CENTERS FOR MEDICARE AND MEDICAID SERVICES
DMEPOS ACCREDITATION PROGRAM

Standards Manual

with Survey Preparation Questions

Third Edition

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INTRODUCTION

What is CARF?

CARF, or the Commission on Accreditation of Rehabilitation Facilities, is a private, nonprofit organization that promotes the quality, value, and optimal outcomes of health and human services through accreditation. Founded in 1966, CARF currently accredits in the following areas:

- Aging services
- Behavioral health
- Child and youth services
- Durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS)
- Employment and community services
- Medical rehabilitation
- Opioid treatment programs

DMEPOS Accreditation

To participate in the Medicare Part B program, a DMEPOS supplier must be accredited by an organization deemed by the Centers for Medicare and Medicaid Services (CMS). CARF is approved by CMS as a national deeming authority. CARF accredits suppliers of DMEPOS in the following product categories:

Mobility Assistive Equipment

- Canes and Crutches (M01)
- Patient Lifts (M02)
- Power Operated Vehicles—Scooters (M03)
- Seat Lift Mechanisms (M04)
- Walkers (M05)
- Wheelchairs—Complex Rehabilitative Manual (M08)
- Wheelchairs—Complex Rehabilitative Manual—Related Accessories (M08a)
- Wheelchairs—Complex Rehabilitative Power (M09)
- Wheelchairs—Complex Rehabilitative Power—Related Accessories (M09a)
- Wheelchairs—Standard Manual (M06)
- Wheelchairs—Standard Manual—Related Accessories (M06a)
- Wheelchairs—Standard Power (M07)
- Wheelchairs—Standard Power—Related Accessories (M07a)
- Wheelchairs—Seating/Cushions (M10)

Orthotics and Prosthetics

- Diabetic Shoes/Inserts—Custom (S02c)
- Diabetic Shoes/Inserts—Non-Custom/ Off-the-Shelf (S02)
- Limb Prostheses (PR01)
- Orthoses—Custom Fabricated (OR01)
- Orthoses—Off-the-Shelf (OR03)
- Orthoses—Prefabricated (Non-Custom Fabricated) (OR02)
- Speech Generating Devices (DM19)
- Voice Prosthetics (PD10)

Other DMEPOS

- Blood Glucose Monitors and Supplies—Mail Order (DM06)
- Blood Glucose Monitors and Supplies—Non-Mail Order (DM05)
- Commodes/Urinals/Bedpans (DM02)
- Continuous Passive Motion Devices (DM03)
- Contracture Treatment Devices—Dynamic Splint (DM04)
- Enteral Nutrients (PE03)
- Enteral Equipment and/or Supplies (PE04)
- Heat and Cold Applications (DM08)
- Hospital Beds—Electric (DM09)
- Hospital Beds—Manual (DM10)
- Infrared Heating Pad Systems (DM11)
- Negative Pressure Wound Therapy Pumps and Supplies (DM15)
- Neuromuscular Electrical Stimulators (DM16)
- Neurostimulators (PD04)
- Osteogenesis Stimulators (DM17)
- Ostomy Supplies (PD06)
- Pneumatic Compression Devices (DM18)
- Support Surfaces—Pressure Reducing Beds/ Mattresses/Overlays/Pads (DM20)
- Surgical Dressings (S01)
- Traction Equipment (DM21)
- Transcutaneous Electrical Nerve Stimulators (DM22)
- Ultraviolet Light Devices (DM23)
- Urological Supplies (PD09)

The product categories for which CARF will accredit suppliers may be revised from time to time.

About this Manual

Purposes of the Manual

The CARF standards manual is organized to meet a variety of needs and accomplish several purposes, including:

- To provide suppliers with a means of ongoing self-evaluation and continuous systems improvement for service delivery.
- To provide suppliers with an authoritative resource to use to prepare for a survey and accreditation.
- To provide suppliers with an educational resource on good business and service practices.

Organization of the Standards Manual with Survey Preparation Questions

The standards are tangible tools for suppliers to use in the development and delivery of quality services. In addition to the Introduction section of the standards manual, this publication contains the following sections: Accreditation Policies and Procedures, Standards, Glossary, and Supplements. Fullest use of the manual is aided by an understanding of the basic contents of these sections.

- The section titled **Accreditation Policies and Procedures** describes the steps in the accreditation process, the application

and survey process, and policies and procedures concerning obtaining and maintaining accreditation. Also included are CARF's **Accreditation Conditions**, applied before, during, and after the survey, that a supplier must meet to obtain or maintain accreditation, as well as a description of the possible **Accreditation Decisions**. A supplier should review this section carefully both as part of the self-study process and before requesting a survey.

- The supplier is expected to demonstrate conformance to the applicable **standards** during the survey so that CARF will be able to determine the supplier's overall level of conformance and the accreditation decision.
- Many standards are followed by **examples** that illustrate potential ways a supplier may demonstrate conformance to the standards.
- Following each standard are **survey preparation questions** that will assist the supplier in assessing its conformance to the standards. These questions also form the basis of the self-evaluation that the supplier submits to CARF prior to the survey.
- The **Glossary** defines certain terms used in the manual. It is advisable to refer to the Glossary and to become familiar with the terms that have special definitions within the context of DMEPOS and CARF accreditation.
- **Supplement A** identifies the documents and other materials required to be submitted to CARF along with the Intent to Survey (application).
- **Supplement B** contains sample forms and checklists the supplier may use in connection with standards conformance.

Accreditation Policies and Procedures

CARF accreditation policies and procedures relate to the accreditation process, including the survey. Because all aspects of the accreditation process are reviewed regularly for appropriateness, these policies and procedures may be changed periodically. Notification of changes, additional information, and clarification can be obtained by contacting CARF. Changes and informational updates are also posted on CARF's website, **www.carf.org.** Suppliers that are currently accredited or have begun the process of becoming accredited and have obtained Customer Connect access can obtain current accreditation policies and procedures at the Customer Connect website, **customerconnect.carf.org**.

Note: *Customer Connect is CARF's secure, dedicated website for accredited organizations and organizations seeking accreditation. To increase efficiency, minimize the use of paper, and support CARF's commitment to the environment, Customer Connect has been implemented as the primary means of transmitting certain documents such as the survey fee invoice and quality improvement plan. Rather than sending these documents through the mail, they are posted to Customer Connect and an e-mail is sent to the individual identified as the organization's Survey Key Contact. Organizations should use Customer Connect regularly to view accreditation- and survey-related documents and to keep CARF informed of any changes in the name or e-mail address of the key contact person.*

Submitting a completed application—the Intent to Survey—constitutes the supplier's agreement to adhere to CARF policies and procedures in effect on the date on which the Intent to Survey is signed and to all subsequent changes as they become effective. The review and appeal process set forth in these policies and procedures, as amended from time to time, will be the supplier's sole remedy with respect to the survey, accreditation decision, and accreditation continuation or termination. By submitting the Intent to Survey, the supplier expressly waives and releases CARF from any and all claims, demands, actions, lawsuits, and damages that may arise from or relate to, directly or indirectly, the survey, accreditation decision, and accreditation continuation or termination.

Accreditation Conditions

The following Accreditation Conditions must be satisfied for a supplier to achieve or maintain CARF accreditation:

1. **The supplier must provide records, reports, and other information requested by CARF.**

Intent Statements

The intent of this condition is for CARF to have access to all information deemed necessary to assess conformance to the standards. This condition applies to information requested by CARF before, during, and after the survey.

It is the supplier's responsibility to provide satisfactory evidence of conformance to the surveyor(s). Access to stakeholders, including beneficiaries, is covered by this condition as is access to all documents, including, but not limited to, files of beneficiaries (active and closed), human resource files, strategic plans and reports, and financial statements.

Federal regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) define the term *healthcare operations* to include accreditation activities. Therefore, the surveyor(s) does not need to identify consent or authorization to view records of beneficiaries, all of which are subject to review.

2. **A Quality Improvement Plan (QIP) must be submitted within 90 days following notice of accreditation. This plan will address the supplier's current and future efforts to address all areas for improvement identified through the survey.**

Intent Statements

CARF will provide the supplier with the format to use for this plan with its notification of the accreditation decision.

If assistance is needed when completing the QIP, the supplier is encouraged to contact CARF.

If a supplier requests a review of a One-Year or Provisional Accreditation decision, the QIP must be submitted to CARF within 45 days of notice of the outcome of that review.

3. **A supplier that achieves a Three-Year Accreditation must submit a signed Annual Conformance to Quality Report (ACQR). The report is submitted in each of the two years following the Three-Year Accreditation award.**

Intent Statements

To maintain accreditation, suppliers are expected to operate in conformance to CARF's Centers for Medicare and Medicaid Services (CMS) DMEPOS standards and comply with CARF's policies and procedures on an ongoing basis. They must incorporate changes to the standards, accreditation conditions, and policies and procedures as they are published and made effective by CARF. CARF will provide the supplier with the format for this report.

NOTE: *If any of the Accreditation Conditions are not met, CARF will determine the appropriate course of action, which may include denial or withdrawal of an accreditation award.*

Accreditation Decisions

To be accredited by CARF, a supplier must satisfy each of the CARF Accreditation Conditions and demonstrate through a survey that it meets the DMEPOS standards. Although a supplier may not be in full conformance to every applicable standard, the accreditation decision will be based on the balance of its strengths with those areas in which it needs improvement.

CARF uses the following guidelines to determine each accreditation decision.

Three-Year Accreditation

The supplier satisfies each of the CARF Accreditation Conditions and demonstrates substantial conformance to the standards. It is designed and operated to benefit beneficiaries. Its current method of operation appears likely to be maintained and/or improved in the foreseeable future. The supplier demonstrates continuous conformance from any previous period of CARF accreditation.

One-Year Accreditation

The supplier satisfies each of the CARF Accreditation Conditions and demonstrates conformance to many of the standards. Although there are significant areas of deficiency in relation to the standards, there is evidence of the supplier's capability to correct the deficiencies and commitment to progress toward their correction. On balance, the services benefit beneficiaries, and the supplier appears to protect their health, welfare, and safety.

A supplier may be functioning between the levels of a Three-Year Accreditation and a One-Year Accreditation. In this instance, accreditation will be awarded for one year.

A supplier will not be awarded a second consecutive One-Year Accreditation.

Provisional Accreditation

Following the expiration of a One-Year Accreditation, Provisional Accreditation is awarded to a supplier that is still functioning at the level of a One-Year Accreditation. A Provisional Accreditation is awarded for a period of one year. A supplier with a Provisional Accreditation must be functioning at the level of a Three-Year Accreditation at its next survey or it will receive an accreditation decision of Nonaccreditation.

Nonaccreditation

The supplier has major deficiencies in several areas of the standards, and there are serious questions as to the benefits of services; there are serious questions as to the health, welfare, or safety of beneficiaries; the supplier has failed over time to bring itself into substantial conformance to the standards; the supplier has failed to satisfy one or more of CARF's Accreditation Conditions; or there was an absence of key supplier staff or inaccessibility of the supplier location on the date of the on-site verification survey.

Overview of the Steps to Accreditation

Step 1.	Contact CARF.
Step 2.	Conduct a self-evaluation.
Step 3.	Submit the Intent to Survey.
Step 4.	CARF conducts the survey.
Step 5.	CARF renders the accreditation decision.
Step 6.	Submit a QIP.
Step 7.	Submit the ACQRs.

Steps to Accreditation

Accreditation is a process that generally takes several weeks to several months to complete, involving a substantial amount of preparation. Allowing plenty of time to adequately prepare is an effective way for a supplier to ensure survey readiness.

Step 1. Contact CARF

A supplier's first contact with CARF may be to visit CARF's DMEPOS website (**www.carf.org/dmepos**) or contact a CARF resource specialist. On the website, a supplier can review information about the accreditation program and download a free standards manual. CARF resource specialists are available for assistance regarding the accreditation process and technical assistance regarding standards conformance. Following contact, the supplier should review the standards manual.

Step 2. Conduct a Self-Evaluation

To earn accreditation, a supplier must satisfy the criteria for a Three-Year, One-Year, or Provisional Accreditation decision. The starting point is an assessment by the supplier of its current practices against the standards in the standards manual. This can be achieved by answering the survey preparation questions in this manual. Depending on the level at which the supplier initially assesses its conformance, a number of successive assessments may be appropriate. When conducting self-evaluations, the supplier is encouraged to seek technical assistance from CARF for guidance in meeting the standards.

Once the supplier believes it is in conformance to the standards, it completes the self-evaluation process by entering answers to all the survey preparation questions for each standard in Sections 1 and 2 of this manual, and any applicable standards in Section 3, on a self-evaluation form supplied by CARF.

Step 3. Submit the Intent to Survey

Intent to Survey and Other Submissions

When a supplier seeking accreditation is ready for a survey, it submits to CARF a completed Intent to Survey, which requests detailed information about the supplier and its leadership, product categories to be accredited, and locations. The Intent to Survey also allows the supplier to identify up to ten business days over an eight-month period on which the on-site portion of the survey should not be conducted for reasons such as vacations and observed holidays. The supplier must be available for an on-site survey all other days.

The Intent to Survey is completed and submitted via Customer Connect, CARF's secure, dedicated website for accredited organizations and organizations seeking accreditation. To gain access to Customer Connect, contact a CARF resource specialist

Along with the Intent to Survey, the supplier submits the completed self-evaluation form, copies of certain required documents and other materials listed in Supplement A of this manual, and the accreditation fee.

Submitting the completed Intent to Survey confirms the supplier's agreement to all terms and conditions contained therein, its desire for the survey, and its readiness for an unannounced on-site visit at any time.

If any information in the Intent to Survey changes after submission, the supplier should notify CARF immediately.

Selection of DMEPOS and Locations to Be Surveyed

In the Intent to Survey, the supplier identifies the DMEPOS product categories for which it is seeking accreditation and the physical locations where DMEPOS products and services are delivered. An accreditation award applies only to the specific DMEPOS and locations identified in the Intent to Survey.

If one survey includes multiple locations for accreditation and any one location is operating at a lower level of conformance to the standards than the others, the level of accreditation awarded for that survey will be the level at which the weakest location is functioning. A supplier may submit more than one Intent to Survey if it wishes to have separate surveys for each location it operates. In separate surveys, each accreditation decision is independent and based solely on the individual survey and level of conformance demonstrated by the supplier with respect to the included locations. In this case, different decisions may be awarded for each survey.

Accreditation Fee

An accreditation fee is assessed for each service delivery location that the supplier includes in its Intent to Survey. The accreditation fee is due at the time the Intent to Survey is submitted to CARF, and no survey will be conducted until CARF receives the entire accreditation fee. Because preparation, planning, travel arrangements, and off-site review may begin immediately on CARF's receipt of the Intent to Survey, the accreditation fee is not refundable in whole or in part. For current fees, contact a CARF resource specialist.

CARF will not process an Intent to Survey from any supplier that has an outstanding past due debt to CARF until that debt has been paid in full. CARF reserves the right to withhold an accreditation decision up to 90 calendar days, at which time a decision will be made to not award accreditation if an outstanding debt remains. CARF may modify a supplier's existing accreditation, up to and including accreditation termination in the event any fees are not paid in a timely manner.

Step 4. CARF Conducts the Survey

Before the Survey

Following submission of the Intent to Survey, self-evaluation, and accompanying materials, CARF determines, at its sole discretion, the number and identity of surveyors and length and date(s) of the on-site portion of the survey.

The on-site survey is scheduled during the supplier's workweek and normal hours of operation. Use of Saturdays and Sundays as survey days is limited to suppliers that operate on those days. The supplier will receive no advance notice of the on-site survey date(s).

On submission of the Intent to Survey, the supplier should assemble records, documents, and other materials needed to substantiate conformance to the standards for surveyor use throughout the on-site survey.

The Survey

The survey is conducted in two phases: off-site review and on-site verification. Together the phases are designed to determine the supplier's conformance to the standards.

Phase 1. Off-Site Review

During the off-site review, CARF will review the supplier's Intent to Survey, self-evaluation form, and required documents and other materials to form a preliminary assessment of the supplier's conformance to the standards. The off-site review also helps plan and guide the conduct of the on-site verification, including identification of subject matter of interviews, stakeholders to interview, and additional documents and other materials to review.

Phase 2. On-Site Verification

On the date of the on-site verification, the surveyor(s) arrives at the supplier's location and informs leadership (or other personnel if leadership is unavailable) that the on-site survey will begin. The surveyor(s) observes the supplier's service delivery; tours the physical facilities; interviews beneficiaries, leadership, personnel, and other stakeholders; and reviews beneficiary records, financial statements and reports, administrative records, and other materials relevant to determine conformance to the standards. Stakeholders for interview and materials for review will be selected by the surveyor(s). The surveyor(s) notifies the supplier's leadership or other personnel when the on-site survey is complete.

A responsible representative of the supplier must be on the premises at all times to facilitate the process and answer questions for the surveyor(s); however, this person may not attend stakeholder interviews.

The surveyor(s) makes reasonable efforts to minimize disruption to the supplier's regular operations. If any issues or questions arise during the on-site survey that the supplier cannot resolve with the surveyor(s), the supplier should call CARF for guidance and resolution.

After the Survey

After the survey, all questions or concerns should be directed to CARF rather than the surveyor(s).

Step 5. CARF Renders the Accreditation Decision

The surveyor(s) reports the findings of the on-site verification to CARF for consideration with the results of the off-site review in determining the accreditation decision. Approximately six to eight weeks after the on-site verification, the accreditation decision and a QIP template are sent to the supplier. The QIP template identifies standards the supplier did not meet. When the supplier is resurveyed, it is held accountable for follow-up on the identified areas for improvement.

NOTE: *CARF personnel, acting during the course and within the scope of their employment, are the only persons authorized to officially represent CARF in interpreting its policies, procedures, standards, and Accreditation Conditions.*

Step 6. Submit a Quality Improvement Plan

Within 90 days of the date of the accreditation decision, the supplier submits to CARF a QIP in which it outlines actions that have been or will be taken in response to the areas for improvement identified in the QIP template. The supplier uses the QIP template provided by CARF with the accreditation decision to

input its responses. CARF may be contacted for assistance if any areas for improvement require further explanation or the supplier needs assistance in determining whether its planned action is adequate to demonstrate conformance to the standards.

Submission of the completed QIP is required by Accreditation Condition 2 to maintain accreditation.

If a supplier requests a review of a One-Year or Provisional Accreditation decision, the QIP must be submitted to CARF within 45 days of notice of the outcome of that review.

Step 7. Submit the Annual Conformance to Quality Reports

As part of the commitment to ongoing performance excellence that all CARF-accredited suppliers are expected to demonstrate, each supplier that achieves a Three-Year Accreditation must submit an ACQR in a format supplied by CARF for each year of its accreditation. The report is due on the first and second anniversary dates.

Through the ACQR, the supplier certifies that it at all times conforms to the standards, satisfies the Accreditation Conditions, and complies with CARF's policies and procedures as changes are published and made effective from time to time.

Submission of the completed ACQR is required by Accreditation Condition 3 to maintain accreditation.

Falsification of Documents

Information provided by a supplier seeking CARF accreditation is a critical element in the accreditation process and determining the supplier's conformance to the standards. Such information may be obtained via interviews or direct observation by surveyors or may be provided through documents reviewed by the surveyor(s) or submitted to CARF.

CARF presumes that each supplier seeking accreditation is doing so in good faith and all information, including documentation, is accurate, truthful, and complete. Failure to participate in good faith, including CARF's reasonable belief that any information used to determine conformance to the standards during or subsequent to the survey has been falsified, may be grounds for Nonaccreditation or a decision to modify or withdraw existing accreditation.

In the event a supplier loses accreditation or is not accredited because of CARF's reasonable belief of falsification of documents or information, CARF may elect to not accept a new Intent to Survey from the supplier. CARF may also notify the appropriate state and federal agencies.

Public Information

Identification of Accreditation by the Supplier

A supplier that has been awarded accreditation may identify this achievement publicly. Use of the CARF logo by an accredited supplier for this purpose is encouraged. All references to CARF accreditation by the supplier must clearly identify each DMEPOS product category for which it is accredited.

CARF personnel and surveyors may not be referred to or quoted in any public release involving accreditation without CARF's prior approval.

Certificate of Accreditation

A supplier is provided, at no charge, one certificate of accreditation. Additional certificates are available for purchase. This free certificate, which is suitable for framing, identifies the supplier that submitted the Intent to Survey, the level of accreditation, the DMEPOS product categories for which it is accredited, and the month and year in which the accreditation expires. A supplier may use or display its certificate of accreditation to demonstrate conformance to the standards, but may not use or display the certificate in any manner that is

inconsistent with the purposes of CARF and its accreditation function or that misrepresents the availability or quality of the services offered by the supplier. The certificate should never be used either explicitly or implicitly as a claim, promise, or guarantee of successful service. Accreditation indicates a supplier's demonstrated use of professionally approved standards and practices, and the certificate is regarded as providing information and guidance for the public at large and for beneficiaries.

Each unexpired certificate must be returned upon dissolution of the supplier or loss of accreditation for any reason. In the event the supplier's accreditation is revoked, the certificate must be surrendered to CARF, and the supplier must refrain from representing itself as accredited and cease to use or display the certificate or the CARF logo in any manner. Similarly, if accreditation is suspended, the supplier must not represent itself as accredited or use or display the certificate or CARF logo until and unless accreditation is restored.

Release of Information by CARF

To enhance the value of accreditation to beneficiaries, CARF may release information related to a supplier and its accreditation to the extent not confidential or protected by law, including, but not limited to:

1. Whether CARF has received an Intent to Survey from a specific supplier.
2. Whether a survey has been completed.
3. The date of expiration of accreditation of a particular supplier.
4. The DMEPOS product categories for which a supplier is accredited.
5. A supplier's accreditation decision and status.
6. Whether a supplier has requested review of a One-Year Accreditation, Provisional Accreditation, or Nonaccreditation decision.
7. Whether a supplier is involved in appealing or may still appeal a Nonaccreditation decision.
8. A survey summary and/or other general information (all suppliers surveyed by CARF are required to provide information concerning their accreditation, services, and programs directly to the public).
9. As required by law or contract.

For convenient access to information, CARF includes on its web page a searchable list of accredited suppliers, including identifying information such as name, address, and phone number. This posting allows the public to review the accreditation status of a supplier at any time.

Ongoing Communication with CARF

During the term of accreditation, the supplier must communicate certain events, described below, and related information to CARF. A reporting form is available online in the Resources section of Customer Connect. Some situations may require further actions to be taken.

Communication Regarding Administrative Items

The following administrative items must be communicated to CARF within 30 calendar days of their occurrence:

1. A change in the leadership
2. A change in the ownership
3. Relocation of an accredited location
4. A change in mailing address
5. Significant reorganization of the personnel associated with the accredited location
6. Expansion, reduction, or elimination of an accredited location

7. Severe financial distress
8. Acquisition, merger, consolidation, or joint venture

Changes in ownership and/or leadership, acquisitions, mergers, consolidations, and joint ventures may require payment of an administrative fee or a supplemental survey.

Communication Regarding Significant Events

The following significant events, and the supplier's responses, must be communicated to CARF within 30 calendar days of their occurrence:

1. Investigations
2. Material litigation
3. Catastrophes
4. Sentinel events
5. CMS sanctions, bans on admissions, fines, penalties, or revocations of Medicare billing privileges

Subsequent Surveys

Depending on the circumstances, CARF may conduct three types of surveys of the supplier following the initial survey. These survey types are described below.

Resurveys

To maintain accreditation beyond the expiration date of its current survey, a supplier must be resurveyed or in the process of a resurvey by the expiration date. CARF notifies a supplier of the need for a resurvey approximately seven months before expiration of its accreditation.

The resurvey process is the same as the initial survey process in that a completed Intent to Survey and accreditation fee are required and all applicable standards are applied. However, during a resurvey the supplier is expected to be able to demonstrate conformance during the entire period since its last survey. Also, special attention is given to the QIP from the previous survey.

Supplemental Surveys

The main objective of a supplemental survey is to recognize the dynamic status of suppliers and permit changes in accreditation between surveys. If a supplemental survey is required, the supplier must submit to CARF a completed Intent to Survey and nonrefundable accreditation fee.

The maximum term of accreditation for a supplemental survey is the remaining term of the current accreditation. If during the supplemental survey the supplier is found to be functioning at a lower level of accreditation than the existing award, the result will be a reduction in the level and term of the entire accreditation.

