commenters believe this necessary is not necessary. They believe the requirements for the supplier are addressed in the supplier product specific service standards.

Response: We agree and deleted this standard.

Appendix N: Commodes

Comment: Many commenters believe this necessary is not necessary. They believe the requirements for the supplier are addressed in the supplier product specific service standards.

Response: We agree and deleted this standard.

Appendix O: Bedpans and Urinals

Comment: Many commenters believe this necessary is not necessary. They believe the requirements for the supplier are addressed in the supplier product specific service standards.

Response: We agree and deleted this standard.