Supplemental surveys may be required under two circumstances:

1. **When a supplier changes leadership or ownership or engages in a merger, consolidation, joint venture, or acquisition transaction.**

When a supplier's leadership or ownership changes after the survey is conducted, it may be necessary to conduct a supplemental survey to determine the extent of continued conformance to the standards. For the same reason, a supplemental survey may also be required when a supplier is party to a merger, consolidation, joint venture, or acquisition transaction.

CARF will determine the need for a supplemental survey once the supplier notifies CARF, in writing, of the changes. CARF will contact the supplier for details if necessary.

2. **When an organization wishes to add DMEPOS or locations to an existing accreditation.**

A supplier must have a supplemental survey to add DMEPOS or locations to its existing accreditation. The supplier may also elect to have the additional DMEPOS or locations surveyed as part of a separate accreditation. Please contact CARF to discuss available options.

Monitoring Visits

CARF may from time to time conduct unannounced monitoring visits of accredited suppliers. A monitoring visit may be conducted any time CARF receives information that a supplier may no longer be conforming to the standards. The supplier's accreditation award may be modified as a result of a monitoring visit and submission of a new QIP may be required. CARF may assess an accreditation fee for a monitoring visit.

Allegations, Suspensions, and Stipulations

Upon being informed by any source of a change in a supplier's conformance to CARF's Accreditation Conditions, standards, or policies and procedures, CARF, at its sole discretion, may review and modify the supplier's accreditation status up to and including revocation of accreditation. CARF may also suspend or place stipulations on continued accreditation. During suspension, the supplier is not accredited and may not communicate to third parties that it is CARF accredited.

CARF's review may involve a request for an immediate response from the supplier, submission of documents and other information, solicitation of information from external organizations and individuals, and/or the undertaking of an unannounced monitoring visit to the site at CARF's discretion. Refusal to respond or unsatisfactory response to a CARF inquiry regarding an allegation may result in modification of accreditation status. When a change in status is deemed warranted, CARF will notify the supplier of this action and review available relevant information.

If an allegation is received after a survey but before the accreditation decision is released, CARF may withhold the release of the decision until an investigation of the allegation has been completed and the matter resolved.

In the event of any accreditation revocation, withdrawal, revision, or other remedial or adverse action or any nonconformance to standards that poses immediate jeopardy to the supplier's beneficiaries or hazard to the general public, CARF will promptly notify CMS, the National Supplier Clearinghouse, and ombudsman programs as appropriate.

Disputed Decisions

Review of One-Year or Provisional Accreditation Decisions

When a One-Year or Provisional Accreditation is awarded, the supplier may submit a written request for an on-site review of the identified areas for improvement to determine whether, in light of this on-site review, the One-Year or Provisional Accreditation decision is appropriate. In connection with this review, the following procedures apply:

1. The supplier must submit a written request for a review of the accreditation decision, to be received by CARF within 30 calendar days of the date of the accreditation letter. In the written request for review, the supplier must identify in detail its specific disputes regarding each identified area for improvement in dispute. The request must be accompanied by the regular accreditation fee appropriate for the number of locations included in the survey under review. CARF will send the supplier a letter confirming receipt.
2. CARF will conduct an unannounced, on-site review survey following timely receipt of a sufficient written request and the appropriate accreditation fee. During the on-site review survey, the supplier must provide evidence of conformance in the disputed areas for improvement. The CARF surveyor(s) conducts interviews and reviews documentation to the extent necessary to determine whether any revisions to previous findings should be made.

3. Findings from the on-site review survey are submitted to CARF for reconsideration of the accreditation decision.
4. Following the accreditation decision-making process, the supplier is informed as to whether sufficient evidence of conformance has been presented to warrant a change in the accreditation decision. The supplier is notified of its accreditation status and new expiration date as appropriate.
5. If the supplier does not submit a sufficient written request for review or appropriate payment within the required time frame, it waives the right to a review of its One-Year or Provisional Accreditation decision.

Review and Appeal of Nonaccreditation Decisions

CARF has established a review and appeal procedure for suppliers that receive a Nonaccreditation decision. This procedure offers a supplier the opportunity to sequentially challenge such a decision at two levels: on-site review and appeal hearing.

The supplier is informed of the Nonaccreditation decision and has 30 calendar days in which to submit a written request for an on-site review.

If the outcome of this on-site review is Nonaccreditation, the supplier may appeal this decision. This final appeal will be based only on questions of whether the survey was conducted in a manner consistent with CARF's survey policies and procedures.

NOTE: *If the supplier's Nonaccreditation decision is based on absence of key supplier staff or inaccessibility of the supplier location on the date of the on-site verification survey, review and appeal of the decision are not available.*

Request for Review

A supplier that receives a Nonaccreditation decision may initiate a review by submitting a written request for review to CARF along with an additional accreditation fee for each location included in the survey under review. The written request must be received by CARF no later than 30 calendar days following the date of CARF's letter notifying the supplier of the decision. Within seven calendar days of receiving the written request, CARF will send the supplier written confirmation of its receipt.

NOTE: *If the supplier does not submit a written request for review or appropriate payment within the required time frame, it waives the right to a review of its Nonaccreditation decision.*

On-Site Review

The on-site review survey is a full, unannounced survey. The surveyor(s) observes the supplier's service delivery; tours the physical facilities; interviews beneficiaries, leadership, personnel, and other stakeholders; and reviews beneficiary records, financial statements and reports, administrative records, and other materials relevant to determine conformance to the standards. The supplier must present information to demonstrate conformance to the standards.

The surveyor(s) will submit findings to CARF within five calendar days after the on-site survey has ended. Within 30 calendar days after receiving the findings, CARF will determine if the Nonaccreditation decision should be upheld or revised. CARF may:

a. Affirm the Nonaccreditation decision. This decision is final unless the supplier notifies CARF in writing of its decision to appeal, pursuant to the following section.

   or

b. Reject the Nonaccreditation decision. CARF may award a Provisional, One-Year, or Three-Year Accreditation. CARF may also establish specific stipulations that the supplier must meet. This decision is final.

Appeal Hearing

If the result of the review is to reaffirm the Nonaccreditation decision, the supplier, upon written notice to CARF, is entitled to a hearing

before a designated appeal panel. The supplier's notice of appeal must be received by CARF within fourteen calendar days of the date of the letter that communicates the decision from the review survey. This final appeal will be based only on questions of whether the review survey was conducted in a manner consistent with CARF's survey policies and procedures. The appeal panel will not consider the supplier's conformance to the standards.

Review at this final level is accomplished by submitting materials supporting the supplier's appeal, which are presented verbally to the appeal panel via conference call or an in-person presentation. Written materials supporting the supplier's appeal and notice as to whether the supplier wishes to present via conference call or in person must be received by CARF within 30 calendar days of the supplier's notification to CARF of its decision to appeal. CARF will schedule the hearing within 60 calendar days of receiving of the supplier's materials, if practical.

The appeal panel may review the written information submitted by the supplier, the QIP, and any other information, including comments from the original surveyor(s), that it considers relevant. Counsel may represent the supplier. CARF will record the proceedings, and a copy will be available to the supplier upon request. Within seven calendar days after completion of the hearing, the appeal panel renders one of the following decisions, which is final:

a. Affirm the Nonaccreditation decision.

   or

b. Reject the Nonaccreditation decision and issue another decision. This may be a Provisional, One-Year, or Three-Year Accreditation. The panel may also attach specific stipulations to the accreditation.

Other Provisions

1. The supplier is responsible for the cost of the on-site review survey, including payment of the accreditation fee. All costs incurred by the supplier or by CARF in connection with the appeal will be the responsibility of the party incurring the expenses. Fees and expenses incurred by the supplier are not refundable in whole or in part.
2. Time notification requirements may be waived or modified only if agreed to in writing by CARF.
3. Failure by a supplier to adhere to any of the terms of the review or appeal procedures will constitute a waiver and relinquishment of its right to review or appeal the Nonaccreditation decision.
4. The supplier has no right to review CARF's books or records.

Applicable Standards

All suppliers seeking CARF DMEPOS accreditation must meet the standards in Sections 1 and 2. Certain suppliers must also meet the standards in Sections 3.A., 3.B., and/or 3.C., as indicated below:

Mobility Assistive Equipment

- Power Operated Vehicles—Scooters (M03)
  Apply Section 3.A.
- Wheelchairs—Complex Rehabilitative Manual (M08)
  Apply Sections 3.A. and 3.B.
- Wheelchairs—Complex Rehabilitative Manual—Related Accessories (M08a)
  Apply Sections 3.A. and 3.B.
- Wheelchairs—Complex Rehabilitative Power (M09)
  Apply Sections 3.A. and 3.B.
- Wheelchairs—Complex Rehabilitative Power—Related Accessories (M09a)
  Apply Sections 3.A. and 3.B.
- Wheelchairs—Standard Manual (M06)
  Apply Section 3.A.
- Wheelchairs—Standard Manual—Related Accessories (M06a)
  Apply Section 3.A.
- Wheelchairs—Standard Power (M07)
  Apply Section 3.A.
- Wheelchairs—Standard Power—Related Accessories (M07a)
  Apply Section 3.A.
- Wheelchairs—Seating/Cushions (M10)
  Apply Section 3.A.

Orthotics and Prosthetics

- Diabetic Shoes/Inserts—Custom (S02c)
  Apply Section 3.C.
- Limb Prostheses (PR01)
  Apply Section 3.C.
- Orthoses—Custom Fabricated (OR01)
  Apply Section 3.C.

SECTION 1

Supplier Business Services Requirements

A. Administration

1. The supplier governs its business to obtain and provide appropriate, quality equipment, items, and services to its beneficiaries.

Examples

The leadership ensures that specific activities are conducted to enhance its ability to guide the supplier ethically, effectively, and efficiently. Leadership, whether it is a single owner, a board and CEO, or a management team, is knowledgeable of the needs of the beneficiaries whom the supplier serves. Leadership ensures that the business stays current and strategically focused to better meet the needs of the marketplace.

The supplier has a system to ensure that it stays informed of changes and remains current within the industry.

Survey Preparation Questions

1. Explain the strategic aspects of your business decision making that guide you in determining which equipment, items, and services to provide to beneficiaries.

Describe how you keep current with trends in the marketplace to ensure that you continue to provide the appropriate equipment, items, and services to beneficiaries.

2. The supplier identifies one or more individuals who:

a. Perform leadership functions.

b. Have the authority, responsibility, and accountability to direct:

(1) The organization.

(2) Its key activities.

(3) Operations.

Examples

The term *leadership* does not necessarily imply that there must be a formal group or committee. The supplier can meet this requirement through various means as long as essential leadership functions occur.

An owner can lead an owner-operated business, such as a physician's office. The supplier may use any form of organization, such as a partnership, sole proprietorship, or corporation. Depending on the company's organizational structure, examples of leadership positions may include the owner(s), governing body, chief executive officer, and other individuals responsible for managing services provided by the organization.

The leadership structure can be documented in the form of an organizational chart or narrative description of the positions and lines of authority within the company. Guidelines such as bylaws, policies, and job descriptions may clarify the functions and roles of management and describe leadership. The governance authority, chief executive, and management demonstrate knowledge of this relationship.

Survey Preparation Questions

2. Define your business structure:

- ❑ Sole proprietorship
- ❑ Partnership
- ❑ Franchise
- ❑ Corporation
  - ❑ C corporation
  - ❑ S corporation
- ❑ Limited liability company
- ❑ Part of a larger entity; e.g., a division or unit within a company, corporation, or government agency
- ❑ Separate legal entity with separate federal tax identification number; e.g., subsidiary of a parent corporation)
- ❑ 501(c) organization

Identify the leadership structure within your company.

Describe the roles and responsibilities of the company's leadership.

Identify by name(s) and title(s) the individual(s) in your company who has/have the authority, responsibility, and accountability to direct:

- The organization.
- Key activities of the company.
- Operations.

Survey Preparation Tip:

The surveyor(s) verifies that whoever is identified fulfills the responsibilities of leadership. This may be done by review of your company's organizational chart; interviews with boards, councils, the management team, and owner(s); review of bylaws or minutes of meetings; and observation. If your company or practice is incorporated in your state, you must furnish a copy of your corporation's bylaws.

3. **The identified leadership guides the following:**
   a. **Establishment of the mission and direction of the supplier.**
   b. **Promotion of the value/achievement of outcomes in the services offered.**
   c. **Balancing the expectations of both the beneficiaries and other stakeholders.**
   d. **Financial solvency.**
   e. **Compliance with insurance and risk management requirements.**
   f. **Ongoing performance improvement.**
   g. **Development and implementation of social responsibilities.**
   h. **Compliance with all legal and regulatory requirements.**

Examples

The leadership of the company or practice ensures that specific activities are conducted to enhance its ability to guide the supplier ethically, effectively, and efficiently. The delegation of activities, the feedback and collaboration between the various levels within the company's organizational structure, and the checks and balances that the leadership has created should be evident.

3.a. As the supplier's mission impacts service delivery, the achievement of outcomes, and strategic planning activities, a regular review of the mission statement assesses and reinforces the values of personnel and board members (when applicable) regarding the beneficiaries and ensures that everyone is in agreement regarding the direction of the supplier. A small supplier may speak about goals and the direction of its business.

3.b. Suppliers recognize that their company's ongoing good performance, successes, and accomplishments have value. Therefore, in a consumer-driven market, promotion of the supplier's achievements and good record to its beneficiaries and other stakeholders is an essential part of its business practices. The achievement of outcomes can be communicated in a number of ways, including a printed short summary or fact sheet, posting of the information on its website, annual reports, press releases, articles or features in local news media, advertisements, incentives offers, and presentations to local community service organizations and businesses.

3.c. The supplier is aware of the needs and desires of the beneficiary and other stakeholders. Input from the beneficiaries and other stakeholders can influence the mission as needs, desired outcomes, and other factors change over time. The supplier is responsive to its environment and conducts regular planning to position itself strategically in its market. In strategic planning, the supplier may begin by doing an environmental assessment and inviting all relevant stakeholders for their input.

3.d. In order to maintain its business operations, a supplier must have the processes in place and the means for ensuring that liquid funds are available to meet expenses and, if desired, to expand in response to increased demands from the marketplace. Ways in which leadership can ensure that it continues to meet the company's financial obligations are through decreasing the company's debts, increasing collateral, maintaining a high credit rating,

establishing lines of credit, borrowing from reputable lending institutions when necessary, and building reserves through savings or investments.

3.e. Leadership ensures that insurance coverage is in place to adequately protect the needs, risks, and assets of the supplier. The review should be conducted with the assistance of someone who is knowledgeable about insurance needs and types of coverage. This may be an insurance broker or agent, attorney, or anyone else with appropriate knowledge and experience.

Risk management often focuses on matters of insurance; however, there are other major areas to consider when assessing risk for your company. This involves reviewing organizational operations, identifying potential threats to the organization and the likelihood of their occurrence, and then taking appropriate actions to address the most likely threats. Some of the major areas for consideration of managing your company's risk include sound operations management, personnel policies, legal protection, well-designed insurance for the company's liability coverage and assets protection, financial risk management, and resource management; e.g., people, computers, and the physical plant. For an overview of resource materials regarding risk management, visit the Free Management Library website at **www.managementhelp.org/risk_mng/risk_mng.htm**.

3.f. The leadership works to achieve and improve identified performance outcomes. Information on outcomes is used to guide performance improvement efforts such as strategic planning.

3.g. *Social responsibility* is defined as a supplier's efforts, activities, and interest in integrating into, contributing to, and supporting the communities where it delivers services to better address the needs of the beneficiaries.

The supplier is a member of the community in which it operates. Its role in the community and how it is viewed are critical for its success. Examples of social responsibilities include participation in community health fairs, sponsorship of community events, screenings at local senior centers, support of local fundraising for specific groups (e.g., diabetes, cancer), donating used equipment to veterans' groups or other charitable organizations, active recycling, and being a "green" company.

3.h. The supplier demonstrates its knowledge and implementation of applicable federal, state, and local laws and regulations. This may include retaining the services of an attorney.

The supplier has a system to ensure that it stays informed of changes and remains current with legal requirements.

Survey Preparation Questions

3. How would you, as the leader of the company or practice, explain to a surveyor:

- Your business' or practice's purpose for existing?

- Your business' or practice's core values and/or vision statement, if applicable?

- Your (or your leadership's) administrative/management philosophy?

What is your mission?

How do you promote your business' achievements and performance outcomes?

Describe your guiding principles for meeting the many expectations of the beneficiaries and other stakeholders in your business.

How do you ensure that your business or practice remains financially solvent?

Describe your risk management program and insurance coverage for asset protection, liability, and property damage.

Describe how you use performance outcomes information to improve your business.

Describe any programs or activities in which your company supports your local community or the community at large.

Describe how you meet federal, state, and local legal and regulatory requirements.

Describe how you ensure that your company stays informed of changes and remains current with applicable federal, state, and local laws and regulations; legal requirements; and Medicare rules and regulations.

Survey Preparation Tip:

The activities of leadership, the delegation of activities, the feedback and collaboration between the various levels of the leadership, and the checks and balances that the leadership has created may be observed; heard in

interviews; or read in minutes, reports, and orientation materials for boards and management during the survey.

4. The supplier operates from a physical location.

Examples

Local health and licensing agencies can provide guidance in this area.

Survey Preparation Questions

4. Please identify your physical location(s):

- Location name and address:

_____

_____

- ❑ Freestanding office space; e.g., a building solely occupied by the supplier or rental space in a shopping center or large office building
- ❑ Office space in another healthcare practitioner's office
- ❑ Office space in a healthcare system; e.g., hospital, skilled nursing, assisted living
- ❑ Office space in a non-healthcare setting; e.g., gym, fitness center
- ❑ Other (please specify):

_____

- Location name and address:

  ❑ Freestanding office space; e.g., a building solely occupied by the supplier or rental space in a shopping center or large office building

  ❑ Office space in another healthcare practitioner's office

  ❑ Office space in a healthcare system; e.g., hospital, skilled nursing, assisted living

  ❑ Office space in a non-healthcare setting; e.g., gym, fitness center

  ❑ Other (please specify):

- Location name and address:

  ❑ Freestanding office space; e.g., a building solely occupied by the supplier or rental space in a shopping center or large office building

  ❑ Office space in another healthcare practitioner's office

  ❑ Office space in a healthcare system; e.g., hospital, skilled nursing, assisted living

  ❑ Office space in a non-healthcare setting; e.g., gym, fitness center

  ❑ Other (please specify):

If your company has more than three locations, list all locations for which you are applying for accreditation on a separate sheet. Provide the location name, address, and type of setting.

Survey Preparation Tip:

The information above should match the information provided on your Intent to Survey.

5. **The supplier displays in an accessible area for beneficiaries and others its:**
   a. **Licenses.**
   b. **Certificates.**
   c. **Permits.**

Examples

A supplier should consider the needs of the beneficiaries it serves when publicly displaying information such as licenses, certificates, and permits. Some examples of promoting accessibility include enlarging print for ease of reading; translating, if necessary; and, for those who might not read, preparing an audiotape of what the licenses, certificates, and permits say.

Survey Preparation Questions

5. Please explain where you currently display your:

- Licenses.

_____

_____

- Certificates.

_____

_____

- Permits.

_____

_____

What is your practice for ensuring the accessibility of these items to beneficiaries and other customers with special needs?

_____

_____

_____

6. **The supplier provides, on request, to any government officials or authorized agents copies of:**
   a. **Licenses.**
   b. **Certificates.**
   c. **Permits.**

Examples

The supplier demonstrates a process to comply with legal and regulatory requirements, as applicable, for the provision, upon request, of copies of licenses, certificates, and permits to government officials or authorized agents.

Survey Preparation Questions

6. Explain how you make available your licenses, certificates, and permits to government officials or authorized agents who request them.

7. The supplier only provides durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), and other items that meet applicable Food and Drug Administration (FDA):

a. Regulations.

b. Medical device effectiveness standards.

c. Safety standards.

Examples

The FDA's Center for Devices and Radiological Health (CDRH) is responsible for regulating firms that manufacture, repackage, relabel, and/or import medical devices sold in the United States. In addition, CDRH regulates radiation-emitting electronic products (medical and nonmedical) such as lasers, X-ray systems, ultrasound equipment, microwave ovens, and color televisions. An overview of FDA regulations can be found at **www.fda.gov/cdrh/devadvice/overview.html**.

Medical devices are classified into Classes I, II, and III. Regulatory control increases from Class I to Class III. The device classification regulation defines the regulatory requirements for a general device type. Most Class I devices are exempt from Premarket Notification 510(k), most Class II devices require Premarket Notification 510(k), and most Class III devices require Premarket Approval. A description of device classification and a link to the Product Classification Database are available at **www.fda.gov/cdrh/devadvice/312.htm**.

Manufacturers and suppliers are instructed by the Centers for Medicare & Medicaid Services (CMS) and through the Durable Medical Equipment Medicare Administrative Contractor (DME MAC) supplier manual and advisories to contact the Pricing, Data Analysis, and Coding Healthcare Common Procedure Coding System (PDAC HCPCS) contractor to obtain proper billing codes for DMEPOS. For coding assistance and fee schedule prices, visit the Noridian Administrative Services PDAC website at **www.dmepdac.com**.

Manufacturers' websites and bulletins are also resources for suppliers to obtain information about FDA approval and FDA-mandated recalls.

Survey Preparation Questions

7. How, where, and how often do you obtain your information that the equipment and/or items you provide are FDA approved (i.e., meet FDA regulations, medical device effectiveness standards, and safety standards), have been recalled, or are exempt from FDA approval?

_____

_____

_____

8. For each type of non-custom-fabricated item, the supplier obtains from the manufacturer copies of the following:

a. Features.

b. Warranties.

c. Instructions.

Survey Preparation Questions

8. For each type of non-custom-fabricated item you provide, do you have manufacturer copies of:

- The item's features? ❑ Yes ❑ No
- Warranties? ❑ Yes ❑ No
- Instructions? ❑ Yes ❑ No

Where are these kept?

_____

_____

_____

Survey Preparation Tip:

The surveyor(s) will need to see copies of owners' manuals or specification sheets containing the features, warranties, and instructions as provided by the manufacturer.

9. The supplier complies with Medicare:

a. Statutes.

b. Regulations, including disclosure of ownership and control information requirements at 42 CFR §420.201 through §420.206.

c. Contractor policies and articles.

d. Manuals.

e. Program instructions.

Examples

9.a. Suppliers should be aware of the section of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA 2003) that covers DMEPOS. The legislative summary of the act can be found at **www.cms.hhs.gov/MMAUpdate/downloads/PL108-173summary.pdf**.

Suppliers should also be aware of the reforms in DMEPOS accreditation under the Medicare Modernization Act section Medicare Improvements for Patients and Providers Act (MIPPA), Section 154(b), which was enacted into law in July 2008. A MIPPA fact sheet, Section 154(b) can be found at **www.cms.hhs.gov/MedicareProviderSupEnroll/03_DeemedAccreditationOrganizations.asp**. Click the link to the DMEPOS Accreditation MIPPA Fact Sheet.

9.b. All DMEPOS rules and regulations are published on a regular basis in the Federal Register, which can be accessed by visiting the U.S. Government Printing Office website at **www.gpoaccess.gov/index.html**.

Under regulation 42 CFR §424.57(c), all DMEPOS suppliers must be in compliance with the Supplier Standards in order to obtain and retain Medicare billing privileges. **Note that a supplier must disclose these standards to all Medicare beneficiaries (standard 16).** It is the responsibility of the supplier to demonstrate that it maintains its compliance with these Supplier Standards. The standards can be found at **www.palmettogba.com/palmetto/providers.nsf/files/25%20standards%20full.pdf/$File/25%20standards%20full.pdf**.

Under regulation 42 CFR §420.201 through §420.206, Medicare Part B suppliers, intermediaries, and carriers are required to disclose ownership and control information and the identities of managing employees. It also sets forth requirements for disclosure of information about a Part B supplier's owners; those with a controlling interest; or managing employees convicted of criminal offenses against Medicare, Medicaid, or the title V (Maternal and Child Health Services) and title XX (Social Services) programs. The 42 CRF 42 §420.201 through §420.206 can be found at **www.access.gpo.gov/nara/cfr/waisidx_02/42cfr420_02.html**.

9.c.–e. The Medicare website also contains many valuable references and resources. The supplier should be familiar with this information and should check for updates frequently at **www.cms.hhs.gov/home/regsguidance.asp**. Helpful links include, but are not limited to:

- Fee schedules.
- Coding information.
- Supplier directory.
- Supplier manual as provided by the area's DME MAC.
- *Medicare National Coverage Determinations Manual*.
- *Medicare Claims Processing Manual*.
- *Medicare Benefit Policy Manual*.

- Form CMS-855S.
- Local/regional coverage determination provided by your area's DME MAC.

DME Coding System (DME CS) provides HCPCS coding assistance and national pricing information via searches for HCPCS Level II codes and modifiers, DMEPOS, and CMS national fee schedules. DME CS is designed to assist the public with the coding of DMEPOS for submission to the DME MAC. For instructions on searching DME CS for HCPCS information, modifiers, fee schedules, and product classifications provided in the DME CS Guide, log on to the Medicare PDAC website at **www.dmepdac.com/dmecs/index.html**.

In addition to the Medicare website, many trade publications, trade organizations, and home medical equipment member service groups provide information to their members about the statutory requirements established in the MMA 2003, updates on Medicare rules and regulations pertaining to DMEPOS, information on claims processing and payment policies, and any proposed legislation before Congress relevant to DMEPOS.

Survey Preparation Questions

9. What resources do you utilize to guide you in your knowledge of and compliance with Medicare:

- Statutes?

_____

_____

- Regulations?

_____

_____

- Contractor policies and articles?

_____

_____

- Manuals?

_____

_____

- Program instructions?

_____

_____

How often do refer to your resources to keep up with changes in Medicare laws, regulations, rules, manuals, contractor policies and articles, and program instructions?

Describe your process for meeting regulation 42 CFR §424.57(c) that requires you to be disclosing the Supplier Standards to all the Medicare beneficiaries that you serve.

Have you reported any of the following to CMS (per 42 CFR §420.201–§420.206) in the last three years:

- Changes in ownership, financial, or control interest in your business? ❑ Yes ❑ No

  If *yes*, please describe.

- Changes in your business transactions? ❑ Yes ❑ No

  If *yes*, please describe.

- Program-related crimes? ❑ Yes ❑ No

  If *yes*, please describe.

- The hiring of an intermediary's former employee(s)? ❑ Yes ❑ No

If *yes*, please describe.

_____

_____

_____

10. The supplier implements business practices to prevent and control fraud, waste, and abuse by:

a. Using procedures that reflect standards of conduct to ensure the supplier's compliance with applicable laws and regulations.

b. Designating one or more individuals in leadership positions to address compliance issues.

Examples

The acceptance of federal funding means acceptance of the responsibility to demonstrate the skills required for and the knowledge that a DMEPOS supplier is accountable for tracking the funds and determining and overseeing how funds are being used and reported.

Business practices may include implementation of a corporate compliance program. Under corporate compliance systems, suppliers develop and implement processes to assess compliance issues, take corrective measures, and continually monitor compliance in all areas including clinical services and records or fiscal services.

A corporate compliance program must be "effective" as defined by the U.S. Sentencing Guidelines and be "…reasonably designed, implemented, and enforced so that it generally will be effective in preventing and detecting criminal conduct." The implementation of a corporate compliance program establishes an atmosphere that prompts early detection of any wrongdoing before it becomes too serious and/or before it is detected through a regulatory or governmental audit or survey. Additional benefits of an effective corporate compliance program are:

- Reducing the likelihood of a violation occurring.
- Reducing the likelihood of civil liability, which comes chiefly in the form of demands for return of overpayments, civil money penalties, and whistleblower lawsuits.
- Demonstrating transparency to government funding sources of an accurate view of the supplier's business operations.
- Establishing a structure of information relevant to the compliance program.
- Establishing a structure to maximize the right of confidentiality under the attorney-client privilege.

A compliance program should include the following:

- Written ethical codes of conduct.
- Written procedures to deal with allegations of violations of ethical codes.

- Policies to educate personnel and other stakeholders on ethical codes of conduct.
- Policies and written procedures on waste, fraud, abuse, and other wrongdoing that include:
  - A no reprisal approach for personnel reporting.
  - A time frame to initiate an investigation.
- Policies on contractual relationships.
- Demonstrated social responsibility.

The government has made a sizeable commitment to the elimination of healthcare fraud, waste, and abuse. Suppliers are subject to audits of how funds that they have received are used. Suppliers can encourage their personnel to maintain high ethical standards by making an organizational commitment to such standards abundantly clear.

The policies concerning ethical conduct could be developed using information from such sources as state practice acts for the various disciplines/professions involved in services; the ethical codes of professional associations for the various disciplines/professions involved in services; the ethical codes of business, marketing, and human resource management associations; and the supplier's own mission and core values statements.

The supplier identifies, develops, and documents its required ethical practices and values. Although these codes may be found in various written materials such as personnel policies and operations manuals, many suppliers find it helpful to include this information in one set of documents, which makes it easier to use in staff and board member training. A supplier might find information from professional organizations and associations useful as a reference in developing its codes of ethical conduct. By conducting an Internet search for "fraud, waste, and abuse" you can find many different organizations' fraud, waste, and abuse prevention procedures on their websites and learn about the variety of information included in these prevention procedures. For additional resources, visit the Free Management Library's website at **www.managementhelp.org/risk_mng/risk_mng.htm**.

The supplier should have a mechanism in place to follow up and address all allegations of violations of its ethical codes. A supplier could use a mechanism such as an ethics committee to investigate and act on allegations of violations of ethical conduct. It could also use the same or a similar mechanism to address both allegations of violations of ethical conduct and allegations of infringements of the rights of the beneficiaries.

If the supplier is a sole proprietor with no full-time equivalent employees or contracted personnel, it should have in place an established code of ethics for its business and policies for educating its stakeholders and their right to report any suspected waste, fraud, or abuse without fear of reprisal. Also, beneficiaries should be provided with the Medicare waste, fraud, and abuse hotline number to call to report any suspected waste, fraud, or abuse by the supplier.

CMS publishes a brochure on its Medicare Learning Network website that lists resources for information pertaining to Medicare fraud and abuse and explains what to do if anyone suspects or becomes aware of incidents of potential Medicare fraud or abuse. This brochure can be found at **www.cms.hhs.gov/MLNProducts/downloads/081606_Medicare_Fraud_and_Abuse_brochure.pdf**.

Introduction to Corporate Compliance is a CARF publication that provides basic information on why a corporate compliance program is necessary, identifies the components of a corporate compliance program, and offers examples to assist an organization in developing its corporate compliance program. This publication can be ordered from the CARF eCatalog website (**www.bookstore.carf.org**).

Survey Preparation Questions

10. Describe your business's program for preventing waste, fraud, and abuse.

How do you ensure that the procedures you are using in your compliance program for preventing waste, fraud, and abuse comply with applicable laws and government regulations?

Do you use outside counsel to address compliance? ❑ Yes ❑ No

If *no*:

- Who in your business or practice addresses compliance issues?

- Explain how you ensure compliance with fraud, waste, and abuse prevention through your business practices.

Survey Preparation Tip:

There should be evidence that employees are aware of your company's compliance program and steps they may take when wrongdoing has been detected.

B. Financial Management

1. **Financial management practices are implemented that ensure accurate:**
   a. **Accounting.**
   b. **Billing to:**
      (1) **Beneficiaries.**
      (2) **Medicare program.**

Examples

The supplier should:

- Establish and maintain fiscal policies and procedures that may include internal control practices.
- Provide initial and ongoing training on billing and coding procedures for personnel with these responsibilities.

1.a. Policies and procedures may address methods for receiving cash, checks, or other financial instruments; disbursing funds, including petty cash, other cash, checks, or other financial instruments; managing the use, receipt, or disbursement of funds through purchase orders, invoices, organizational credit cards, and lines of credit with outside vendors; and investing funds.

The supplier may want to seek guidance from a source with expertise to confirm that it is in accordance with legal requirements and generally accepted accounting practices.

1.b. If the supplier bills for services provided, a review of a representative sampling of records of the beneficiaries may be conducted periodically to:

- Document that dates of services provided coincide with billings for equipment, items, and services.
- Determine that the bills accurately reflect the equipment, items, and services that were provided.
- Identify necessary corrective action.

The review should be conducted by persons trained to compare the dates and service codes on the supplier's billing system to the dates, units, and types of equipment, items, and services provided to the beneficiaries.

Survey Preparation Questions

1. What internal controls have you implemented to ensure that your accounting practices are accurate?

Do you use the following mechanisms to ensure that you are billing beneficiaries and Medicare accurately:

- Sampling of billing records? ❑ Yes ❑ No

  If *yes*, how often?

  _____

- Review of denials? ❑ Yes ❑ No

  If *yes*, how often?

  _____

- Review of all bills during annual audit or review process? ❑ Yes ❑ No

Describe any additional mechanisms you use to ensure accurate billing.

_____

_____

_____

_____

_____

How frequently do you employ these mechanisms?

_____

_____

_____

2. **Financial records are:**
   a. **Accurate.**
   b. **Complete.**
   c. **Current.**

Examples

An effective system of internal controls can minimize the possibility of inaccurate and incomplete financial records. The sophistication of the system of internal controls is partially based on the sophistication of the supplier's fiscal activities.

Financial records should be maintained by qualified personnel and reviewed by management. An annual review or audit by an independent CPA may be conducted for additional assurance.

The supplier may want to seek guidance from a source with the expertise to confirm that it is in accord with legal requirements and following generally accepted accounting practices.

Survey Preparation Questions

2. Describe your system for ensuring that your financial records are:

- Accurate.

_____

_____

_____

- Complete.

_____

_____

_____

- Current.

_____

_____

_____

Who in your business is responsible for reviewing your accounting practices?

_____

Is this person on site? ❑ Yes ❑ No

3. Financial records reflect accrual or cash-based accounting practices.

Examples

The supplier may want to seek guidance from a source with the expertise to confirm that it is in accord with legal requirements and following generally accepted accounting practices.

Survey Preparation Questions

3. Which accounting practice is utilized in your organization?

❑ Cash-based accounting

❑ Accrual-based accounting

4. Accounts are maintained that link the equipment and items to the beneficiary.

Examples

Determining that equipment matches with beneficiaries' claims is a proactive method for a supplier to help reduce or eliminate costly mistakes.

Survey Preparation Questions

4. Describe your system for matching beneficiary accounts with the equipment and items they were provided.

5. The supplier manages revenues and expenses on an ongoing basis as they relate to beneficiary services, including:

a. Reconciliation of charges to the beneficiary for equipment, supplies, and services to:

(1) Invoices.

(2) Receipts.

(3) Deposits.

b. Operating budget, as appropriate to the supplier's size and scope of services.

c. Mechanism to track actual revenue and expenses.

Examples

A review of a representative sampling of records of the beneficiaries may be periodically conducted to:

- Determine that invoices for and/or receipts of ordered equipment or supplies coincide with billed Medicare claims.
- Determine that the charges accurately reflect the equipment, supplies, and services that were provided.
- Identify necessary corrective action.

Determining that reimbursement claims match product and service information in the records of the beneficiaries is a proactive method for a supplier to help reduce or eliminate costly mistakes.

The review should be conducted by persons trained to compare the dates and product codes on the supplier's billing system to the dates, units, and types of equipment; supplies; and services provided to the beneficiaries.

Survey Preparation Questions

5. Describe your system for reconciling beneficiaries' charges with invoices for equipment and supplies purchased.

Describe your system for reconciling beneficiaries' charges with receipts for equipment and supplies purchased.

Describe your system for reconciling beneficiaries' charges with deposits of reimbursements.

Is your payment for Medicare claims funds electronically transferred to your business bank account? ❑ Yes ❑ No

If *yes*, describe your system for reconciling your bank deposits for equipment, supplies, and services for which you were reimbursed.

Describe your system for tracking your revenues and expenses.

Do you prepare financial reports:
(Check all that apply)

- ❑ Monthly?
- ❑ Quarterly?
- ❑ Annually?

If you do not prepare financial reports, how often do you review your financial records?

6. **There is an operating budget based on the business's size and scope of services that plans to:**
   a. **Meet the needs of the beneficiaries.**
   b. **Maintain business operations.**

Examples

The annual budget reflects projected income and expenses that are based on the goals or strategic direction of the business; e.g., expansion, status quo, or reduction. In addition, the budget should reflect income and expense projections to ensure that the company meets the needs of the beneficiaries it serves by maintaining its financial solvency to continue its operations for successive fiscal years. Input from professional and administrative personnel in budget development demonstrates the supplier's intent to anticipate its fiscal needs.

Survey Preparation Questions

6. How do you define, **in financial terms**, the size and scope (types of products/services you provide, how expansive your market area is, and your customer base) of your business or practice?

Describe how you project your income and expenses in terms of your business' goals or strategic direction to ensure that your budget meets the needs of the beneficiaries you serve.

Describe the basis for projecting your annual income and operating expenses to ensure that you have budgeted adequately to maintain your operations for the coming year.

How often do you review your budget?

On average, how often do you make adjustments to your budget in a fiscal year?

C. Human Resource Management

1. **The supplier implements policies to verify:**
   a. **The required credentials of professional licensed and/or certified personnel, where applicable.**
   b. **That required credentials of professional licensed and/or certified personnel remain current.**
   c. **That copies of licenses, registrations, certifications, and competencies of professional credentialed personnel are:**
      (1) **Maintained.**
      (2) **Made available upon request to:**
         (a) **Accreditation organizations.**
         (b) **Government officials or their authorized agents.**

Examples

The supplier has policies for how each of the areas listed is verified. CARF expects that the supplier will follow all of its procedures and time frames that the supplier has established and that it adheres to all applicable guidelines and legal requirements in determining its procedures. It is essential that the supplier is informed about all professions requiring licensure in the state in which it conducts its business.

Evidence of healthcare practitioners' licenses and their effective dates may be verified through the websites of state boards of licensing for each profession. Certificates and registrations may be verified through the credentialing organization responsible for certifying a required credential for an orthotist, prosthetist, pedorthist, and other certified personnel. For example, the credentials of a certified rehabilitation technology supplier (CRTS) can be verified with the National Registry of Rehabilitation Technology Suppliers (NRRTS); a certified assistive technology professional (ATP) can be verified with the Rehabilitation Engineering Society of North America (RESNA); certified orthotists, prosthetists, and pedorthists (CO, CPO, or CPed) can be verified with the American Board for Certification in Orthotics and Prosthetics, (ABC); and the Board for Orthotist/Prosthetist Certification (BOC) can verify Orthotist, BOC-certified (BOCO) or Prosthetist, BOC-Certified (BOCP) personnel.

Evidence of procedures for the verification of credentials and backgrounds may include documentation, such as a standard form or checklist that is used by designated personnel who are responsible for obtaining verification of credentials and other employee information. Verification should also address excluded parties lists. Sites to review include:

- **www.epls.gov**
- **http://exclusions.oig.hhs.gov**

The supplier also has policies in place in the event that credentials cannot be verified.

Survey Preparation Questions

1. Describe your company's policies for:

- How you verify credentials of licensed, certified, or registered personnel, if applicable.

- How you verify that the credentials of licensed, certified, or registered personnel are current, if applicable.

- Steps to take in the event credentials of licensed, certified, or registered personnel cannot be verified, if applicable.

- Where you keep licenses, certifications, and registrations and how you make them available to those who need to review those items.

Survey Preparation Tip:

The surveyor(s) will want to review your policies to ensure that you verify licenses and certifications of all credentialed/professional personnel with the appropriate licensing body or credentialing organization or registry.

2. **Consistent with the specialized equipment, items, and services it provides to beneficiaries, the supplier develops job descriptions that specify personnel:**
   a. **Qualifications.**
   b. **Training.**
   c. **Licensure or certification, where applicable.**
   d. **Experience.**
   e. **Continuing education requirements.**

Examples

Qualified personnel are critical to the success of the supplier. It is essential that written job descriptions are developed for all personnel to ensure that those providing services for the supplier are qualified and adequately trained to perform their duties competently and safely.

2.a. The supplier identifies in employees' job descriptions the necessary qualifications, previous training, skills, and knowledge that personnel must attain to be successful in their jobs. These skills and competencies relate to the types of services provided to the beneficiaries.

Skill sets may be identified through assessment tools, job task analyses, and consideration of the unique needs of the beneficiaries. Examples of skill sets or competencies are specific evaluation and/or treatment techniques, use of specialized equipment, and demonstration of sensitivity to the diversity of the beneficiaries.

The skills and competencies may already be part of the person's repertoire or may have to be developed on the job.

Local, state, federal, provincial, or national/professional associations may be excellent resources for establishing qualifications and competencies.

2.b. The supplier ensures that personnel who are new to a program are adequately trained prior to their providing direct services. A variety of techniques may be used, such as holding staff meetings focused on theoretical concepts; presenting training films or guest speakers; or reviewing other reference materials, which could include books, articles, professional journals, magazines, newspapers, and Internet access. Besides training on the direct services they were hired to perform, at a minimum, employees should be trained in responding to emergencies and disasters, HIPAA regulations, and the company's safety program.

2.c. Where applicable, a supplier should identify in its human resource policies the type of licensure or certification that is required for an individual to perform the duties and responsibilities of a particular job. The job description should identify the license or certification necessary for performing any job for which a license or certification is required by Medicare rules and the state in which the supplier is located.

2.d. Job descriptions should also identify minimum related work experience and the number of years performing similar work that job applicants are required to have in order to perform their job duties and responsibilities adequately in the supplier's company. Applications for employment are a means

by which job applicants can identify their directly related prior work experience and acquired skills. Suppliers may confirm the job applicant's stated experience and skills through interviews with the applicant and previous employers and the use of pre-employment competency tests.

2.e. Continuing education is required for all credentialed personnel to maintain their licensure, certification, or registration. The job description must contain information related to this requirement for credentialed personnel and the expectations for verification. If applicable for non-credentialed personnel to have in advance, a job description may ask an applicant to account for any continuing education received that serves to enhance his or her skills and competencies directly related to the job for which he or she is applying.

Also, suppliers can use a variety of mechanisms to provide opportunities for personnel to learn and grow during their employment. These mechanisms might include staff meetings, inservices, budgeted travel and conference funds, guest lecturers, audio and videotapes, journal review clubs, manuals, subscriptions, collecting of articles and resource materials, online courses, and Internet access

Survey Preparation Questions

2. Who in your company is responsible for developing job descriptions for all employees?

Where do you maintain copies of each job description?

At a minimum, does each job description contain all information that will verify the employee's qualifications, training, and licensure or certification; experience; and continuing education requirements needed to perform all duties and responsibilities required of the job? ❑ Yes ❑ No

If *no*, describe which of the information required by this standard is missing and explain your rationale for it being excluded.

3. **The supplier provides copies of job descriptions to:**
   a. **Accreditation organizations.**
   b. **Government officials or their authorized agents.**

Survey Preparation Questions

3. Describe your procedure for making available copies of all personnel job descriptions to the organizations or officials who need to review them.

4. **Technical personnel demonstrate competency in:**
   a. **Delivering equipment.**
   b. **Setting up equipment.**
   c. **Training beneficiaries.**

Examples

Minimum skills and competencies related to the delivery and setup of equipment and training the beneficiary are identified by the supplier as those that technical personnel must attain in order to perform the duties and responsibilities of the job competently and safely. It is possible that personnel may come to the job with the necessary skills and competencies already acquired. However, it is essential for a supplier to verify an employee's skill set through an evaluative process of any of the following:

- Direct observation
- Demonstrations
- Competency checklists
- Specific assessment tools
- Job task analyses

Survey Preparation Questions

4. Describe the methods you use to ensure that technical personnel are competent in the following:

- Delivering equipment

- Setting up equipment

- Training beneficiaries

5. The supplier ensures that professional licensed, certified, or registered personnel provide services consistent with the scope of their practice as prescribed by applicable licensure, certification, or registration requirements.

Examples

It is essential that professional personnel provide only those services that fall within their scope of practice as defined by the practice acts in the state where they are licensed and working or with the credentialing organization under which they are certified or registered. It is the supplier's responsibility to never request or require, as a condition of employment or for any other reason, a professional licensed, registered, or certified employee to perform a function or service outside of his or her scope of practice. Similarly, if a professional is observed performing services that may be suspected of falling outside his or her scope of professional practice, it is the supplier's responsibility to verify both with the employee and by contacting the state licensing board for the profession under which the employee is licensed or the credentialing organization under which he or she certified or registered.

NOTE: *If you do not employ or contract with any credentialed (licensed, certified, or registered) personnel, this standard does not apply.*

Survey Preparation Questions

5. Describe the procedures you have in place to ensure that licensed, certified, or registered personnel provide services consistent with the scope of practice as defined by:

- Practice acts in the state in which they are licensed

- The credentialing organization with which they are certified or registered.

D. Consumer Services

1. **When providing equipment, items, and services to beneficiaries, the supplier ensures that it:**
   a. **Provides clear written or pictorial and oral instructions, as appropriate, for the equipment and items related to their:**
      (1) **Use.**
      (2) **Maintenance.**
      (3) **Potential hazards.**
   b. **Provides the beneficiary with information regarding expected time frames for receipt of delivered items.**
   c. **Verifies that the beneficiary has received:**
      (1) **Equipment.**
      (2) **Items.**
      (3) **Services.**
   d. **For any non-custom equipment and/or items provided, documents in the beneficiary's records the equipment's and/or item's:**
      (1) **Make and model number.**
      (2) **Any other identifier, if applicable.**
   e. **Provides beneficiaries with essential contact information for rental equipment.**
   f. **Provides options for the beneficiaries to rent or purchase equipment and items, when applicable.**
   g. **Provides the beneficiary with information and telephone numbers for customer service assistance regarding:**
      (1) **Regular business hours.**
      (2) **After-hours access.**
      (3) **Item repair.**
      (4) **Emergency coverage.**

Examples

Regarding the equipment and supplies necessary for rehabilitation, the supplier:

- Obtains appropriate prescriptions.
- Ensures communication with relevant stakeholders regarding:
  - Costs.
  - Purchase/rental options.
  - Delivery of equipment.
  - Customer service assistance.
- Assists individuals with obtaining equipment and supplies.
- Provides education about the appropriate use of equipment and supplies.
- Provides referrals for expertise in equipment and supplies, as appropriate.

Survey Preparation Questions

1. Describe the written and/or pictorial instructions you give to beneficiaries, when appropriate, on how to:

- Use the equipment or item you provide.

- Maintain the equipment or item you provide.

- Identify and avoid potential hazards with the equipment or item you provide.

Describe the verbal instructions you give to beneficiaries, when appropriate, on how to:

- Use the equipment or item you provide.

- Maintain the equipment or item you provide.

- Identify and avoid potential hazards with the equipment or item you provide.

How do you inform beneficiaries when their equipment or item will be delivered?

How do you verify that beneficiaries have received their equipment or item?

How do you inform beneficiaries about how to rent equipment?

When applicable, what options do you provide to beneficiaries to either rent or purchase equipment?

If you *do* use make and model numbers as identifiers for non-custom equipment and/or items you provide to beneficiaries, how do you ensure that this information is documented in each beneficiary's record and at what stage in the process between acquiring the equipment and/or item and delivering it to the beneficiary do you record this information?

If you do *not* use make and model numbers as identifiers for non-custom equipment and/or items you provide to beneficiaries:

- Describe your company's system for identifying non-custom equipment and/or items.

- How do you ensure that this information is documented in each beneficiary's record and at what stage in the process between acquiring the equipment and/or item and delivering it to the beneficiary do you record this information?

How do you provide beneficiaries with information and telephone numbers for customer service regarding regular business hours; after-hours access, if applicable; equipment or item repair; and emergency coverage?

Survey Preparation Tip:

During the survey, the surveyor(s) will want to interview beneficiaries who have received services to verify supplier conformance to the standard.

2. The supplier notifies the prescribing physician or other authorized healthcare team member within five calendar days if the supplier cannot or will not provide the equipment, items, or services prescribed for the beneficiary.

Examples

A fax, telephone call, e-mail, form, letter, or card could be used to notify the physician. This notification would contain the following information:

- Beneficiary name
- Item/equipment/supply ordered
- Date supplier was notified that item is not available
- Prescribing physician:
  - Name
  - Date notified
- Healthcare team member
  - Name
  - Date notified

There is evidence of notifications to physicians either in the beneficiary's records or in a log, file, or notebook designated for documenting this information.

Survey Preparation Questions

2. Describe your process for notifying the prescribing physician/other healthcare team member within five calendar days if you cannot or will not provide an item.

How and where do you keep a record of the notifications to physicians or other authorized healthcare team members when you cannot or will not provide the equipment, items, or services prescribed for the beneficiary?

3. **Within five calendar days of receiving a beneficiary's complaint, the supplier notifies the beneficiary that the complaint:**
   a. **Has been received.**
   b. **Is being investigated.**

Examples

Viable formats for notification include in person, telephone, e-mail, fax, and letter.

Survey Preparation Questions

3. What is your means for notifying beneficiaries within five calendar days that their complaints have been received and are being investigated?

What is your system for documenting beneficiary complaints and your responses?

Survey Preparation Tip:

The supplier should be prepared to provide the surveyor(s) with evidence of timely (within five days) notification to beneficiaries.

4. **Within fourteen calendar days of receiving the complaint, the supplier provides to the beneficiary written notification of:**
   a. **The results of its investigation.**
   b. **The supplier's response to the complaint.**

Survey Preparation Questions

4. Describe your process for notifying the beneficiary in writing within fourteen days of the results of and responses to the investigation. If you have had no complaints to investigate, describe your process for this if such an event were to occur.

Survey Preparation Tip:

The supplier should be prepared to provide the surveyor(s) with evidence of timely (i.e., within fourteen days) notification to beneficiaries, if applicable.

5. The supplier maintains documentation on all complaints, including:

a. Copies of investigations.

b. Responses to beneficiaries.

Survey Preparation Questions

5. Describe your process for documenting investigations of beneficiary complaints and your responses. If you have had no complaints to investigate, please describe your process for documenting them were any to occur.

Where do you (or would you) keep these copies?

E. Performance Management

1. **The supplier has a performance management plan that measures:**
   a. **Outcomes of consumer services.**
   b. **Billing practices.**
   c. **Adverse events.**

Examples

The supplier should have a performance management plan that establishes performance objectives for each objective domain and then collects the data in order to measure results (or outcomes). Performance objectives (goals) should be observable, measurable, and achievable within the time period set by the supplier. The development of a performance target in each objective domain ensures that there will be action for improvement if the target is not met. Performance indicators (what is being measured) are identified for each objective. As the performance management plan is implemented, the company's leadership monitors the performance indicators so that strategies for meeting the objectives can adapt to any unforeseen events in the organization or the environment. In this way, the company can continue to operate strategically. Evidence that a supplier has met its performance targets comes from information gathered about outcomes achieved; quality of business practices; and satisfaction with service delivery from the persons served, employees, and other stakeholders. The performance management plan for measuring **outcomes of consumer services**, **billing practices**, and **adverse events** could be recorded using a framework with the following fields:

- Objective domain
- Specific objective
- Indicator
- Applied to
- Time to measure
- Data source
- Obtained by
- Target goal expectancy
- Actual goal achieved

Typical information systems address the types of data to be collected, the tools necessary to collect and process the data, the time frame for collecting the data, and the procedures for keeping data confidential.

Specific examples of the framework for measuring the different objective domains can be found under Standard 1.E.3. Also, refer to the sample Performance Management Plan and sample Performance Management Outcomes Data Report in Supplement B of this manual.

The establishment of a target or performance goal of a level to be achieved is critical. Some suppliers use standardized tools that already have an established

benchmark, while other suppliers develop their own indicator targets by reviewing their historical performance in an identified indicator. Industry magazine articles, governmental agency websites, and industry membership organization websites can be helpful resources.

In determining objectives for the **outcomes of consumer services**, the supplier should be knowledgeable of the needs and goals of the beneficiaries. It is important to also collect information from beneficiaries who the supplier was unable to serve or no longer serves in order to ensure that those individuals who take their business elsewhere or who do not return are included in the performance improvement system. Valuable information for improvement of services can be gathered from persons who no longer utilize the supplier's services. A supplier who follows up only with satisfied customers would not be providing an accurate picture of its outcomes performance.

1.a. Refer to the examples for Standards 1.E.3.a.–d. Each example is given an "objective" number that can serve as the performance management plan to measure **outcomes of consumer services**. If you use this framework to set the specific objective for each objective domain that you are required to measure under Standards 1.E.3.a.–d. and then determine what and how you will measure each objective, this same information can serve as your performance management plan for **outcomes of consumer services** and meets this standard.

1.b. Refer to the example for Standard 1.E.3.e. The example given can serve as the performance management plan to measure **billing practices**. If you use this framework to set the specific objective for this particular objective domain that you are required to measure under Standard 1.E.3.e. and then determine what and how you will measure the objective, this same information can serve as your performance management plan for **billing practices**. You may set more than one performance objective for this objective domain, but you must have at least one performance objective for measuring **billing practices** to meet this standard.

1.c. Refer to the example for Standard 1.E.3.f. The example given can serve as the performance management plan to measure **adverse events**. If you use this framework to set the specific objective for this particular objective domain that you are required to measure under Standard 1.E.3.f. and then determine what and how you will measure the objective, this same information can serve as your performance management plan for **adverse events**. You may set more than one performance objective for this objective domain, but you must have at least one performance objective for measuring **adverse events** to meet this standard.

Survey Preparation Questions

1. In the framework given above, or in a similar framework, describe your current performance management plan for the following objective domains:

- Outcomes of services

- Billing practices

- Managing adverse events (even if none have occurred)

2. **When considering data to be collected, the supplier addresses the aspects of services that:**
   a. **Have the potential to cause harm or injury.**
   b. **Occur frequently.**
   c. **Create a greater than expected number of:**
      (1) **Adjustments.**
      (2) **Repairs.**
      (3) **Replacements.**
   d. **Require significant instruction to ensure safe use and benefit of items.**

Examples

To appropriately select data for collection, suppliers must be knowledgeable about their operations, trends in incidents, risk exposures, and actual performance with current and past beneficiaries. This information can be obtained by asking the appropriate questions in surveys or questionnaires. Also, these data can be tracked from information provided in beneficiary complaints during follow-up calls or in other forms of communication.

Survey Preparation Questions

2. In the data you collect, explain how you capture information that accounts for aspects of services that may:

- Have the potential to cause harm or injury.

- Occur frequently.

- Have a larger than expected number of adjustments, repairs, and replacements.

- Require significant instruction to ensure safe use and benefit of items.

3. **At a minimum, the supplier measures:**
   a. **Beneficiary satisfaction with products and services.**
   b. **Beneficiary complaints about products and services.**
   c. **Timeliness of response to beneficiary:**
      (1) **Questions.**
      (2) **Problems.**
      (3) **Concerns.**
   d. **Impact of the supplier's business practices on the adequacy of beneficiary access to:**
      (1) **Equipment.**
      (2) **Items.**
      (3) **Services.**
      (4) **Information.**

e. Frequency of billing and coding errors.

f. Adverse events to beneficiaries due to inadequate or malfunctioning equipment, items, and services.

Examples

Collection of information is based on the establishment of a level of performance to be achieved during a specific time period. The supplier should establish measurable objectives in each objective domain and then collect the data to measure results. Performance indicators are identified for each objective. The indicators a supplier chooses to measure relate to the information that the supplier, beneficiaries, and other stakeholders want to know about its business operations and services. Evidence of a supplier's successes and areas for improvement comes from information about outcomes achieved and the level of satisfaction among its customers. It is important to share the outcomes information with stakeholders in order to celebrate successes and demonstrate your commitment, as a supplier, to improving your company's performance. It is essential to share the outcomes information with your employees for the implementation of corrective action for performance improvement to be successful and complete.

Examples of the framework for measuring the different objective domains might look like this (also refer to the sample Outcomes Measurement Form in Supplement B of this manual):

3.a. Objective 1: Beneficiary satisfaction with products and services

- Objective domain: *Satisfaction of all customers served*
- Specific objective: *Customers will be satisfied with the products they receive*
- Indicator: *__% of customers who rate themselves on a survey overall as very satisfied or satisfied with the products and services they receive*
- Applied to: *Customers that received products and service*
- Time to measure: *Semiannually each calendar year*
- Data source: *Customer survey/questionnaire*
- Obtained by: *Clerk*
- Target goal expectancy: *90%*
- Actual goal achieved: *93% (exceeded target)*

3.b. Objective 2: Beneficiary complaints about products and services

- Objective domain: *Customer complaints*
- Specific objective: *Decrease the number of customer complaints about the products and services received*
- Indicator: *Number of complaints received about products and services*
- Applied to: *All customers who complain*
- Time to measure: *Semiannually each calendar year*
- Data source: *Complaints log*

- Obtained by: *Clerk*
- Target goal expectancy: *less than 15*
- Actual goal achieved: *18 (did not meet target)*

3.c. Objective 3: Timeliness of response to the beneficiary

- Objective domain: *Timeliness of response to stakeholder questions, problems, or concerns*
- Specific objective: *Increase satisfaction among all stakeholders with company's response time to all inquiries*
- Indicator: *Number of customers, referral sources, and vendors that respond to satisfaction survey by scoring 4 or 5 on question 5 ("Staff responded promptly to my phone calls, e-mails, faxes, or letters") on customer satisfaction survey*
- Applied to: *All customers, referral sources, and vendors that fill out customer satisfaction survey*
- Time to measure: *Semiannually each calendar year*
- Data source: *All returned satisfaction surveys*
- Obtained by: *Customer service representative*
- Target goal expectancy: *90%*
- Actual goal achieved: *89% (did not meet target)*

3.d. Objective 4: Adequacy of beneficiary access to equipment, items, services, and information that impacts supplier's business practices

- Objective domain: *Impact on business (loss of potential business) due to nonprovision of product lines specifically requested by beneficiaries, prescribing physician, and/or healthcare team members*
- Specific objective: *To determine if measured decrease in potential revenue necessitates adding new product to company's existing products line, thereby increasing company's access to its products and services to beneficiaries*
- Indicator: *Total loss of potential revenue due to nonprovision of certain product lines*
- Applied to: *Reported number of beneficiaries denied access to our business and services due to unavailability of requested line of products or equipment*
- Time to measure: *January through December*
- Data source: *Denial of products and services log, which tracks product category, manufacturer, and reimbursable amount for product unable to provide*
- Obtained by: *Sales representative*

- Target goal expectancy: *If total loss of potential revenues, due to reported lack of accessibility to our company's products and services, exceeds 2% of annual gross revenues (actual)*
- Actual goal achieved: *2.5% of actual annual gross revenues (case to be made for adding new product lines)*

3.e. Objective 5: Frequency of billing and coding errors includes the number of Medicare claims denied and/or errors the supplier finds in its own records after it has been notified of a claims denial

- Objective domain: *Frequency of Medicare billing and coding errors*
- Specific objective: *Decrease the number of billing and coding errors*
- Indicator: *Number of returns of claims due to company errors*
- Applied to: *All Medicare claims submitted to Medicare claims processor*
- Time to measure: *Quarterly*
- Data source: *Tabulation of Medicare claims denials*
- Obtained by: *Billing clerk*
- Target goal expectancy: *5 or less per quarter*
- Actual goal achieved: *2nd quarter's total = 13 (did not meet target)*

3.f. Objective 6: Beneficiary adverse events due to inadequate or malfunctioning equipment, items, and services

Data collection of adverse events includes injuries, accidents, signs and symptoms of infection, and hospitalization, which may be reported by or identified through follow-up with the prescribing physician, other healthcare team member, or beneficiary and/or caregiver.

- Objective domain: *Adverse events or injuries to beneficiaries due to inadequate or malfunctioning equipment*
- Specific objective: *Eliminate injuries to beneficiaries served as a result of inadequate or malfunctioning equipment*
- Indicator: *Number of beneficiary injuries reported to company directly due to inadequate or malfunctioning equipment*
- Applied to: *Customers served*
- Time to measure: *January through December*
- Data source: *Critical incident reports for Medicare beneficiaries*
- Obtained by: *Owner*
- Target goal expectancy: *No injuries of customers reported during 2009*
- Actual goal achieved: *None (goal met)*

Survey Preparation Questions

3. Explain how you are measuring for each objective(s) you have set in the following objective domains:

- Beneficiary satisfaction with products and services

- Beneficiary complaints about products and services

- Timeliness of response to beneficiary questions, problems, and concerns

- Impact of the supplier's business practices on the adequacy of beneficiary access to equipment, items, services, and information

- Frequency of billing and coding errors

- Adverse events to beneficiaries due to inadequate or malfunctioning equipment, items, and services

4. **When assessing the quality of its operations and services, the supplier seeks input from:**
   a. **Employees.**
   b. **Customers.**
   c. **Referral sources.**

Examples

A variety of tools or mechanisms can be used to seek input from employees, customers, and referral sources for assessing the quality of your company's operations and services. For employees to have the opportunity to express their thoughts or opinions without fear of retribution, the supplier may distribute an employee climate survey every year to be filled out anonymously. Questions on the climate survey can be crafted to ask for employees' input regarding the company's performance in its day-to-day operations and quality of services. Alternative mechanisms that a supplier may use to elicit employees' input include one-on-one meetings, team or departmental meetings, all-staff meetings, or provision of a culture in which company leadership consistently maintains and ensures an open-door policy for employees to talk while protecting their right to confidentiality.

By carefully crafting the questions, the supplier can allow customers the opportunity to give their input about the quality of the company's operations and services using the same mechanism(s) for collecting data about beneficiary satisfaction.

Similar tools or mechanisms used for measuring beneficiary satisfaction may be used to seek input about the quality of the company's operations and services from referral sources.

Survey Preparation Questions

4. For assessing the quality of your operations and services, describe your mechanism for seeking input from:

- Employees.

- Customers

- Referral sources.

How often do you collect this information?

Describe how you use this information for:

- Making improvements to your company's operations and services.

- Sharing successes if assessments reveal satisfactory or exemplary performance.

5. **The supplier demonstrates how it addresses data:**
   a. **Completeness.**
   b. **Accuracy.**

Examples

There are a variety of ways that a supplier can demonstrate that it addresses the integrity of the data it uses for outcomes assessment, performance improvement, and management decision making. These approaches can range from the simple to the sophisticated.

Completeness. The supplier takes steps to ensure that the data used for decision making are as complete as possible, no groups of beneficiaries are omitted from the data gathering or analysis, no data elements or indicators are systematically missing, and any database is checked for completeness of records before final analyses are run and decisions made. For example:

- Staff training for the data-recording activities includes attention to the importance of recording each data field for every beneficiary.
- The individual in charge of managing data routinely cross checks the number of records of the beneficiaries in the database or on file with the claims records during a reporting period to ensure that data are available on all beneficiaries before analysis is conducted and reports are generated.

Missing records are located and entered into the database before analysis is conducted. Accounts receivable and accounts payable, payroll records, inventory, and other ledgers should be routinely checked to ensure that all entries are recorded in order to yield complete financial statements of total revenues and expenses for each reporting period.

Accuracy. The supplier takes steps to ensure that data are recorded properly and that errors are caught and corrected. For example:

- Routine checks of the beneficiaries' claims processed are conducted to ensure that data abstracted from the claims filed match the equipment or item prescribed and delivered to the beneficiary and are contained in the beneficiaries' records. Particular attention should be given to entry of correct billing codes and modifiers, if applicable.
- The data manager routinely reviews the distribution of values in test data runs and asks the sales staff members to double check the accuracy of items that seem to be outside of expectations in terms of maximum or minimum values. (For example, "Did someone really receive 2,000 blood glucose test strips, or was it actually 200 test strips?")

Survey Preparation Questions

5. Explain your practices for ensuring that the data you have gathered are:

- Complete.

- Accurate.

F. Product Safety

1. **The supplier implements a program that:**
   a. **Promotes safe use of equipment and items.**
   b. **Minimizes for personnel and beneficiaries:**
      (1) **Safety risks.**
      (2) **Risk of infections.**
      (3) **Hazards.**
   c. **Identifies, monitors, and reports equipment and item failure.**
   d. **Provides preventative maintenance for beneficiaries' equipment and items.**

Examples

1.a.–b. One of the supplier's goals is to decrease injuries and accidents of both beneficiaries and employees. The company may achieve this by:

- Inviting equipment manufacturers to conduct inservices in the safe use of equipment, identification of risks and hazards, and how to avoid them.
- Sending staff to locally sponsored safety fairs.
- Displaying posters publicly on the walls of the business, shop, or practice that demonstrate the value your company places on safety.
- Holding regular employee inservices on some aspect of safety training. This may include inviting outside speakers from the community such as someone from the police or fire department, local American Red Cross chapter, or a local fire prevention or safety equipment supplier.
- Working with other DMEPOS suppliers in the community to sponsor and advertise for a communitywide safety awareness event.

1.c. A supplier demonstrates awareness of its reporting obligations to the FDA, per 21 CFR Part 803, and provides evidence of any reports submitted, if applicable. Reporting requirements include:

- *Reports of death* to the FDA within ten workdays after becoming aware of the information (FDA Form 3500A). The report must also be submitted to the device/ equipment manufacturer, if known.
- *Reports of serious injury* must be reported to the device manufacturer, if known, within ten days of becoming aware of the information (FDA Form 3500A). If the manufacturer is not known, the report must be submitted to the FDA.
- *Annual reports of death and serious injury* must be submitted to the FDA by January 1 of each year if any medical device reports were submitted by the supplier to the FDA or manufacturers during the year (FDA Form 3419).

To view the final rule for 21 CFR Part 803, visit **www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=803**

1.d. The supplier has a preventative maintenance program that includes:

- Calibration of equipment in accordance with manufacturers' recommendations.
- Preventative maintenance of equipment in accordance with manufacturers' recommendations.
- Thoroughly checking and testing each piece of equipment or item and making the necessary adjustments to ensure its safety prior to being delivered to the beneficiary.

Survey Preparation Questions

1. Describe how you promote safe use of equipment and supplies for your beneficiaries and company personnel.

Describe the practices or measures you employ to minimize the following for your employees and the beneficiaries you serve:

- Safety risks?
- Risk of infection?
- Hazards?

Describe your management program for identifying, monitoring, and reporting equipment or item failure, when necessary.

Describe your preventive maintenance program for equipment and items provided to beneficiaries.

2. **When the supplier becomes aware of an injury, incident, or infection that may have been caused by DMEPOS, the supplier:**
   a. **Investigates within 24 hours if the injury, incident, or infection has resulted in the beneficiary's hospitalization or death.**
   b. **For all other types of occurrences that do not result in hospitalization or death, investigates within 72 hours after being made aware of the incident, injury, or infection.**

Survey Preparation Questions

2. After you become aware that an injury, incident, or infection potentially related to DMEPOS has occurred and has caused hospitalization or death of a beneficiary, describe the process that occurs within 24 hours. If no sentinel event has occurred in your business or practice, describe the procedure you would follow in the event one were to occur.

Have you formalized this process in your company or practice, such as having a policy and procedure for managing a sentinel event? ❑ Yes ❑ No

If *no*, are your employees trained in your company's process or practice for investigating within 24 hours an injury, incident, or infection that has resulted in hospitalization or death caused by DMEPOS? ❑ Yes ❑ No

After you become aware that an injury, incident, or infection potentially related to DMEPOS has occurred and has not caused hospitalization or death of a beneficiary, describe the process that occurs within 72 hours. If no critical incident has occurred in your business or practice, describe the procedure you would follow in the event one were to occur.

Have you formalized this process in your company or practice, such as having a policy and procedure for managing critical incidents? ❑ Yes ❑ No

If *no*, are your employees trained in your company's process or practice for investigating within 72 hours an injury, incident, or infection not resulting in hospitalization or death, caused by DMEPOS? ❑ Yes ❑ No

3. **The investigation includes:**
   a. **Necessary information.**
   b. **Pertinent conclusions about what happened.**
   c. **Whether changes in systems or processes are needed.**

Examples

To facilitate a complete investigation, the supplier may develop a critical incident form so that all necessary information about the incident is gathered. Information to include on the incident form could include the date, time, location, and description of the incident; who was involved; the cause(s); the consequences of the incident; witnesses; who was notified; and follow-up recommendations. All administrative and witnessing personnel completing the form should provide complete descriptive and factual information.

The supplier should also consider preparing a periodic written analysis of all critical incidents that addresses:

- Causes.
- Trends.
- Actions for improvement.
- Necessary education and training of personnel.
- Prevention of recurrence.
- Internal and external reporting requirements.

Such an analysis can be a critical component in the company's or practice's risk management program and performance improvement activities.

Survey Preparation Questions

3. Give an example of a recent sentinel event or critical event that required an investigation and describe:

- Information that was included.

_____

_____

_____

- The pertinent conclusions about what happened.

_____

_____

_____

- The changes, if any, in systems and/or processes were identified.

_____

_____

_____

NOTE: *If no adverse event has occurred in your business or practice, indicate in your above responses, "No adverse event has occurred in company (or practice) under current ownership."* ***Provide a copy of your critical incident form or mechanism for recording the information about an investigation if a sentinel event or critical incident were to occur.***

4. The supplier considers possible links between the items and services furnished and the adverse event.

Examples

The purpose of this analysis is to enable the development of actions for improvement to prevent similar events from occurring in the future. Questions to ask include:

- Did the incident occur as the result of a defect in equipment or item, inadequate employee training, or a failure to follow the recommended usage by the manufacturer?
- Are common themes emerging in the incident reports?

Survey Preparation Questions

4. If applicable, describe your analysis of the adverse event for possible links to the items and services furnished. If no adverse event has occurred in your business or practice, indicate in your response how you would conduct your analysis that considers possible links between the items and services furnished and the adverse event if one were to occur.

5. The supplier has a contingency plan that:

a. Enables the supplier to respond to emergencies and disasters.

b. Includes arrangements with alternative suppliers to provide services in the event the supplier cannot serve its own customers as a result of the emergency or disaster.

Examples

Established emergency procedures promote readiness of employees to quickly and safely respond in an actual emergency. Also, there are emergency procedures for continuation of essential services. The procedures detail actions to be taken in the event of an emergency such as a fire, natural or man made disaster, violent or other threatening situation, utility failure, or medical emergency.

Being prepared and knowing what to do help the beneficiaries and personnel to respond in emergency situations that require an evacuation. The evacuation process guides personnel to assess the situation, take appropriate action, and lay the foundation for the continuation of essential services.

Procedures take into account the essential services that the supplier provides. Procedures identify personnel, both internal and external, who will be

responsible for the continuation of essential services, including alternative suppliers or clinical practices if destruction to your physical location forces an interruption in or cessation of services.

The procedures outline supporting documents that could help in evacuation and emergency situations. Supporting documents include blueprints of the facility with sufficient detail to guide emergency personnel to exits, water shutoffs, stairways, gas valves, air conditioning ducts, storm drains, electrical shutoffs, etc. Procedures also identify the individuals designated to maintain and implement emergency contact lists of essential internal and external personnel, parents/guardians, the health department, the fire department, the police, emergency medical resources, local emergency response teams, hospitals, utilities, the phone company, shelters, and the water department. Also, identifying the mechanism for notifying customers when there will be an interruption or cessation in the provision of services is essential.

Procedures should detail drills that demonstrate immediate response, evacuation, use of appropriate suppression techniques, notification of the proper authorities, and reporting requirements.

Local American Red Cross associations, city and county disaster preparedness groups, and many websites offer current and useful information on the development of emergency plans.

The Federal Emergency Management Agency (FEMA) is a national resource for education, training, and emergency information. FEMA has established an emergency planning guide for business and industry. The guide provides advice for creating and maintaining an overall emergency management plan specific to each supplier's corporate culture. In addition, there are resources on the Internet. Log on to websites such as **www.fema.gov/plan/prepare/plan.shtm** (FEMA's Plan for Emergencies), **www.disabilitypreparedness.org** (Center for Disability and Special Needs Preparedness), and **www.usfa.dhs.gov/applications/publications/** (U.S. Fire Administration) for free copies of pamphlets on emergency preparedness. Any of the procedures listed in these free publications may be requested and then incorporated into your plans.

Other websites that are resources in developing emergency procedures are:

- U.S. Department of Homeland Security: **www.dhs.gov/disabilitypreparedness**
- U.S. Department of Transportation: **www.dotcr.ost.dot.gov/asp/emergencyprep.asp**
- Emergency Evacuation Preparedness: Taking Responsibility for Your Safety—A Guide for People with Disabilities and Other Activity Limitations: **www.cdihp.org/products.html**
- Disaster Resources for People with Disabilities, Disability-related Organizations, and Emergency Managers: **www.jik.com/disaster.html**
- Emergency Preparedness Initiative (EPI) National Organization on Disability: **www.nod.org**

Considerations for emergency management plans include:

A. Establishing a planning team or health and safety committee that initiates planning steps such as:
   1. Establishing a mission statement and policy and procedure to demonstrate the supplier's commitment to emergency management.
   2. Establishing meetings with providers of utilities such as the electric company and community organizations including the American Red Cross, community emergency management, the fire department, and the police department to identify potential emergencies and procedures.
   3. Identifying federal, state, and local regulations such as fire codes, zoning regulations, and occupational health and safety regulations.
   4. Identifying critical products, services, and operations for potential emergencies and backup systems.
   5. Identifying internal resources and capabilities that the supplier would need in case of an emergency. Such resources and capabilities include personnel training; equipment; evacuation plans; and arrangements for backup systems such as payroll, billing records, communications, emergency power, and information systems support.
   6. Establishing procedures to ensure the protection, privacy, security, retention, and storage of records. Protection of records includes recovery of records in the event of fire or water damage.
   7. Identifying external resources that the supplier may need in an emergency, such as the fire department, hospitals, police, utilities, insurance carriers, suppliers of emergency equipment, and hazardous materials response organizations.

B. Analyzing potential hazards and the supplier's capabilities and addressing them with internal plans and policies. Documentation for analysis may include such things as evacuation plans, security procedures, drills, employee manuals, insurance programs, hazardous materials information, a facility closing policy, safety assessments, and risk management plans. Included in the analysis are:
   1. Potential emergencies.
   2. Historical emergencies.
   3. Geographic emergencies.
   4. Technological emergencies.
   5. Human error.
   6. Identification of training needs.
   7. Physical plant emergencies.
   8. Regulatory emergencies.
   9. An assessment of internal and external resources.

Each potential emergency within or surrounding the supplier is considered in the emergency management plan. The plan assesses:

- Probability.
- Potential human impact.
- Potential property impact for loss and damage.
- Organizational impact.

C. Emergency management plan components include direction and control, communications, life safety, property protection, community resources, recovery and restoration, administration, and logistics. Considerations in the plan include:

1. Emergency response procedures in the form of checklists.
2. Specific emergency response procedures for potential situations.
3. Support documents such as emergency call lists, facility site maps, resource lists, and designated responsibility lists.

D. To be optimally effective, the emergency management plan is developed and written for beneficiaries and personnel to enable them to observe, participate, and be trained in all aspects of the emergency plan and evacuation procedures. The plan includes a training schedule, local community resources and communications, communications from the planning committee or health and safety committee, and the analysis of the potential hazards and supplier's capabilities to address them.

Survey Preparation Questions

5. Describe your emergency and disaster plan.

Describe how you will continue to provide services to your customers in the event that disaster/emergency prevents you from doing so at your company's location.

Describe the training of your employees in your company's emergency and disaster plan, including drills and simulations.

Are you and your employees ready to respond to a disaster if one were to happen today? ❑ Yes ❑ No

How often do your employees receive training in emergency procedures?

Describe your company's arrangements with alternative suppliers or clinical practices to provide continued services to your customers in the event a disaster destroys the operational infrastructure at your physical location.

6. Before distributing, dispensing, or delivering products to a beneficiary, the supplier verifies, authenticates, and documents the following:

a. The products are not:

(1) Adulterated.

(2) Counterfeit.

(3) Suspected of being counterfeit.

(4) Obtained by fraud or deceit.

(5) Misbranded.

b. The products are appropriately labeled for their intended distribution channels.

Survey Preparation Questions

6. After you have ordered and/or received the equipment or items that will ultimately be distributed, dispensed, or delivered to beneficiaries, describe your procedure for **verifying** that the products are not:

- Adulterated.

- Counterfeit.

- Suspected of being counterfeit.

- Obtained by fraud or deceit.

- Misbranded.

After you have ordered and/or received the equipment or items that will ultimately be distributed, dispensed, or delivered to beneficiaries, describe your procedure for **authenticating** that the products are not:

- Adulterated.

- Counterfeit.

- Suspected of being counterfeit.

- Obtained by fraud or deceit.

- Misbranded.

After you have ordered and/or received the equipment or items that will ultimately be distributed, dispensed, or delivered to beneficiaries, describe your procedure for **documenting** that the products are not:

- Adulterated.

- Counterfeit.

- Suspected of being counterfeit.

- Obtained by fraud or deceit.

- Misbranded.

G. Information Management

1. **In accordance with privacy and security standards of the Health Insurance Portability and Accountability Act (HIPAA) and other applicable state standards, the supplier maintains beneficiary records that are:**
   a. **Accurate.**
   b. **Pertinent.**
   c. **Accessible.**
   d. **Confidential.**
   e. **Secure.**

Examples

A supplier's or clinician's procedures and practices ensure consistent compliance by all personnel with all HIPAA privacy and security rules and regulations and applicable state laws.

There are policies for beneficiary records that address, at a minimum:

- Accuracy.
- Relevance.
- Confidentiality.
- Beneficiary access to records.
- Retention and storage.
- Protection from fire and water damage.

If electronic records are used, there are policies that address, at a minimum:

- Accuracy.
- Privacy.
- Accessibility.
- Protection and security.
- Retention and storage.

Personnel should demonstrate knowledge of and compliance with all applicable federal, state, and local laws and regulations, including HIPAA law. The website for obtaining a copy of the HIPAA law is **www.ssa.gov/OP_Home/comp2/F104-191.html**.

Survey Preparation Questions

1. Describe your process to ensure that the information in beneficiary records is:

- Accurate.

- Pertinent.

- Accessible to the beneficiary.

- Kept confidential.

- Secure.

Describe the training or process by which you ensure that all staff members comply with HIPAA privacy rules and regulations and other applicable state laws with respect to the maintenance of accurate, pertinent, accessible, confidential, and secure beneficiary records.

How often does your staff receive this training?

2. The supplier has practices to ensure compliance with the following legal and regulatory requirements:

- **a. Rights of the beneficiaries.**
- **b. Reporting requirements.**
- **c. Contractual agreements.**
- **d. Licensing requirements.**

Examples

2.a. The supplier ensures that the rights of the beneficiaries are protected. It is essential that policies regarding the human rights and dignity of the beneficiaries be communicated to personnel and to the beneficiaries in a manner that is understandable to them. The supplier should be prepared to provide a written copy of beneficiary rights and its code of ethics when requested by beneficiaries. A good practice a supplier may follow is to develop a written code of ethics and include this information in its employee handbook or present it during employee orientation through audiotapes, videotapes, pictures, and other media.

Also, standard 16 of the CMS Medicare DMEPOS Supplier Standards requires suppliers to disclose the standards to each beneficiary who receives a Medicare-covered item. The supplier standards, in their entirety, are listed in 42 CFR §424.57(c) and can be found on the following website: **www.palmettogba.com/palmetto/providers.nsf/files/25%20standards%20full.pdf/$File/25%20standards%20full.pdf**.

2.b. Each DMEPOS supplier is required by CMS (per 42 §CFR 420.201–§420.206) to report to the National Supplier Clearinghouse within 30 days of occurrence the following information:

- Changes in ownership, financial, or control interest in your business
- Changes in your business transactions
- Program-related crimes
- The hiring of an intermediary's former employee(s)

To review the final rule, visit: **http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr_2002/octqtr/pdf/42cfr420.1.pdf**.

In addition, each DMEPOS supplier is required to report to the FDA, per 21 CFR Part 803, the following:

- *Reports of death* to the FDA within ten workdays after becoming aware of the information (FDA Form 3500A). The report must also be submitted to the device/equipment manufacturer, if known.
- *Reports of serious injury* must be reported to the device manufacturer, if known, within ten days of becoming aware of the information (FDA Form 3500A). If the manufacturer is not known, the report must be submitted to the FDA.

- *Annual reports of death and serious injury* must be submitted to the FDA by January 1 of each year if any medical device reports were submitted by the supplier to the FDA or manufacturers during the year (FDA Form 3419).

To view the final rule, visit **www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=803**.

2.c. At a minimum, a supplier must ensure that it has signed contracts with agencies, vendors, or individuals with whom it contracts to provide products and services that are not provided by directly employed personnel.

It is advised that each contract be reviewed by an attorney or other qualified professional to ensure that it meets state laws regarding contracts. Free consultation on how to create a contract appropriate for your business can be obtained by contacting the local office of the Small Business Administration.

This standard does not apply to a supplier who has no contracts with individuals or companies to perform any of its services.

2.d. For all licensure (including business, supplier's, agency, licensed/certified professionals, or other state regulatory licenses) required by the state in which a DMEPOS supplier conducts its business and provides equipment, items, and services to its beneficiaries, it is the supplier's responsibility to ensure:

- That licenses are on file or posted in a public area when required.
- That licenses are current.
- Verification that any license has not been revoked or suspended by a state authority.
- Verification that licensed personnel are not currently subject to disciplinary action or scheduled hearings by the licensing authority.

Contacting your state and local health or other regulatory agency or visiting their websites can provide guidance in ensuring that you meet all applicable licensing requirements. The websites of state licensing authorities also provide information about licensing requirements in your state. Be sure to check with the appropriate licensing agency in your state, county, and/or city to determine if you are required to operate with a DME license.

Survey Preparation Questions

2. Describe how you meet federal, state, and local legal and regulatory requirements regarding:

- Rights of the beneficiaries.

- Reporting.

- Contractual agreements.

- Licensing.

SECTION 2

General Product-Specific Services Standards

A. Requirements

1. **All DMEPOS covered under the Medicare program that the supplier provides serve a medical purpose.**

Examples

For a supplier to be reimbursed, CMS requires that DMEPOS equipment or items are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Survey Preparation Questions

1. How do you verify that DMEPOS product categories covered under the Medicare program for which you are seeking CARF accreditation serve a medical purpose?

2. **A supplier verifies that the prescribing physician collaborates and coordinates clinical services with other healthcare professionals regarding applicable DMEPOS.**

Examples

Except for medical equipment and supplies furnished incident to physician services, Medicare rules require additional clinical services for certain equipment or items before they can be delivered to the beneficiary. These services must be performed by a qualified practitioner (e.g., orthotist; prosthetist; occupational, physical, or respiratory therapist; pedorthist; CRTS; ATS; or ATP for positioning, measuring, and fitting the beneficiary properly for the prescribed equipment or item; assembling/programming complex rehabilitative or assistive technology; and molding, casting, and fabricating certain custom-fabricated items. The prescribing physician may include in the original order for the equipment or item approval for the supplier to coordinate these services with other healthcare professionals. Also, a supplier may have to request from the prescribing physician to directly collaborate and coordinate clinical services with other healthcare professionals or request an additional order approving the supplier to collaborate and coordinate clinical services with other healthcare professionals.

Survey Preparation Questions

2. When required, how do you verify that a physician directly collaborates and coordinates clinical services or has approved you, the supplier, to collaborate or coordinate clinical services with other healthcare professionals regarding applicable DMEPOS?

Survey Preparation Tip:

Through a review of sample beneficiary records, the surveyor(s) will verify that the physician has directly collaborated and coordinated clinical services with other healthcare professionals or there are signed orders approving the supplier to collaborate and coordinate clinical services with other healthcare professionals.

B. Intake and Assessment

1. As needed, the supplier consults with the prescribing physician to confirm the order.

Examples

If the DMEPOS supplier is the prescribing physician, there is documentation in the beneficiary's record to verify that any DMEPOS equipment or item was provided to the beneficiary as part of the physician's treatment and services.

Survey Preparation Questions

1. Explain how you determine when there is a need to confirm an order with a prescribing physician.

Provide some examples of when you determined a need to confirm an order with the prescribing physician.

Which of the following methods do you use to confirm orders with the prescribing physicians when needed:

- ❑ By phone
- ❑ By fax
- ❑ By e-mail
- ❑ Other

If *other*, please specify:

2. **As needed, the supplier consults with the prescribing physician, as related to the prescribed equipment, item, or services, about any recommended:**
   a. **Changes.**
   b. **Refinements.**
   c. **Additional evaluations.**

Survey Preparation Questions

2. Describe your process for consulting with the prescribing physician about any recommended changes, refinements, and/or additional evaluations regarding the prescribed item or service?

Describe known situations for which you would consult with the prescribing physician about any recommended changes, refinements, and/or additional evaluations regarding the prescribed item or service.

Do you document your recommended changes, refinements, and/or additional evaluations you discussed with the prescribing physician? ❑ Yes ❑ No

If *yes*, where is this information documented?

If *no*, how do you provide evidence of your consultation with the prescribing physician about any recommended changes, refinements, and/or additional evaluations?

3. For pertinent information related to the beneficiary's condition that affects the provision of DMEPOS equipment and/or related services, in collaboration with the prescribing physician, the supplier:

a. Reviews the beneficiary's records, as appropriate.

b. Makes any necessary revisions to the record.

Examples

If it becomes necessary for the supplier to request a beneficiary's medical records from the prescribing physician, the supplier incorporates any revisions in a beneficiary's record that affect the provision of DMEPOS equipment, items, or related services only in collaboration with the prescribing physician. The supplier must document the revisions in the beneficiary's record after collaborating with the prescribing physician.

Survey Preparation Questions

3. As appropriate, where in the beneficiary's medical record would you place evidence that you have:

- Reviewed the beneficiary's records obtained from the prescribing physician when necessary?

- Incorporated any necessary revisions that affect the provision of DMEPOS and related services due to any changes in the beneficiary's condition?

- Verified the prescribing physician engaged in and collaborated with your recommended revisions?

Give an example of a necessary revision due to a change in the beneficiary's condition that affected the provision of DMEPOS and related services that needed to be documented. If you have not been required thus far to collaborate with a physician to make any changes to beneficiaries' records, describe a scenario in which this could likely occur for the DMEPOS you provide.

Survey Preparation Tip:

Be prepared to make beneficiary records available for the surveyor(s) to review to verify conformance to these standards. The surveyor(s) will randomly select a sampling of beneficiary records to review during the survey.

4. The supplier ensures that the following are kept unaltered in the beneficiary's record.

- **a. DMEPOS prescriptions.**
- **b. Applicable Certificates of Medical Necessity (CMN).**
- **c. Pertinent documentation from the prescribing physician.**

Examples

The supplier follows legal conventions for altering medical records and all documentation contained in a beneficiary's record. For verification of an intended alteration made for legitimate purposes, the author must cross out the original information with one line and record his or her initials and the date. Beneficiaries' records should contain no evidence of presigned doctors' prescriptions, postdated prescriptions, photocopied signatures by the prescribing physician, or any other photocopied documentation that relates to the provision of DMEPOS and related services.

If the supplier receives physicians' orders by fax, the supplier verifies the prescription by a follow-up phone call to the prescribing physician and records a notation to verify this was done. Verification documentation contains the employee's signature and date the order was verified. As with original physician orders, the authenticated faxed order is kept in the beneficiary's record.

Survey Preparation Questions

4. Describe your procedures to verify that DMEPOS prescriptions are authentic and have not been altered.

Describe your procedures that ensure that beneficiary records contain original CMNs signed by the prescribing physician for any DMEPOS for which a CMN applies.

Describe your procedures that ensure that all pertinent information kept in beneficiaries' records is unaltered.

How often does your company conduct audits of beneficiaries' records?

Who in your company is responsible for conducting audits of beneficiaries' records?

Who in your company is ultimately responsible for ensuring that all beneficiaries' records are complete, accurate, and unaltered?

Survey Preparation Tip:

Be prepared to make beneficiary records available for the surveyor(s) to review to verify conformance to these standards. The surveyor(s) will randomly select a sampling of beneficiary records to review during the survey.

C. Delivery and Setup

1. The supplier delivers and sets up, or coordinates setup with another supplier, all equipment and items in a timely manner as agreed on by the:

- **a. Beneficiary.**
- **b. Caregiver, if appropriate.**
- **c. Supplier.**
- **d. Prescribing physician.**

Survey Preparation Questions

1. Does your company deliver and set up all equipment and items? ❑ Yes ❑ No

If *yes*, explain how you obtain agreement from all parties for when equipment or items will be delivered and set up.

If *no*, explain how you:

- Coordinate delivery and setup with another supplier.

- Ensure that there is agreement from all parties for when equipment or items will be delivered and set up by the alternate supplier.

How do you ensure timely delivery and setup in accordance with the agreement?

2. **For the beneficiary and caregiver to operate the equipment or item provided, the supplier:**
   a. **Provides all necessary equipment and items.**
   b. **Performs any necessary adjustments.**

Survey Preparation Questions

2. How do you ensure that all items needed to operate the equipment or item have been provided to the beneficiary and caregiver?

Explain how you verify that this has occurred.

Explain how you assess for adjustments that may be needed for the beneficiary to operate the equipment or item.

Describe your process for providing any further necessary adjustments to ensure that the equipment or item is operational.

Explain how you verify that this has occurred.

3. **If equipment repairs are necessary, the supplier provides or arranges for loaner equipment that is equivalent to the original equipment during any repair period.**

   NOTE: *Not applicable to orthoses and prostheses.*

Survey Preparation Questions

3. Explain how you provide or arrange for loaner equipment when the beneficiary's original equipment is being repaired.

4. **The supplier ensures that all equipment or items delivered to the beneficiary are consistent with:**
   a. **The prescribing physician's order.**
   b. **Other identified needs, risks, and limitations of the beneficiary of which the supplier is aware.**

Examples

The supplier delivers to the beneficiary only the equipment or items that are consistent with his or her identified needs, risks, and limitations. If a beneficiary's needs, risks, or limitations change between the time the equipment or item was prescribed and the supplier's assessment, refer to Section 2.B., Standard 2., which requires the supplier to consult with the prescribing physician, as related to the prescribed item or services, about any changes, refinements, and additional evaluations that may be recommended by the supplier.

Survey Preparation Questions

4. Describe your process or system to ensure that delivered items meet the prescribing physician's orders.

How do you ensure that items you deliver to beneficiaries are consistent with their identified needs, risks, and limitations?

Where is the information documented?

Survey Preparation Tip:

Be prepared to make all records, including beneficiary records, available for the surveyor(s) to review to verify conformance to these standards and to identify specific beneficiary's records that contain the required documentation.

D. Training/Instruction for Beneficiary and Caregiver

1. **The supplier provides or coordinates the provision of appropriate information and/or instructions to the beneficiary and caregiver about the equipment's or item's:**
   a. **Setup, including preparation of enteral nutrients if applicable.**
   b. **Features.**
   c. **Routine use.**
   d. **Troubleshooting.**
   e. **Cleaning.**
   f. **Maintenance.**
   g. **Safety considerations.**
   h. **Infection control practices and issues related to the use of the equipment or item.**

Survey Preparation Questions

1. Explain how you, as the supplier, provide the following information and/or instructions to the beneficiary and caregiver about the equipment's or item's:

- Setup, including preparation of enteral nutrients if applicable.

- Features.

- Routine use.

- Troubleshooting.

- Cleaning.

- Maintenance.

- Safety considerations.

- Infection control issues related to the use of the equipment/item.

2. For initial orders of equipment or items provided by mail order delivery, the supplier:

a. Verifies that the beneficiary and/or caregiver received training and written instructions on the use of the equipment or items.

b. Documents in the beneficiary's record that the beneficiary and/or caregiver received training and written instructions on the use of the equipment or item.

Survey Preparation Questions

2. If you provide mail order equipment or items, describe your procedure for verifying that the beneficiary and/or caregiver received training and written instructions at the time of the **initial** mail order delivery of the equipment or items.

If you provide mail order equipment or items, describe your procedure for documenting in each beneficiary's record that he or she and/or his or her caregiver received training and written instructions on the use of the equipment or items at the time of the **initial** mail order deliver.

3. **For settings of anticipated use by the beneficiary, the supplier ensures the beneficiary's and/or caregiver's:**
   a. **Safe use of all equipment and items provided.**
   b. **Effective use of all equipment and items provided.**

Survey Preparation Questions

3. How do you ensure that the beneficiary and/or caregiver demonstrate safe use of all equipment or items provided for settings of anticipated use?

How do you ensure that the beneficiary and/or caregiver demonstrate effective use of all equipment or items provided for settings of anticipated use?

If you are a provider of manual or power wheelchairs, power mobility devices, and complex rehabilitative wheelchairs (this includes a manual wheelchair that accommodates rehabilitative accessories and features, Group 2 power wheelchairs with power options, or Group 3 and high-power wheelchairs), describe how you ensure the beneficiary's safe and effective use of the equipment in settings both inside and outside the home.

4. Instructions and training for the beneficiary and/or caregiver are commensurate with and relate to the equipment's or item's:

a. Risks.

b. Complexity.

c. Manufacturer's instructions or specifications.

Survey Preparation Questions

4. How do you develop your instructions and training for beneficiaries and/or caregivers to ensure that they are commensurate with and relate to the equipment's or item's:

- Risks.

- Complexity.

- Manufacturer's instructions or specifications.

What kinds of instructional and training methods do you use that are commensurate with and relate to the equipment's or item's risks, complexity, and manufacturer's instructions or specifications?

5. The supplier tailors training, instructional materials, and approaches to the beneficiary's and/or caregiver's:

a. Needs.

b. Abilities.

c. Learning preferences.

d. Language.

Survey Preparation Questions

5. Describe how your training, instructional materials, and approaches are tailored to the diversity of the beneficiaries and caregivers you serve with respect to their:

- Needs.
- Abilities.
- Learning preferences.
- Language.

E. Follow-Up

1. **The supplier provides follow-up services for the beneficiary and caregiver that are consistent with:**
   a. **The type of equipment, items, or services they received.**
   b. **Recommendations from the:**
      (1) **Prescribing physician.**
      (2) **Healthcare team members.**

Survey Preparation Questions

1. Describe how you ensure that your follow-up services for the beneficiary and caregiver are consistent with:

- The type of equipment, items, or services received.

- Recommendations from the:
  - Prescribing physician, when applicable.
  - Health care team members, when applicable.

SECTION 3

Specific Product-Related Services Standards

NOTE: *The standards in Section 3 correspond to Appendices B and C of the* CMS Quality Standards for Suppliers of DMEPOS.

A. Manual Wheelchairs and Power Mobility Devices (CMS Quality Standards Appendix B)

Applicable Standards

The standard in this section applies to suppliers of manual wheelchairs and power mobility devices (PMDs). Manual wheelchairs include standard recliners, heavy-duty wheelchairs, standard lightweight wheelchairs, hemi wheelchairs, arm rests, leg rests, footplates, anti-tipping devices, and other Medicare-approved accessories. PMDs include power wheelchairs, power operated vehicles (POVs), and accessories.

Intake and Assessment

1. **For each beneficiary receiving this category of specific equipment and items, the supplier:**
   a. **Evaluates for:**
      (1) **Seating.**
      (2) **Positioning.**
   b. **Documents the results of the seating and positioning evaluation in the beneficiary record.**

Survey Preparation Questions

1. Describe your company's procedure to ensure that each beneficiary who receives equipment and/or items in this specific product category is evaluated for:

- Seating of the beneficiary in the wheelchair or PMD.

- Positioning of the beneficiary in the wheelchair or PMD.

Describe your company's procedure for:

- Documenting the seating and positioning evaluation of each beneficiary who receives equipment or items in this specific product category

- Keeping a permanent record of this information

Survey Preparation Tip:

For each beneficiary who received this particular product category, there should be evidence in the beneficiary's records of documentation of completed evaluations that are signed and dated by the person responsible. During the survey, the surveyor(s) will review records of beneficiaries who received this category of equipment, items, and related services to verify that the documentation is in evidence.

B. Complex Rehabilitative Wheelchairs and Assistive Technology (CMS Quality Standards Appendix B)

Applicable Standards

The standards in this section apply to suppliers of complex rehabilitative wheelchairs and assistive technology. Complex rehabilitative wheelchairs are Group 2 power wheelchairs with power options, Group 3 and higher power wheelchairs, and manual wheelchairs that can accommodate rehabilitative accessories and features; e.g., tilt-in-space wheelchairs.

Requirements

1. **The supplier employs (W-2 employee) at least one qualified individual as a rehabilitation technology supplier (RTS) per location.**

Intent Statements

Note that the RTS for each location cannot be contracted. The individual must be a W-2 employee of your company if you provide complex rehabilitation wheelchairs and assistive technology.

Survey Preparation Questions

1. How many locations do you have where you provide complex rehabilitative wheelchairs and assistive technology?

_____

Is there currently at least one qualified RTS employed at each location? ❑ Yes ❑ No

If *no*, please explain your strategy for demonstrating conformance to this standard.

_____

_____

_____

_____

_____

2. **A qualified RTS has one of the following credentials:**
   a. **Certified Rehabilitation Technology Supplier (CRTS®).**
   b. **Assistive Technology Professional (ATP).**

Examples

Note that the previous separate RESNA certifications for an Assistive Technology Supplier (ATS) and ATP have been discontinued as of December 31, 2008. Effective January 1, 2009, the only certification now offered by RESNA is for an ATP. Information about converting your current ATS or ATP to an ATP certification is available from RESNA's website at **www.resna.org/certification/index.php**.

For a CRTS registration, only registrants of the National Registry of Rehabilitative Technology Suppliers (NRRTS) may use the credential of Registered Rehabilitation Technology Supplier (RRTS®), or CRTS. A CRTS is an RRTS in good standing for at least two years who has passed the ATP exam administered by RESNA and continues to maintain the ATP credential with RESNA. For more information about a CRTS registration, visit the National Registry of Rehabilitation Technology Suppliers (NRRTS) website at **www.nrrts.org**.

Survey Preparation Questions

2. Which credential(s) does your RTS have?

- ❑ CRTS
- ❑ ATP

What are your procedures for verifying these credentials?

What are your procedures for ensuring that employees' credentials remain current?

If you have any RTS employees who have not yet converted previous RESNA certification as an ATS or ATP to RESNA's current ATP certification, what are your plans and time line for ensuring that they complete the conversion process?

Survey Preparation Tip:

Have these credentials prominently displayed in a public area and available for the surveyor(s) to review.

3. **Depending upon the size and scope of its business, the RTS has at least one trained technician available to service each location.**

Survey Preparation Questions

3. How many trained technicians do you have available to service each location?

How do you determine that you have a sufficient number of trained technicians to handle the volume and scope of business at each location?

4. **Trained technicians meet all of the following criteria:**
   a. **Factory trained by manufacturers of the products provided by the supplier.**
   b. **Experienced in the field of rehabilitation technology, including on-the-job training and familiarity with rehabilitation clients, products, and services.**
   c. **Completed at least ten hours annually of continuing education specific to rehabilitative technology.**
   d. **Ability to program and repair sophisticated electronics associated with power wheelchairs, alternative drive controls, and power seating systems.**

Examples

All of the above criteria must be met by each trained technician directly employed or contracted by the supplier to service each location where complex rehabilitative and assistive technology equipment is provided.

Survey Preparation Questions

4. How do you ensure and verify that the trained technician(s) at each location meets the following qualifications?

- Factory trained by manufacturers of the products you provide

- Experienced in the field of rehabilitative technology

- Completed at least ten hours annually of continuing education specific to rehabilitative technology

- Ability to program and repair sophisticated electronics associated with power wheelchairs, alternative drive controls, and power seating systems

Survey Preparation Tip:

The surveyor(s) will need to see a list of all trained technicians and review proof of their qualifications.

5. The RTS coordinates services with the prescribing physician to:

a. Conduct face-to-face evaluations of the beneficiary.

b. Ensure that face-to-face evaluations take place in an appropriate setting.

c. Include input from other healthcare team members.

Examples

5.b. In selecting an appropriate setting for face-to-face evaluations, it is essential for the RTS to ensure that the setting protects the beneficiary's confidentiality and right to privacy.

5.c. Other healthcare team members may include the physical therapist, occupational therapist, prescribing physician, primary care physician, speech-language pathologists, and nurse practitioner.

Survey Preparation Questions

5. Describe how the RTS coordinates with the prescribing physician to conduct face-to-face evaluations.

What is your process for ensuring that the face-to-face evaluations take place in an appropriate setting?

Describe the setting(s) where the face-to-face evaluations typically occur.

Describe how the RTS involves other healthcare team members in face-to-face evaluations, when appropriate.

6. The RTS, when necessary, provides the beneficiary with appropriate equipment for trials and simulations.

Survey Preparation Questions

6. Describe how your RTS provides beneficiaries with equipment for trials or simulations, when necessary.

Describe situations where providing a beneficiary with appropriate equipment for trials and simulations would be necessary.

7. The record of the beneficiary includes all information gathered during the assessment process.

Survey Preparation Questions

7. Summarize the information that is gathered during a typical assessment for complex rehabilitative wheelchairs or assistive technology.

Where would the information gathered during the assessment be found in the beneficiary's record?

Survey Preparation Tip:

The surveyor(s) will need to review a representative sampling of both active and inactive beneficiary records to verify that assessments are being performed.

8. The RTS implements procedures for:

a. Assembly of equipment.

b. Setup of equipment.

Survey Preparation Questions

8. Describe the procedures that are used for:

- Assembling equipment.

- Setting up equipment.

Where are the complex rehabilitative wheelchairs and/or assistive technology products assembled, set up, and tested?

9. The RTS has a process to verify that the final product meets the specifications of the original product recommendation approved by the prescribing physician.

Survey Preparation Questions

9. Describe the process for verifying that the final product meets the specifications of the original product recommendation approved by the prescribing physician.

Is this process formalized in any manner, such as written procedures? ❑ Yes ❑ No

If *no*, how do you ensure that the process is consistently followed?

_____

_____

_____

_____

10. If a beneficiary is evaluated at the supplier's site, the supplier:

a. Provides evaluation and fitting rooms that are:

(1) Private.

(2) Clean.

(3) Safe.

b. Maintains a repair shop that is located in the facility or in close proximity or accessible from another location of the supplier.

c. Has access to an area appropriate for:

(1) Assembly of products.

(2) Modification of products.

Examples

10.b.–c. The area in which a supplier assembles, modifies, and repairs equipment should meet all applicable local building codes and OSHA requirements. The area should be clean and provide adequate space for maneuvering and performing the necessary work. There should be adequate lighting and air circulation, and the safety of the technicians who work in the area should be ensured at all times by the absence of oil spills and by proper storage of parts, tools, sharp instruments, electrical equipment, and hazardous materials.

To ensure that the area is appropriate for assembling, modifying, and repairing complex rehabilitation wheelchairs and assistive technology, a supplier may wish to seek consultation from any of the following:

- Representative from the local OSHA office
- Representative from the local fire marshal's office or fire department
- Licensed or registered safety engineer
- Architect familiar with this type of facility
- Safety specialist familiar with this type of facility
- Safety consultant who represents your company's insurance carrier
- Safety consultant who represents your company's workers' compensation carrier

- Industrial health specialist
- Risk management specialist/consultant

Survey Preparation Questions

10. Are beneficiaries evaluated at your site(s)? ❑ Yes ❑ No

If *yes*, describe your process for ensuring that the evaluation and fitting rooms are private, clean, and safe.

Which of the following describes where your repair shop is located in relation to your place of business?

- ❑ Located at your place of business
- ❑ Located in close proximity to your place of business
- ❑ Located at another location that is easily accessible

Provide a brief description of the area where you assemble and/or modify complex rehabilitation wheelchairs and/or assistive technology products.

Survey Preparation Tip:

The surveyor(s) will observe the evaluation/fitting rooms, if applicable, as well as repair and assembly areas during the on-site visit. Beneficiaries receiving services on the day of the on-site visit may be interviewed as well.

Intake and Assessment

11. For each beneficiary receiving this category of specific equipment and items, the supplier:

a. Evaluates for:

(1) Seating.

(2) Positioning.

(3) Specialty assistive technology.

b. Documents the results of the seating, positioning, and specialty assistive technology evaluation in the beneficiary record.

Survey Preparation Questions

11. Describe your company's procedure to ensure that each beneficiary who receives complex rehabilitative wheelchairs and assistive technology is evaluated for:

- Seating.

- Positioning.

- Specialty assistive technology.

Describe your company's procedure for:

- Documenting the evaluation for seating, positioning, and specialty assistive technology of each beneficiary who receives equipment or items in this specific product category.

- Keeping a permanent record of this information.

Survey Preparation Tip:

For each beneficiary who received a rehabilitative wheelchair and assistive technology, there should be evidence in the beneficiary's records of documentation of completed evaluations that are signed and dated by the person responsible. During the survey, the surveyor(s) will review records of beneficiaries who received this category of equipment, items, and related services to verify that the documentation is in evidence.

C. Custom-Fabricated and Custom-Fitted Orthoses, Prosthetic Devices, Therapeutic Shoes and Inserts, their Accessories and Supplies, and Custom-Made Somatic Prostheses (CMS Quality Standards Appendix C)

Applicable Standards

These standards apply to suppliers of custom-fabricated, custom-fitted, and custom-made orthoses, therapeutic shoes and inserts, somatic prostheses, and prosthetic devices (speech-generating devices and voice prosthetics).

NOTE: *Refer to the Glossary for definitions of terms.*

Requirements

1. The supplier demonstrates training for staff that encompasses a broad range of treatment options that will ensure that the prescribed item is optimal for the beneficiary's condition.

Survey Preparation Questions

1. To ensure that the prescribed orthoses, prostheses, or diabetic shoes/inserts will be optimal for the condition of each beneficiary, describe the type of and how much training you and/or your staff members have acquired that ensures competency in the following, as applicable:

- Custom fitting

- Custom fabricating

2. Individual(s) providing the custom items and/or devices demonstrate evidence of:

- **a. Specialized education in fitting.**
- **b. Training in fitting.**
- **c. Experience in fitting.**
- **d. Certification.**
- **e. Licensure, where applicable.**

Survey Preparation Questions

2. Explain your procedure for verifying that the individual(s) directly responsible for providing the custom items and/or devices possess the necessary:

- Specialized education in fitting.

- Training in fitting.

- Experience in fitting.

- Certification.

- Licensure, where applicable.

Survey Preparation Tip:

Have these credentials prominently displayed in a public area and available for the surveyor(s) to review.

Intake and Assessment

3. The supplier assesses of the beneficiary's need for and use of the orthosis, prosthesis, or diabetic shoes/inserts.

Examples

Assessments include gathering information about the beneficiary such as a comprehensive history; pertinent medical history including allergies to materials, skin condition, diagnosis, previous use of an orthoses/prostheses, and results of diagnostic evaluations; and beneficiary expectations.

Survey Preparation Questions

3. Do you use a template or form for documenting your assessment of the beneficiary's need for and use of the orthosis or prosthesis ordered? ❑ Yes ❑ No

If *no*, describe how you document all information required for a complete assessment.

What evidence do you have that shows that an assessment related to the beneficiary's need for and use of the custom item or device has been completed?

Where in the beneficiary's record is this documented?

Survey Preparation Tip:

The surveyor(s) will need to review a representative sampling of both active and inactive beneficiary records to verify that need- and use-related assessments are completed.

4. As appropriate, the supplier gathers pretreatment photographic documentation.

Survey Preparation Questions

4. Describe your process for determining when pretreatment photographic documentation is needed.

Survey Preparation Tip:
The surveyor(s) will need to review a representative sampling of active and inactive beneficiary records to verify documentation for this process.

5. As required by the beneficiary's need for and use of the orthosis, prosthesis, or diabetic shoes/inserts ordered, the supplier determines the appropriate item or device that ensures:

a. Optimal therapeutic benefits.
b. Appropriate strength.
c. Appropriate durability.
d. Appropriate function.

Survey Preparation Questions

5. How do you typically determine the appropriate orthosis, prosthesis, or diabetic shoes/inserts, as required by the beneficiary s need for and use of the item or device, to ensure:

- Optimal therapeutic benefits?

- Appropriate strength, durability, and function?

What evidence do you have that shows that a determination for the appropriate orthosis, prosthesis, or diabetic shoes/inserts, as required by the beneficiary's need for use of the item or device, has been completed?

Where in the beneficiary's record is this information documented?

6. The supplier performs an in-person, diagnosis-specific clinical and functional examination related to the beneficiary's need for and use of the orthosis, prosthesis, or diabetic shoes/inserts.

Examples

The examination may include areas such as sensory function, range of motion, joint stability, skin condition (integrity, color, and temperature), presence of edema and/or wounds, vascularity, pain, manual muscle testing, compliance, cognitive ability, and medical history.

Survey Preparation Questions

6. Describe your process for performing an in-person, diagnosis-specific clinical and functional examination related to the beneficiary's need for and use of the orthosis, prosthesis, or diabetic shoes/inserts ordered.

What is your process for documenting this information? (Check all that apply.)

- ❑ A specific form
- ❑ Narrative notes
- ❑ Dictation/transcribed notes
- ❑ Letter
- ❑ Other(s)

If *other(s)*, please specify:

What evidence do you have that shows that an in-person, diagnosis-specific functional and clinical examination related to the beneficiary's need for and use of the item or device has been completed for each beneficiary for whom you provide custom-fabricated orthoses, prostheses, or diabetic shoes/inserts?

Where in the beneficiary's record is this information documented?

7. A treatment plan is formulated for the beneficiary that is:
- **a. Consistent with the prescribing physician's:**
  - **(1) Dispensing order.**
  - **(2) Written plan of care.**
- **b. In accordance with Medicare rules.**
- **c. Done in consultation with the prescribing physician, when appropriate.**

Survey Preparation Questions

7. Describe how you ensure that a treatment plan is formulated for each beneficiary that is consistent with the prescribing physician's:

- Dispensing order.

- Written plan of care.

How do you ensure that each treatment plan is in accordance with Medicare rules?

Describe how treatment plans are formulated in consultation with the prescribing physician, when appropriate.

What evidence to you have to demonstrate conformance to this standard?

Where in the beneficiary's record can the treatment plans be found?

8. The supplier establishes goals and expected outcomes for the use of the orthosis, prosthesis, or diabetic shoes/inserts provided, with feedback from the beneficiary and/or prescribing physician as necessary.

Examples

Goals and expected outcomes for beneficiaries may include reducing pain, increasing comfort, enhancing function and independence, improving joint stability, preventing deformity, increasing range of motion, addressing cosmetic issues, and promoting healing.

Survey Preparation Questions

8. Describe your process for establishing goals and expected outcomes for beneficiaries.

What is your process for documenting this information? (Check all that apply.)

- ❑ A specific form
- ❑ Narrative notes
- ❑ Dictation/transcribed notes
- ❑ Letter
- ❑ Other(s)

If *other(s)*, please specify.

Where in the beneficiary's record is this information documented?

9. For each orthosis, prosthesis, or pair of diabetic shoes/inserts provided to the beneficiary, the supplier ensures that the recommended treatment plan:

a. Includes disclosure of the:

(1) Potential risks of the item or device.

(2) Benefits of the item or device.

(3) Precautions.

(4) Procedures for the repair, replacement, and adjustment of the item or device.

(5) The time frame that the treatment plan is in effect.

b. Is communicated to the:

(1) Beneficiary and/or caregiver.

(2) Prescribing physician.

c. Is consistent with the prescribing physician's dispensing order.

Survey Preparation Questions

9. Describe your process for ensuring that the recommended treatment plan for each orthosis, prosthesis, or pair of diabetic shoes/inserts provided to a beneficiary includes disclosure of the following information:

- Potential risks of the item or device.

- Benefits of the item or device.

- Precautions.

- Procedures for the repair, replacement, and adjustment of the item or device.

- The time frame that the treatment plan is in effect.

Describe your process to ensure that the treatment plan is communicated to the beneficiary and/or caregiver and prescribing physician.

Describe your process to ensure that the treatment plan is consistent with the prescribing physician order.

What evidence do you have that shows that a treatment plan for each beneficiary meets all elements of this standard?

Where in the beneficiary's record is this information documented?

10. Prior to face-to-face fitting and delivery, the orthosis, prosthesis, or pair of diabetic shoes/inserts is assessed for:

a. Being structurally safe for accommodating the beneficiary's weight.
b. All closures being in working order.
c. Being free of defects.
d. Ensuring that the manufacturer's guidelines are being followed.

Survey Preparation Questions

10. Describe your process for ensuring that the orthosis, prosthesis, or pair of diabetic shoes/inserts is assessed prior to the face-to-face fitting and delivery to the beneficiary for:

- Being structurally safe for accommodating the beneficiary's weight.

- All closures being in working order.

- Being free of defects.

- Ensuring that the manufacturer's guidelines are being followed.

What evidence do you have that shows that you assess for all of the above safety features prior to fitting and delivering the item or device to the beneficiary?

Where in the beneficiary's record is this information documented?

Training/Instruction to Beneficiary and Caregiver(s)

11. For specific orthoses, prostheses, or therapeutic shoes/inserts, training and instructions provided to the beneficiary and/or caregiver include, at a minimum, the following:

- **a. Use of the specific item or device.**
- **b. Maintenance of the specific item or device.**
- **c. Cleaning of the specific item or device.**
- **d. Therapy, if recommended by physician or healthcare team member.**
- **e. Residual limb hygiene.**
- **f. How to don and doff the specific item or device.**
- **g. How to adjust closures for proper fit.**
- **h. Skin inspection of the area directly in contact with the item or device to detect:**
  - **(1) Pressure areas.**
  - **(2) Discoloration (redness).**
  - **(3) Irritation.**
  - **(4) Skin breakdown.**

(5) Pain.

(6) Edema.

i. Utilization of the appropriate interface (e.g., stockinettes, socks, gloves, shoes) to accommodate the specific item or device, where appropriate.

j. Reporting problems related to the use of the specific item or device if any of the following are noted:

(1) Changes in skin condition.

(2) Increased pain.

(3) Increased edema.

(4) Wound concerns.

(5) Changes in general health, height, and weight.

(6) Intolerance to wearing the specific item or device.

k. Scheduling for follow-up appointments, as necessary.

l. Establishing an appropriate schedule for incrementally increasing tolerance to wearing or using the specific item or device.

Survey Preparation Questions

11. Describe the instructions given to beneficiaries and/or caregivers on the:

- Use of the specific item or device.

- Maintenance of the specific item or device.

- Cleaning of the item or device.

- Physician's or healthcare team member's recommendation to schedule for follow-up therapy.

- Proper hygiene of the residual limb.

- Donning and doffing of the item or device.

- Procedures to follow for adjusting closures for a proper fit.

- Regular inspection of skin in the area directly in contact with the item or device to report changes in skin condition such as the presence of pressure areas, discoloration, irritation, skin breakdown and wound concerns, edema, and pain; general health, height, and weight; and intolerance to wearing the item or device:

- Utilization of the appropriate interface (e.g., stockinettes, socks, gloves, shoes) to accommodate the specific item or device, where appropriate.

- Procedures for scheduling for follow-up appointments, when necessary.

- Appropriate schedule for incrementally increasing tolerance to wearing or using the specific item or device.

How do you ensure that all required education and training is provided to every beneficiary and/or caregiver who receives the prescribed item or device?

What method(s) do you use for providing all the instructions required by this standard? (Check *yes* for all that apply.)

- Manufacturer's user's guide or manual ❑ Yes
- Additional written instructions developed by your company ❑ Yes
- Pictorial instructions developed by your company or by the manufacturer ❑ Yes
- Brochures ❑ Yes
- Verbal ❑ Yes
- Demonstration given by supplier ❑ Yes

- Demonstration given by supplier followed by demonstration by beneficiary ❑ Yes
- Videos and/or instructional compact discs shown to beneficiary ❑ Yes
- Videos and/or instructional compact discs given to beneficiary to keep ❑ Yes
- Other (please describe): ❑ Yes

_____

_____

12. The supplier provides necessary supplies for the prescribed item or device and information on how to subsequently obtain the supplies in order to:

a. Attach them.

b. Maintain them.

c. Clean them.

Examples

Supplies may include, but are not limited to, adhesives, solvents, lubricants, or cleaning products.

Survey Preparation Questions

12. Give examples of the supplies you provide to the beneficiary used for:

- Attaching the prescribed item or device.

_____

_____

_____

- Maintaining the prescribed item or device.

_____

_____

_____

- Cleaning the prescribed item or device.

Do you keep a record of the provision of these supplies? ❑ Yes ❑ No

If *yes*, where in your records is this information contained?

If *no*, explain how you will verify that you meet this standard.

Describe the information you give the beneficiary on how to subsequently obtain the supplies.

How do you provide the information to the beneficiary on how to subsequently obtain the supplies?

13. For intervention that is beyond the supplier's scope of practice, the supplier ensures that the beneficiary is referred back to the prescribing physician.

Survey Preparation Questions

13. Describe the specific procedures that you require your employees to follow in order to identify the following:

- When the intervention required by the beneficiary is beyond the scope of practice of your credentialed profession.

- The steps taken to refer the beneficiary to the prescribing physician for the necessary intervention that you find to be beyond the scope of your practice.

- The specific guidelines and/or your state's practice act, if applicable, that you follow to guide you in your decision making.

Follow-Up

14. For the provision of custom-fabricated and/or custom-fitted orthoses, prostheses, or diabetic shoes/inserts, the supplier demonstrates access to a facility with the necessary equipment to provide follow-up treatment and services that include:

a. Fabrication of the specific item or device.
b. Modification of the specific item or device.
c. Adjustment of the specific item or device.
d. Maintenance of the specific item or device.
e. Repair of the specific item or device.

Examples

If the supplier utilizes a shop owned by another supplier, arranged either through a formal contractual arrangement or an informal arrangement, there should be adequate access so that modifying or adjusting the item for the beneficiary can be done in a timely manner.

Survey Preparation Questions

14. Where do you fabricate, modify, adjust, maintain, and repair items or devices received by the beneficiary as part of your follow-up services? (Check all that apply.)

- ❑ Shop located at main business location
- ❑ Supplier-owned shop at a location separate from main business location
- ❑ Access to another supplier's equipment

Describe your facility's appropriate equipment for follow-up services to:

- Fabricate the specific item or device.

_____

_____

- Modify the specific item or device.

_____

_____

- Adjust the specific item or device.

_____

_____

- Maintain the specific item or device.

_____

_____

- Repair the specific item or device.

_____

_____

If you only have access to another supplier's equipment:

- Are you given *unlimited* access to use the other supplier's equipment? ❑ Yes ❑ No
- Are you given *limited* access to use the other supplier's equipment? ❑ Yes ❑ No

- Does the other supplier perform the services of modifying and adjusting the equipment for you? ❑ Yes ❑ No

If you do *not* fabricate, modify, adjust, maintain, or repair customized items and devices you provide to beneficiaries, describe how you fulfill your responsibility to ensure that these follow-up services are provided to your beneficiaries.

If customized items or devices are sent out for modification, adjustment, maintenance, or repair, describe your quality assurance process to ensure that the returned items or devices meet the ordered specifications.

Survey Preparation Tip:

The surveyor(s) will observe your own area or the off-site facility where the custom items or devices are modified, adjusted, repaired, and maintained.

15. Follow-up treatment is provided to the beneficiary that is consistent with:

a. The types of orthoses, prostheses, or diabetic shoes/inserts provided.
b. The beneficiary's diagnosis.
c. The specific care rendered.
d. Recommended maintenance.

Examples

Follow-up is a critical component of the process of supplying DMEPOS. It facilitates practices that are based on a quality framework. It also allows a supplier to realize whether or not its work has been understood and followed through with on the part of the beneficiary and caregiver. It allows for good learning on the part of the supplier if results are analyzed.

Survey Preparation Questions

15. Describe your follow-up treatment for the beneficiary to ensure that it is consistent with the:

- Types of orthoses, prostheses, or diabetic shoes/inserts provided.

- Beneficiary's diagnosis.

- Specific care rendered.

- Recommended maintenance.

As a rule, who generally initiates the follow-up treatment?	❑ You	❑ The beneficiary
Do you document the follow-up treatment in the beneficiary's record?	❑ Yes	❑ No

If *yes*, where in the beneficiary's record is this information documented?

If *no*, what evidence do you have that shows that follow-up treatment is provided for each beneficiary for whom you provide custom-fabricated orthoses, prostheses, or diabetic shoes/inserts?

16. Follow-up services are provided to the beneficiary to:

- **a. Continue to assist the beneficiary until the orthosis, prosthesis, or diabetic shoe/insert reaches the optimal level of fit and function consistent with the treatment plan.**
- **b. Review and make changes to the treatment plan based on the beneficiary's current medical condition.**

Survey Preparation Questions

16. For each beneficiary to whom you provide custom orthoses, prostheses, or diabetic shoes/inserts, describe how your follow-up care is consistent with the beneficiary's individual treatment plan for reaching optimal level of fit and function of the custom item or device.

Describe your processes for making changes to the beneficiary's treatment plan based on changes in his or her medical condition when it becomes necessary to do so.

What evidence do you have that shows that you provide follow-up services, as necessary, to beneficiaries to ensure that optimal fit and function have been reached and changes are made in the treatment plan based on their medical condition?

Where in the beneficiary's record is this information documented?

17. To determine the effectiveness and appropriateness of the orthosis, prosthesis, or diabetic shoes/inserts, the supplier elicits feedback from the beneficiary and prescribing physician, as necessary, regarding:

- **a. Proper usage.**
- **b. Function.**
- **c. Wear schedule and tolerance.**
- **d. Comfort level.**
- **e. Perceived benefits.**
- **f. Perceived detriments.**
- **g. Ability to don and doff.**
- **h. Overall beneficiary satisfaction.**

Survey Preparation Questions

17. Describe your process for eliciting feedback from the beneficiary and/or caregiver and prescribing physician, as necessary, about the effectiveness and appropriateness of the orthosis, prosthesis, or diabetic shoes/inserts to obtain information regarding:

- Proper usage.

- Function.

- Wear schedule and tolerance.

- Comfort level.

- Perceived benefits.

- Perceived detriments.

- Ability to don and doff.

- Overall satisfaction with the custom item or device.

How often do you contact the beneficiary to elicit the necessary feedback?

What is your process for making the necessary corrections until the custom item or device meets all the beneficiary's needs required by this standard?

What evidence do you have that shows that you elicit feedback from the beneficiaries to ensure that their needs are met satisfactorily according to this standard?

Where do you document the information you obtain from the beneficiary?

GLOSSARY

Acquisition: The purchase by one legal entity of some or all of the assets of another legal entity. In an acquisition, the purchasing entity may or may not assume some or all of the liabilities of the selling entity. Generally, the selling entity continues in existence.

Advance Beneficiary Notice (ABN): A written notice a physician or supplier gives to a Medicare beneficiary before items or services are furnished when the physician or supplier believes that Medicare probably or certainly will not pay for some or all of the items or services on the basis of one of seven statutory exclusions.

Adverse event: An untoward, undesirable, and usually unanticipated event such as a death of a person served, an employee, a volunteer, or a visitor in a provider organization. Incidents such as a fall or improper administration of equipment or a device are also considered adverse events even if there is no permanent effect on the individual or person served.

Beneficiary: A person who is entitled to Medicare benefits.

Catastrophe: A disaster or accident that immediately impacts a supplier's ability to provide DMEPOS or significantly impacts how DMEPOS will be provided in the future.

Certificate of Medical Necessity (CMN): A form or other document containing information required by the carrier to be submitted to show that an item is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member

Claims modifier: A code added on to the regular CPT code to recognize additional work and resources required to document the need for the equipment, items, or services billed for.

Complex rehabilitation and assistive technology: Adaptive seating, positioning, and complex mobility devices that are evaluated, fitted, configured, adapted, and modified based on the unique clinical and functional needs of persons with severe disabilities.

Consolidation: The combination of two or more legal entities into a single legal entity, where the entities unite to form a new entity and the original entities cease to exist. In a consolidation, the consolidated entity has its own name and identity and acquires the assets and liabilities of the disappearing entities.

CPT codes: Current Procedural Terminology. Codes used when filing insurance and/or Medicare claims to identify services rendered or procedures used in the medical treatment of an individual.

Custom fabricated: A custom fabricated item is one that is individually made for a specific patient. No other patient would be able to use the item.

1. A *custom fabricated* item is defined as a device that is fabricated based on a clinically derived rectified casting, tracings, measurements and/or images (such as x-rays) of the body part. It may involve using calculations, templates, and components. The process starts with basic materials including, but not limited to, plastic, metal, leather, and or cloth in the form of uncut or unshaped sheets, bars, or other basic forms. It involves substantial work such as vacuum forming, cutting, bending, molding, sewing, drilling, and finishing prior to fitting on the patient.

2. A *molded-to-patient-model* item is a particular type of custom fabricated device in which either:
   a. An impression (usually by means of a plaster or fiberglass cast) of the specific body part is made directly on the patient, and this impression is then used to make a positive model of the body part from which the final product is crafted; or
   b. A digital image of the patient's body part is made using a computer-aided design/computer-aided manufacturing (CAD/CAM) systems software. This technology includes specialized probe/digitizers and scanners that create a computerized positive model and then direct milling equipment to carve a positive model. The device is then individually fabricated and molded over the positive model of the patient.

Custom fitted: A prefabricated (also referred to as custom-fitted) device that is manufactured in quantity without a specific patient in mind. The device may or may not be supplied as a kit that requires some assembly and/or fitting and adjustment, trimming, bending, molding (with or without heat), or is otherwise modified by an individual with expertise in customizing the item to fit and be used by a specific patient.

DME MAC: Durable Medical Equipment Medicare Administrative Contractor. There are four regions in the United States: regions A, B, C, and D. These are carriers that are contracted by CMS to be its administrator in each region.

Durable medical equipment: Equipment used in the home that can withstand repeated use, is primarily and customarily used to serve a medical purpose, and is generally not useful in the absence of an illness or injury.

HCPCS: Healthcare Common Procedure Coding System. The means by which DMEPOS services are identified for Medicare billing.

ICD-9: *International Classification of Diseases—9th Edition/Revision.* A statistical classification and numeric coding system that arranges diseases or injuries into groups according to criteria established by the World Health Organization and is revised approximately every ten years. Since 1988, diagnostic coding using ICD-9 has been mandatory for filing Medicare claims. The ICD-9 codes are assigned by the prescribing healthcare practitioner.

Inserts: Total contact, multiple density, and removable inlays that are directly molded to the patient's foot or are based on a model of the patient's foot. Inserts are made of suitable material with regard to the patient's condition.

Investigation: A detailed inquiry or systematic examination by a third party into the appropriateness of acts by a supplier or its personnel, if such acts (a) related directly to conformance or nonconformance to applicable standards; or (b) are of such breadth or scope that the supplier's entire operations may be affected.

Joint venture: A business undertaking by two or more legal entities in which profits, losses, and control are shared, which may or may not involve the formation of a new legal entity. If a new entity is formed, the original entities continue to exist.

Material litigation: A legal proceeding initiated by a third party concerning the appropriateness of acts by a supplier or its personnel, if such acts (a) relate directly to conformance or nonconformance to applicable standards; or (b) are of such breadth or scope that the supplier's entire operations may be affected.

Merger: The combination of two or more legal entities into a single legal entity, where one entity continues in existence and the others cease to exist. In a merger, the surviving entity retains its name and identity and acquires the assets and liabilities of the disappearing entities.

Objective: Specific statement of expected outcomes, which are observable, measurable, and achievable within a defined time period.

Off-the-shelf orthoses: Orthoses that require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit the beneficiary. (Note: Appendix C of the *CMS Quality Standards for Suppliers of DMEPOS* does not apply to off-the-shelf orthoses.)

Orthotic devices: Rigid or semi-rigid devices used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body.

Outcome: An end point or result achieved through a process of collecting, measuring, and compiling data at a defined point of time following delivery of products and services.

PDAC: Pricing, Data Analysis and Coding contractor for the CMS. Effective August 18, 2008, Noridian Administrative Services, LLC (NAS) has been named the PDAC contractor to perform the following activities that Palmetto GBA, as the Statistical Analysis DME Regional Carrier (SADMERC), previously performed:

- Provide data analysis support to the DME Program Safeguard Contractors (PSCs).
- Guide manufacturers and suppliers on the proper use of the HCPCS for Medicare billing purposes through product reviews and decisions, the DMECS system, and the HCPCS Helpline.
- Conduct national pricing functions for DMEPOS services.
- Assist CMS with DMEPOS fee schedules.

Performance indicators: Measurable values that provide an indication of the condition or direction of the company or organization. Performance indicators relate to the information that suppliers, beneficiaries, or other stakeholders want to know about the company's or organization's business practices that will bring about the desired effect of the quality of the products and services it provides.

Policy: Written course of action or guidelines adopted by leadership. Policies should be consistent with actual practice.

Positive model of the patient:

1. Molded to a patient model is a negative impression taken of the patient's body member and a positive model rectification is constructed.
2. CAD/CAM system, by use of digitizers, transmits surface contour data to software that the practitioner uses to rectify or modify the model on the computer screen. The data depicting the modified shape are electronically transmitted to a commercial milling machine that carves the rectified model.
3. Direct formed model is one in which the patient serves as the positive model. The device is constructed over the model of the patient and is then fabricated to the patient. The completed custom fabrication is checked and all necessary adjustments are made.

Prefabricated: A prefabricated (also referred to as custom-fitted) device that is manufactured in quantity without a specific patient in mind. The device may be supplied as a kit or prefabricated parts that require some assembly and/or fitting and adjustment, or a device that must be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific patient (i.e., custom fitted).

Procedure: A how-to description of actions to be taken. Often procedures follow a policy statement.

Prosthetic devices: Devices (other than dental) that replace all or part of an internal body organ, including contiguous tissues, or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ and includes replacement of such devices. This does not require a determination that there is no possibility that the patient's condition may improve sometime in the future. If the medical record, including the judgment of the attending

physician, indicates that the condition is of long and indefinite duration, the test of permanence is considered met. Examples of prosthetic devices include colostomy bags and supplies directly related to colostomy care, one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens, cardiac pacemakers, cochlear implants, electrical continence aids, electrical nerve stimulators, and tracheostomy speaking valves.

Sentinel event: An unexpected occurrence within an accredited supplier involving death or serious physical or psychological injury or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase *or the risk thereof* includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called sentinel because they signal the need for immediate investigation and response.

Somatic prostheses: Custom-fabricated somatic prostheses replace areas of the human body not included under definitions of facial and ocular prosthetics, but require visual and functional integration in order to be acceptable. Somatic prosthetics typically include finger, thumb, partial hand, hand, and toe disfigured by traumatic injury, disease, ablative surgery, or congenital malformation

Stakeholder: Individuals or groups who have an interest in the activities and outcomes of a supplier and its products and services. They include, but are not limited to, the beneficiaries, caregivers, families, governance or designated authority, purchasers, regulators, referral sources, personnel, employers, advocacy groups, contributors, supporters, landlords, business interests, and the community.

Supplier: A physician or other practitioner, or a business or corporate entity other than a Medicare provider, furnishing CMS-listed product categories and related services under Medicare Part B. One category of supplier includes one that furnishes DMEPOS. Other categories of DMEPOS suppliers include physicians or other practitioners who provide any covered DMEPOS product categories as part of their professional services and who are certified to bill for reimbursement under Medicare Part B.

Therapeutic shoes: Includes depth or custom-molded shoes along with inserts for individuals with diabetes.

1. *Custom-molded shoes:*
   - Are constructed over a positive model of the patient's foot.
   - Are made from leather or other suitable material of equal quality.
   - Have removable inserts that can be altered or replaced as the patient's condition warrants.
   - Have some form of shoe closure.
2. *Depth shoes:*
   - Have full-length, heal-to-toe filler that, when removed, provides a minimum of 3/16 inch of additional depth used to accommodate custom-molded or customized inserts.
   - Are made from leather or other suitable material of equal quality.
   - Have some form of shoe closure.
   - Are available in full and half sizes with a minimum of three widths so that the sole is graded to the size and width of the upper portions of the shoes according to the American standard last sizing schedule or its equivalent. (The American standard last sizing schedule is the numerical shoe sizing system used for shoes sold in the United States.)

Wheelchair: 42 CFR 414.202 interprets the term wheelchair to include both power wheelchairs and power-operated vehicles (POVs or scooters) and collectively refers to power wheelchairs and power-operated vehicles as power mobility devices (PMD).

SUPPLEMENT A

Documents to Provide Prior to Survey

Current copies of the following items must be sent to CARF with the Intent to Survey. Prior review of documentation streamlines the survey. Related standard numbers are provided for reference.

- **1.A.2.** Organizational chart; bylaws, if the supplier is a corporation; and management job descriptions
- **1.A.3.** Declaration sheets for insurance policies
- **1.A.6.** Licenses, certificates, and permits
- **1.A.10.** Procedure for dealing with fraud, waste, and abuse
- **1.B.6.** Annual budget, including projected income and expenses
- **1.C.2.** Training schedules, inservices, and/or documentation of attendance at trainings
- **1.D.1.a.** Sample of written or pictorial equipment/item instructions provided to beneficiaries
- **1.D.1.e.** Sample of rental equipment contact information provided to beneficiaries, if applicable
- **1.D.1.g.** Sample of customer service assistance contact information provided to beneficiaries
- **1.E.1.** Most recent performance management plan that establishes measurable objectives and how data will be collected to measure results of:
  - Outcomes of consumer services
  - Billing practices
  - Adverse events
- **1.E.3.** Most recent performance management outcomes data in the following areas:
  - Beneficiary satisfaction
  - Beneficiary complaints
  - Timeliness of responses to beneficiary questions, problems, and concerns
  - Impact of business practices on beneficiary access to equipment/items, services, and information
  - Frequency of billing and coding errors
  - Adverse events
- **1.F.5.** Contingency plan and emergency and disaster plan

- Additional CMS-related documents:
  - **1.A.9.a.–b.** Copy of most recently submitted Form 855S (Form CMS-855S per **www.cms.hhs.gov/MedicareProviderSupEnroll/Downloads/Durable-MedicalEquip.pdf**) Medicare enrollment application for DMEPOS suppliers (Section 2 only)
  - **1.A.9.c.** Copy of blank Advanced Beneficiary Notice (ABN)
  - **1.G.2.a.** Copy of HIPAA Notice of Privacy Practices
- Specific product-related services documents, when applicable:
  - **3.B.2.** Copy of credentials of CRTS or ATP, as applicable
  - **3.B.4.a.** Evidence (certificate, syllabus, or program) of technician(s)' factory training by manufacturer of products supplied by supplier
  - **3.B.4.c.** Evidence of completion of at least 10 hours of continuing education (certificate, syllabus, or program) by technician(s)
  - **3.B.11.** Sample assessment form, if one is used, or a copy of a completed assessment with personal health information redacted
  - **3.C.2.** Copy of certification or licensure (in states where licensure is required) of individual(s) who provide the custom-fabricated and custom-fitted ortheses, prostheses, or diabetic shoes/inserts
  - **3.C.6.** Sample form, if applicable, for recording information from diagnosis-specific clinical and functional examination related to the need for and use of item. If no form is used, a copy of a completed examination with personal health information redacted
  - **3.C.7.**, **3.C.8.**, and **3.C.17.** Sample form(s), if applicable, for recording treatment plans, goals and expected outcomes, and beneficiary feedback about the effectiveness of the items provided. If no form is used, provide a copy from a sample record with personal health information redacted that will confirm this standard is met.
  - **3.C.11.** Sample instruction sheet that contains all elements of this standard

Subsequent Surveys (Resurveys)

At the time you are required to submit your Intent to Survey on subsequent surveys, CARF will identify which of the above documents may be excluded. However, you are required to submit with your Intent to Survey for a resurvey the following item:

- **Updated Quality Improvement Plan (QIP).** Although you are required to submit a QIP within 90 days following receipt of the notice of accreditation, the survey team must have an updated QIP that demonstrates your efforts to correct all areas of improvement identified on your previous survey have been addressed and completed.

SUPPLEMENT B

Sample Forms and Checklists

The forms provided in this section are not official forms; they are merely examples intended as a starting point for suppliers in developing their own forms for use. Use of these forms is not required for accreditation, but may be helpful in developing or enhancing processes and services to conform to the standards.

- Contents of Corporate Bylaws

  Related Standard: 1.A.2.
  This list provides an example of the articles generally contained in corporate bylaws.

- Sample Corporate Bylaws

  Related Standard: 1.A.2.
  This document provides an example of a company's corporate bylaws.

- Equipment Warranty Information Form

  Related standard: 1.A.8.
  This form gives an example of a warranty policy to be provided to and discussed with beneficiaries.

- Code of Ethical Conduct

  Related Standard: 1.A.10.
  This document provides an example of a written code of ethical conduct, which becomes part of a company's fraud, waste, and abuse prevention program.

- Fraud, Waste, and Abuse Reporting Form

  Related Standard: 1.A.10.
  This form provides an example of how to collect information on potential fraud, waste, and abuse. The option to provide this feedback anonymously demonstrates a supplier's commitment to prevent retaliation for reporting.

- Fraud, Waste, and Abuse Checklist

  Related Standard: 1.A.10.
  This checklist provides an example of situations and time lines to consider in the prevention of fraud, waste, and/or abuse.

- Equipment Warranty Information Form

  Related Standard: 1.D.1.
  This form gives an example of warranty policy to be provided to and discussed with beneficiaries.

- Item Unavailability Notification Form

  Related Standard: 1.D.2.
  This form provides an example of how to track and document notification of the prescribing physician when equipment, items, or services prescribed to the beneficiary are unavailable.

- Beneficiary Complaint Log Form

  Related Standards: 1.D.3.–1.D.5.
  This form provides an example of how to log beneficiary complaints, including information regarding notification and investigation.

- Performance Management Plan

  Related Standard: 1.E.1.
  This table provides an example of a company's performance management plan that describes the objective domains, indicators to be measured, information wanted from the data gathered, frequency of data analysis, and ultimate use of the information obtained.

- Performance Management Outcomes Data Report

  Related Standard: 1.E.3.
  This table provides an example of a framework to use for reporting the outcomes as required by the standards.

- Beneficiary Satisfaction Survey

  Related Standard: 1.E.3.a.
  This form provides an example of a written survey given to beneficiaries to rate the company's performance on providing products and services.

- Injury/Accident Description Form

  Related Standard: 1.F.3.
  This form provides an example of how to collect relevant information regarding an injury or accident related to the supplier's products and/or services.

- Sample Notice of Privacy Practices

  Related Standard: 1.G.1.
  This document informs customers about the uses and disclosure of their personal health information and how they can gain access to this information.

- Medicare DMEPOS Supplier Enrollment Standards

  Related Standards: 1.G.2.
  This document is a shortened version of the standards to which suppliers are required to be in conformance and must disclose to each Medicare beneficiary to whom a supplier supplies Medicare-covered DMEPOS equipment or items.

- Prescription Change Recommendation Form

  Related Standard: 2.B.2.
  This form provides an example of how a supplier could document recommended changes to prescriptions of items and/or services to both the prescribing physician and in its own records.

- Sample Care and Maintenance Guidelines

  Related Standard: 3.C.11.
  This sample shows a set of guidelines to be provided to beneficiaries receiving an ankle/foot orthosis. It could be used as a template for creating guidelines for each item a supplier provides.

- Sample Beneficiary Instruction Checklist

  Related Standard: 3.C.11.
  This sample shows an instructional checklist to be provided to and discussed with beneficiaries receiving an arm and/or hand splint. It could be used as a template for creating this type of checklist for each item a supplier provides.

CONTENTS OF CORPORATE BYLAWS

Articles:

I -- General
Sections: 1) Name of company/organization; 2) Office; 3) Objects and Purposes

II -- Membership (of organization) – if applicable

III -- Elected Officers
Sections: 1) Officers; 2) Election; 3) Duties of Officers; 4) Executive Director or CEO; 5) Attendance; 5) Term of Office; 6) Vacancy; 7) Compensation

IV -- Board of Director or Directors
Sections: 1) Membership; 2) Duties; 3) Vacancy; 4) Meetings of BOD; Executive Committee; 5) Qualifications; 6) Vote; 7) Removal

V -- Committees
Sections: 1) Summary paragraph; 2) Identified standing committees

VI -- Meetings
Sections: 1) Annual meeting of membership; 2) Special Meetings; 3) Quorum; 4) Right to vote; 5) Ballot

VII -- Nomination and Election of Directors
Sections: 1) Nominating Committee; 2) Procedure for Nominations; 3) Term for Nominating Committee

VIII – Advisors – if applicable
Sections: 1) Election; 2) Duties; 3) Vacancy

IX – Finances
Sections: 1) Fiscal Year; 2) Checks

X -- Liability and Indemnification
_____ shall indemnify every Officer and Director of the Association against any and all expenses, including counsel fees, reasonably incurred by or imposed upon any Officer or Director in connection with any action, suit or other proceeding (including the settlement of any such suit or proceeding if approved by the then Board or Directors of the Association) to which the Officer or Director may be made a party by reason of being or having been an Officer or Director of the Association whether or not such person is an Officer or Director at the time such expenses are incurred. The Officers and Directors of the Association shall not be liable to the members of the Association for any mistake of judgment, negligence, or otherwise, except for their own individual willful misconduct, or bad faith. The Officers and Directors of the Association shall indemnify and forever hold such Officer and Director free and harmless against any and all

liability to others on account of any such contract or commitment. Any right to indemnification provided for herein shall not be exclusive of any other rights to which any Officer or Director of the Association, or former Officer or Director of the Association may be entitled.

XI -- Amendments

Sections: 1) Offering amendments; 2) Ratification

XII – Dissolution

_____ shall use its funds only to accomplish the objectives and purposes specified in these By-Laws and no part of said funds shall inure, or be distributed to the Members of the Association. On dissolution of the Association, any funds remaining after the payment of outstanding obligations shall be distributed to one or more regularly organized and qualified charitable, educational, scientific or philanthropic organizations to be selected by the Board of Directors.

SAMPLE CORPORATE BYLAWS

These are the by bylaws of Name of Company, a state it is located in type corporation.

Shareholders
Name: 50% of Corporate shares
Name 50% of Corporate shares

ARTICLE I: MEETING OF SHAREHOLDERS

1. The **annual meeting** will be held on the third Sunday in January. The annual meeting of shareholders will begin at 1:00 p.m. MST and will take place at the principal business location of the corporation or the corporate offices at the discretion of the shareholders.
2. At the annual meeting, the shareholders named above constitute the **board of directors.**
3. A **special meeting** of the shareholders may be called at any time by the president.
4. For a special meeting, the agenda may include the purposes of the meeting; no **action** can be taken at a special meeting except as stated in the notice, unless all shareholders consent.
5. Shareholders may attend a meeting either in person or by proxy. A **quorum** of shareholders at any shareholders meeting will consist of the owners of a majority of the shares outstanding. If a quorum is present, the shareholders may adjourn from day to day as they see fit, and no notice of such adjournment need be given. If a quorum is not present, the shareholders present in person or by proxy may adjourn to such future time as they agree upon; notice of such adjournment must be mailed to each shareholder at least 15 days before such adjourned meeting.
6. Each shareholder, whether represented in person or by proxy, is **entitled to one vote** for each share of stock standing in his or her name on the books of the company.
7. **Proxies** must be in writing.
8. Shareholders may, by **written consent**, take any action required or permitted to be taken at an annual or special meeting of shareholders. Such action may be taken without prior notice to shareholders. The written consent must:
   state the action taken, and
   be signed and dated by the owners of shares having at least the number of votes that would be needed to take such action at a meeting.

ARTICLE II: STOCK

1. Stock certificates must be **signed** by the president and secretary of the corporation.
2. The name of the **person owning shares** represented by a stock certificate, the number of shares owned, and the date of issue will be entered in the corporation's books.
3. All **stock certificates transferred** by endorsement must be surrendered by cancellation. **New certificates** will be issued to the purchaser or assignee.

4. Share of stock can be **transferred** only on the books of the corporation and **only by the secretary**.

ARTICLE III: BOARD OF DIRECTORS

1. The **board of directors will be made up** by the officers of the corporation and will manage the business of the corporation and will exercise all the powers that may be exercised by the corporation under the statutes of the state of _____, the articles of incorporation or the corporate bylaws.
2. A **vacancy on the board of directors** by reasons of death, resignation, or other causes may be filled by an heir of the shareholders, or the board may leave the position unfilled, in which case it will be filled by the direction of the remaining shareholder at a special meeting or at the next annual meeting. During periods when there is an unfilled vacancy on the board of directors, actions taken by the remaining director(s) will constitute actions of the board.
3. The **board of directors will meet** concurrently at the corporate shareholders annual meeting. The board of directors may also hold other regular meetings, at times and places to be fixed by unanimous agreement of the board. At annual or regular meetings, the **board may take any actions allowed** by the law or these bylaws.
4. A **quorum** for a meeting will consist of both shareholders/directors.
5. Directors will act only by **unanimous assent of the directors**.
6. The directions will **not be compensated** for serving as such. A director may, however, serve in other capacities with the corporation and receive compensation for such service.
7. **Directors** may **take any action** required or permitted to be taken at a directors' meeting. Such action may be taken without prior notice to the directors.
8. Directors may meet or **participate in meetings by telephone** or other electronic means as long as all directors are continuously able to communicate with one another.

ARTICLE IV: OFFICERS

1. The **officers** of the corporation will consist of:
   A president
   A secretary/treasurer
2. The **president will preside at all meetings** of the directors and shareholders, and will have general charge of the business of the corporation, subject to approval of the board of directors.
3. In **case of the death, disability or absence of the president**, the secretary will perform and be vested with all the duties and powers of the president.
4. The **secretary will keep the corporate records** of shareholders' and directors' meetings.
5. The **treasurer will keep accounts** of all moneys of the corporation received or disbursed, and will deposit all money and valuables in the name of the corporation in the banks and depositories that the directors designate. **Checks against company accounts** will be signed as directed by the board of directors.

6. The **salaries of all officers** will be fixed by the board of directors and may be changed from time to time by the board of directors.

ARTICLE V: FISCAL

1. The **books of the corporation will be closed** at a date to be selected by the directors prior to the filing of the first income tax return due from the corporation. The books will be kept on an accrual basis.
2. Within 75 days after the corporation fiscal year ends, the treasurer will **provide each shareholder with a financial statement for the corporatio**n.

ARTICLE VII: AMENDMENTS

Any of these bylaws may be **amended or repealed** by a majority vote of the shareholders at any annual meeting or at any special meeting called for that purpose.

Adopted by the shareholders of

Name of company
Address
City, State, Zip Code

Adopted on: _____
Date

By: _____, President

By: _____, Secretary/Treasurer

Equipment Warranty Information Form

Every product sold or rented by our company carries a one-year manufacturer's warranty.

[SUPPLIER'S NAME] will notify all Medicare beneficiaries we serve of this warranty coverage, and we will honor all warranties under applicable law.

[SUPPLIER'S NAME] will repair or replace, free of charge, Medicare-covered equipment that is under warranty.

In addition, an owner's manual with warranty information will be provided to beneficiaries for all durable medical equipment we provide whenever this manual is available.

I have been instructed on and understand the warranty coverage on the product I have received.

Beneficiary's signature: _____ Date: _____

Beneficiary's printed name: _____

CODE OF ETHICAL CONDUCT

<Insert company name> will not discriminate against or refuse employment opportunities or professional services to anyone on the basis of race, color, national origin, gender, religion, citizenship status, veteran's status, age, sexual orientation, disability, or any other status protected by law. <Insert company name> will not engage in or condone any form of harassment.

<Insert company name> will extend respect and cooperation to all stakeholders. This includes respecting their rights and views and treating them with fairness, courtesy, and good faith.

<Insert company name> will strive to earn the trust of the public, its customers, employees, and every effort will be made to maintain good working relationships that promote the company's mission.

<Insert company name> will act in accordance with standards of professional integrity, is committed to providing the highest quality of services to internal and external customers, will show a genuine interest in its customers and all stakeholders, and will dedicate itself to their best interests.

<Insert company name> will maintain confidentiality and demonstrates respect of privacy toward organizations, individuals served, employees, and colleagues.

<Insert company name> will continually assess its strengths, limitations, biases, and effectiveness through its efforts to strive for continuous quality improvement the company's organizational management and in the delivery of products and services it provides.

<Insert company name> will accurately represent, advertise, and promote the products and services it provides. <Insert company name> will correct, when possible, misleading or inaccurate information and representations made by anyone inside or outside the company about the pricing, quality, and provision of its products and services.

<Insert company name> or its employees will not accept gifts, gratuities, rebates, or favors, regardless of value, by a vendor of supplies, equipment, items, and services as an inducement and/or in order to influence <insert company name> to procure only their products and services at the exclusion of all others.

<Insert company name> will fully comply with all federal, state, and local laws, rules, and regulations which govern its business practices and all contracts with which it is required to comply. <Insert company name> will not engage in business practices that are clearly defined as outside the bounds of federal, state, and local laws, rules, regulations, and contracts.

<Insert company name> understands that violation of the Ethical Code of Conduct may be subject to, in some cases, reporting to federal, state, local law enforcement and/or regulatory agencies, and funding sources by any of its stakeholders. <Insert company name> will cooperate with any of the aforementioned entities in investigations of alleged violations of the Ethical Code of Conduct.

<Insert company name> will not retaliate against employees or other stakeholders who report a reasonable belief of violations of law or contract or the demonstration of poor business ethics, and the confidentiality of the reporting employee or other stakeholder insofar as possible will be maintained.

I attest that I have read and reviewed the Code of Ethical Conduct for <Insert company name>.

_____

Print employee's name

_____

Employee's signature

_____

Date

(Signed copy will be placed in employee's personnel file)

Fraud, Waste, and Abuse Reporting Form

This form should be completed and delivered to [SUPPLIER NAME]'s Compliance Officer if you have a reasonable belief that [SUPPLIER NAME], or any employee acting on its behalf, has violated or will violate any section of the [SUPPLIER NAME] Corporate Compliance Manual.

1. Date(s) of conduct: _____

2. Employee(s) who violated/will violate the Corporate Compliance Manual:

   _____

   _____

3. Section of the Corporate Compliance Manual violated/to be violated:

   _____

   _____

4. Detailed description of conduct:

   _____

   _____

   _____

   _____

   _____

5. Persons who may have relevant information:
   (include addresses and telephone numbers of non-employees)

   _____

   _____

   _____

Signature (optional): _____ Date: _____

Printed name (optional): _____

Fraud, Waste, and Abuse Checklist

Item for Review	(Depending on supplier structure)		Review Date	Actions to be Taken	Completion Date
	Checked By	Reviewed By			
Event-Based Reviews of Compliance					
Entering of any contract transaction	Compliance Officer	— CFO — Legal counsel — Owner/CEO		— Ensure supplier representative to authorize transaction has authority — Determine supplier's obligations under the transaction — Recommend any needed changes to contract and/ or terms and provisions	
Hiring of new and/or returning employees	Human Resources Manager			— Ensure and document employee receipt of the supplier's *Code of Ethical Conduct*	
Responding to subpoenas, court orders, or other legal requests for information	Compliance Officer	— Legal counsel — Owner/ CEO		— Ensure all such matters are reviewed promptly — Determine supplier's legal requirements regarding subpoena/ request — Release requested information, when appropriate and in conformance with supplier policy	

Item for Review	(Depending on supplier structure)		Review Date	Actions to be Taken	Completion Date
	Checked By	Reviewed By			
Quarterly Reviews of Compliance					
Reports made regarding violation of law, breach of contract, and/or unethical conduct	Compliance Officer	— Risk Management Committee — Risk Manager — Owner/ CEO		— Identify any trends — Recommend remedial actions as deemed appropriate	
Annual Reviews of Compliance					
Employment laws	Human Resources Manager	Compliance Officer		— Identify any changes in employment laws affecting the supplier — Identify any areas of known noncompliance — Identify any remedial actions to take/ undertaken	
Contract compliance	All supplier representatives who have executed contracts in the past calendar year	— Compliance Officer — CFO — Legal counsel — Owner/ CEO		— Confirm compliance with contracts and related obligations — Identify any areas of known noncompliance — Identify any remedial actions to take/ undertaken — Prepare written compliance report	

Item for Review	(Depending on supplier structure)		Review Date	Actions to be Taken	Completion Date
	Checked By	Reviewed By			
Collection and payment of any and all taxes imposed by any taxing authority, as required by law	CFO	— Compliance Officer — Legal counsel — Owner/ CEO		— Ensure all applicable taxes are being collected, including sales and use taxes — Ensure all applicable taxes are being paid on time to the proper taxing authority — Identify any areas of noncompliance — Identify any remedial actions to be taken	
Fiscal policies	CFO	— Compliance Officer — Owner/ CEO		— Ensure all applicable supplier fiscal policies and procedures are being followed — Identify any areas of noncompliance — Identify any remedial actions to be taken	

Item for Review	(Depending on supplier structure)		Review Date	Actions to be Taken	Completion Date
	Checked By	Reviewed By			
Financial statements, reports, and annual information/tax returns	CFO	— Compliance Officer — Owner/ CEO		— Ensure all financial statements, reports, and annual information/tax returns from the past year were prepared in accordance with generally accepted accounting principles — Identify any areas of noncompliance — Identify any remedial actions to be taken	
Code of ethical conduct	Human Resources Manager	— Compliance Officer — Legal counsel — Owner/ CEO		— Ensure the supplier's Code of Ethical Conduct is current and in conformance with any applicable legal requirements — Identify any areas of noncompliance or requiring changes — If changes are needed: — Make any rewrites — Redistribute to all employees — Document receipt of revised Code with employee signatures	

Item for Review	(Depending on supplier structure)		Review Date	Actions to be Taken	Completion Date
	Checked By	Reviewed By			
Conflict of interest policy	Human Resources Manager	— Compliance Officer — Legal counsel — Owner/ CEO		— Ensure the supplier's Code of Ethical Conduct contains a current explanation of what activities are considered a conflict of interest — Identify any noncompliance with said explanation	
Confidentiality policy	Human Resources Manager	— Compliance Officer — Legal counsel — Owner/ CEO		— Ensure the supplier's confidentiality policy contains a current explanation of the supplier's confidentiality rules — Identify any noncompliance with said explanation — Identify any employee records without signed confidentiality policy statement and obtain signatures	
HIPAA compliance	Privacy Officer	— Compliance Officer — Legal counsel — Owner/ CEO		— Ensure the supplier is complying with all applicable privacy policies and procedures — Identify any areas of known noncompliance and any remedial actions taken	

Equipment Warranty Information Form

Every product sold or rented by our company carries a one-year manufacturer's warranty.

[SUPPLIER'S NAME] will notify all Medicare beneficiaries we serve of this warranty coverage, and we will honor all warranties under applicable law.

[SUPPLIER'S NAME] will repair or replace, free of charge, Medicare-covered equipment that is under warranty.

In addition, an owner's manual with warranty information will be provided to beneficiaries for all durable medical equipment we provide whenever this manual is available.

I have been instructed on and understand the warranty coverage on the product I have received.

Beneficiary's signature: _____ Date: _____

Beneficiary's printed name: _____

Item Unavailability Notification Form

— Beneficiary name: _____

— Item/equipment/supply ordered: _____

— Date supplier was notified that item is not available: _____

— Prescribing physician:

  – Name: _____

  – Date notified: _____

— Healthcare team member:

  – Name: _____

  – Date notified: _____

Beneficiary Complaint Log Form

Date complaint received: _____

Beneficiary's name: _____ Phone number: _____

Beneficiary's address: _____

City: _____ State: _____ Zip code: _____

Beneficiary's Medicare or Health Insurance Claim Number: _____

_____

Description of complaint: _____

_____

_____

_____

_____

Date beneficiary was notified that complaint is being investigated: _____

_____

Action taken to resolve the complaint: _____

_____

_____

_____

_____

Date beneficiary was notified of investigation conclusions: _____

_____

Representative's signature: _____ Date: _____

Representative's printed name: _____

PERFORMANCE MANAGEMENT PLANS
ABC MEDICAL SUPPLY

Plan Domain	Indicators/What will be measured	Information wanted	How often reviewed?	How information will be used
Outcomes of consumer services	Customers satisfaction with products and services	How customers rate their satisfaction with the products and services they receive from ABC Medical Supply	Bi-annually	1. Review information to identify where and what types of performance improvement measures are needed if target goals not met. 2. Provide to accreditation org. 3. Share with employees to develop performance improvement plan. 4. Monitor progress towards meeting target goals and revise P&P if needed. 5. Share with private insurance companies when applying to join networks. 6. Possible marketing uses if/when targets are consistently met or exceeded.
	Customer complaints about the products and services they receive.	Actual number of complaints received about products and services	Bi-annually	1. Review information to identify where and what types of performance improvement measures are needed if target goals not met. 2. Identify areas about which most complaints are received for targeting remediation. 3. Provide necessary training for employees and the most appropriate and cost effective type of training. 4. Monitor progress towards meeting target goals & revise P&P if needed. 5. Identify areas where follow-up may be needed.

Plan Domain	Indicators/What will be measured	Information wanted	How often reviewed?	How information will be used
	Timeliness of responses to customers' concerns, questions, or problems	How successful is ABC Medical Supply in meeting its target goal for responding to all customer calls about questions, concerns, or problems?	Bi-annually	1. Review information to identify where and what types of performance improvement measures are needed if target goals not met. 2. Look for trends in types of calls and identify need for correction action. 3. Provide necessary training or remediation for employees to improve performance. 4. Monitor progress towards meeting target goals & revise P&P if needed. 5. Revise goals as necessary 6. Identify areas where follow-up may be needed
Outcomes of customer services	Impact of supplier's business practices on the adequacy of customer access to equipment, items, services, and information.	How successful is ABC Medical Supply in shortening the delay time to 5 days or less between when the physician's order is received and when customer (who receives non- inventory items that must be fitted ordered and delivered) actually received the item/ equipment and all necessary training?	Bi-annually	1. Review information to identify causes for target not being met. 2. Share with employees for feedback on how to improve performance. 3. Monitor progress towards meetings goals. 4. Revise goals as necessary.
Billing practices	Frequency of billing and coding errors	How successful is ABC Medical Supply in decreasing the number of billing and coding errors (determined to be company errors) in the Medicare claims denied	Quarterly	1. Review information to identify causes for errors if target is not met. 2. Share only with employees responsible for filing claims/billing data entry 3. Look to see if there are trends in frequency and types of errors 4. Take remedial action with individual employees to reduce errors 5. Identify and provide training and training opportunities 6. Monitor progress towards meeting goals.

Plan Domain	Indicators/What will be measured	Information wanted	How often reviewed?	How information will be used
Adverse events	Adverse events reported of customers that were due to inadequate or malfunctioning equipment	Number of injuries or deaths reported to company that were investigated and determined to result from inadequate or malfunctioning equipment	Annually	1. Review information to identify any trends in causes. 2. If trends reveal faulty equipment was primary cause check P&P to make sure they were followed for reporting to mfr. 3. Discuss w/employees for implementing improved preventive safety measures. 4. Determine need for improving safety education & training of customers, develop corrective action plan, and implement. 5. Monitor progress towards goal of no reported adverse events.

ABC Medical Supply Outcomes Data

For period ending: _____

Domain/Related Standard	Objective	Indicator	Applied to	Time to Measure	Data Source	Collected by	Target Goal	Actual Results
Customer satisfaction with products and services *[Related standard: 1.E.3.a.]*	Customers will be satisfied with the products and services they receive from ABC Medical Supply	% of customers that rate themselves on a survey overall as *very satisfied* (score of 5) or *satisfied* (score of 4) with the products and services they receive	Customers that received products and services from ABC Medical Supply	Every six months during the calendar year	Customer satisfaction question-naires returned to office	Office Manager	90%	93% [target exceeded]
Customer complaints *[Related standard: 1.E.3.b.]*	Decrease the number of beneficiary complaints about the products and services they receive.	Actual number of complaints received about products and services	Customers who contacted ABC Medical Supply to register a complaint about the products and services	Every six months during the calendar year	Complaints log	Receptionist	<15	18 [target not met]
Timeliness of response to customers *[Related standard: 1.E.3.c.]*	Response time to customers' questions, problems, or concerns will be within 24 hours	% of customers' calls or emails that were responded to within 24 hours	All customers who contact ABC Medical Supply about a problem, concern or a question about products and/or services they received	Every six months during the calendar year	Calls log and emails	Office Manager	95%	98% [target exceeded]

Domain/Related Standard	Objective	Indicator	Applied to	Time to Measure	Data Source	Collected by	Target Goal	Actual Results
Impact of supplier's business practices on the adequacy of customer access to equipment, items, services, and information *[Related standard: 1.E.3.d.]*	Shorten delay in giving customers access to ABC Medical Supply's equipment, items, services, and information to 5 days or less of receipt of physician's order	% of customers who were delivered their equipment/items, given training and received all necessary information about equipment/item within 5 days of receipt of the physician's order	All customers who receive non-inventory items that must be fitted, ordered, and delivered	Every six months during the calendar year	Excel spread sheet designed for tracking these data	Office manager	98%	90% [below target]
Frequency of billing and coding errors *[Related standard: 1.E.3.e.]*	Decrease the number of billing and coding errors (determined to be company errors)	Number of Medicare claims denied due to company-made billing and coding errors	All claims submitted to Medicare for DMEPOS equipment or items each quarter	Every quarter of the calendar year	Reports run at the end of each quarter from billing software	Bookkeeper	5	13 [below target]
Adverse events *[Related standard: 1.E.3.f.]*	No reported injuries to customers served as a result of inadequate or malfunctioning equipment	Number of injuries reported to company that were investigated and determined to result from inadequate or malfunctioning equipment	All customers	Annually – between January 1 thru December 31	Critical incidents reports and investi-gations log	Owner	0 (as of Dec 31)	0 (goal met)

COMPANY LOGO HERE

Thank you for allowing **ABC Medical Supply Company** to provide the equipment or items prescribed by your doctor.

Please complete this short survey so that we improve our services to our customers by circling the appropriate score.

	Poor	Satisfactory	Good	Excellent	No Opinion
1. Please rate our promptness in delivering your equipment.	**1**	**2**	**3**	**4**	**N/O**
2. How well did we explain the use of your equipment?	**1**	**2**	**3**	**4**	**N/O**
3. Were all your questions answered in a timely manner?	**1**	**2**	**3**	**4**	**N/O**
4. Rate the courtesy and professionalism of our staff.	**1**	**2**	**3**	**4**	**N/O**
5. Rate your overall satisfaction with equipment.	**1**	**2**	**3**	**4**	**N/O**
6. Rate your overall satisfaction with our service.	**1**	**2**	**3`**	**4**	**N/ O**
7. Would you recommend our services/ equipment to others?	**1**	**2**	**3**	**4**	**N/ O**

8. Were you given copies of NOTICE OF PRIVACY PRACTICES and the PATIENT RIGHTS forms?

☐ Yes **☐ No**

9. If your answer is YES, how well was the Information explained to you?	**1**	**2**	**3**	**4**	**N/O**

Please share your comments so we can better serve you. _____

_____

Injury/Accident Description Form

Statement provider's name: _____ Report date:_____

Investigator name: _____ Case number: _____

Related product/service: _____

_____

— Involvement in accident (e.g., injured party, involved party, witness): _____

_____

— Location of accident: _____

_____

— Date and time of accident: _____

— Full description of accident (add pages if necessary): _____

_____

_____

_____

_____

— Description of bodily injury sustained (be specific about body parts affected): _____

_____

_____

— Recommendations on preventing future injuries/accidents of this type: _____

_____

_____

_____

Statement provider's signature: _____ Date:_____

ABC Medical Supply Company
Notice of Privacy Practices

Uses and Disclosures

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. --------- PLEASE REVIEW IT CAREFULLY.

Provision of products and services. Your health information may be used by staff members or disclosed to other health care professionals for the purpose of evaluating and providing the best possible product for you. For example, information from the prescribing physician supporting medical necessity for the product specifically prescribed for you will be available in our record to all health professionals who may provide may provide services or may be consulted by staff members.

Payment. Your health information may be used to seek payment from your health plan, from other sources of coverage such as an automobile insurer, or from credit card companies that you may use to pay for products and services. For example, your Medicare advantage plan provider may request and receive information on dates of service, the services and products provided, any the diagnosis underlying the reason for the prescription of the particular equipment, item, or supply.

Operations. Your personal health information may be used as necessary to support the day-to-day activities and management of ABC Medical Supply Company. For example, the information on the products and services you received ay be used to support budgeting and financial reporting, and activities to evaluate and promote quality of services.

Regulatory requirements and law enforcement. Your health information may be disclosed to law enforcement agencies to facilitate investigations and to representatives from government agencies to support government audits and inspections, government-required accreditations, and to comply with government-mandated reporting.

Public health reporting. Your health information may be disclosed to public health agencies as required by law. For example, we are required to report certain communicable diseases to the state's public health department.

Other uses and disclosures require your authorization. Disclosure of your health information or its use for any purpose other than those listed above requires your specific written authorization. If you change your mind after authorizing a use or disclosure of your information you may submit a written revocation of the authorization. However, you decision to revoke the authorization will not affect or undo any use or disclosures of information that occurred before you notified us of your
decision to revoke your authorization.

Individual Rights. You have certain rights under the federal privacy standards. These include the right to:

- Request restrictions on the use and disclosure of your protected health information.
- Receive confidential communications concerning your medical condition and products and services provided.
- Inspect and request a copy of your protected health information.
- Amend or submit corrections to your protected health information.
- Receive an accounting of how and to whom your protected health information has been disclosed.
- Receive a printed copy of this notice.

ABC Medical Supply Company's responsibilities. We are required by law to maintain the privacy of your protected health information and to provide you with this notice of privacy practices. We also are required to abide by the privacy policies and practices that are outlined in this notice.

Right to revise Privacy Practices. As permitted by law, we reserve the right to amend or modify our privacy policies and practices. These changes in our policies and practices may be required by changes in federal and state laws and regulations. Upon request, we will provide you with the most recently revised notices during any visit to our business. The revised policies and practices will be applied to all protected health information we maintain.

Requests to inspect protect health information. You may generally inspect or request a copy of the

protected health information that we maintain. As permitted by federal regulation, we require that requests to inspect or copy protected health information be submitted in writing. You may obtain a form to request access to your records by contacting the President of the company. Your request will be reviewed and will generally be approved unless there are legal or medical reasons to
deny the request.

Complaints. If you would like to submit a comment or complaint about our privacy practices, you can do so by sending a letter outlining your concerns to:

President, ABC Medical Supply Company, 1234 Main Street, Point Barrow, AK 90000

If you believe that your privacy rights have been violated, you should call the matter to our attention by sending a letter describing your concern to the same address. You will not be penalized or otherwise be retaliated against for filing a complaint. Send to:

President, ABC Medical Supply Company, 1234 Main Street, Point Barrow, AK 90000

The name and address of the personal you can contact for further information concerning our privacy practices is:

President, ABC Medical Supply Company, 1234 Main Street, Point Barrow, AK 90000
Phone: 907-123-4567

Effective date: This Notice is effective on or after April 19, 2006.

Medicare DMEPOS Supplier Standards

All Medicare DMEPOS suppliers must be in compliance with these Supplier Standards in order to obtain and retain their billing privileges. These standards, in their entirety, are listed in 42 C.F.R. § 424.57(c) and went into effect December 11, 2000, unless otherwise noted. A supplier must disclose these standards to all customers/patients who are Medicare beneficiaries (standard 16). A shortened version has been created to help suppliers comply with this requirement.

1. A supplier must be in compliance with all applicable Federal and State licensure and regulatory requirements and cannot contract with an individual or entity to provide licensed services.

2. A supplier must provide complete and accurate information on the DMEPOS supplier application. Any changes to this information must be reported to the National Supplier Clearinghouse within 30 days.

3. An authorized individual (one whose signature is binding) must sign the application for billing privileges.

4. A supplier must fill orders from its own inventory, or must contract with other companies for the purchase of items necessary to fill the order. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or from any other Federal procurement or non-procurement programs.

5. A supplier must advise beneficiaries that they may rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental equipment.

6. A supplier must notify beneficiaries of warranty coverage and honor all warranties under applicable State law, and repair or replace free of charge Medicare covered items that are under warranty.

7. A supplier must maintain a physical facility on an appropriate site. This standard requires that the location is accessible to the public and staffed during posted hours of business. The location must be at least 200 square feet and contain space for storing records.

8. A supplier must permit CMS, or its agents to conduct on-site inspections to ascertain the supplier's compliance with these standards. The supplier location must be accessible to beneficiaries during reasonable business hours, and must maintain a visible sign and posted hours of operation.

9. A supplier must maintain a primary business telephone listed under the name of the business in a local directory or a toll free number available through directory assistance. The exclusive use of a beeper, answering machine, answering service or cell phone during posted business hours is prohibited.

10. A supplier must have comprehensive liability insurance in the amount of at least $300,000 that covers both the supplier's place of business and all customers and employees of the supplier. If the supplier manufactures its own items, this insurance must also cover product liability and completed operations.

11. A supplier must agree not to initiate telephone contact with beneficiaries, with a few exceptions allowed. This standard prohibits suppliers from contacting a Medicare beneficiary based on a physician's oral order unless an exception applies.

12. A supplier is responsible for delivery and must instruct beneficiaries on use of Medicare covered items, and maintain proof of delivery.

13. A supplier must answer questions and respond to complaints of beneficiaries, and maintain documentation of such contacts.

14. A supplier must maintain and replace at no charge or repair directly, or through a service contract with another company, Medicare-covered items it has rented to beneficiaries.

15. A supplier must accept returns of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and rented or sold) from beneficiaries.

16. A supplier must disclose these supplier standards to each beneficiary to whom it supplies a Medicare-covered item.

17. A supplier must disclose to the government any person having ownership, financial, or control interest in the supplier.

18. A supplier must not convey or reassign a supplier number; i.e., the supplier may not sell or allow another entity to use its Medicare billing number.

19. A supplier must have a complaint resolution protocol established to address beneficiary complaints that relate to these standards. A record of these complaints must be maintained at the physical facility.
20. Complaint records must include: the name, address, telephone number and health insurance claim number of the beneficiary, a summary of the complaint, and any actions taken to resolve it.

21. A supplier must agree to furnish CMS any information required by the Medicare statute and implementing regulations.

22. All suppliers must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services, for which the supplier is accredited in order for the supplier to receive payment of those specific products and services (except for certain exempt pharmaceuticals). Implementation Date - October 1, 2009

23. All suppliers must notify their accreditation organization when a new DMEPOS location is opened.

24. All supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare.

25. All suppliers must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation.

26. Must meet the surety bond requirements specified in 42 C.F.R. 424.57(c). Implementation date- May 4, 2009

27. A supplier must obtain oxygen from a state- licensed oxygen supplier.

28. A supplier must maintain ordering and referring documentation consistent with provisions found in 42 C.F.R. 424.516(f).

29. DMEPOS suppliers are prohibited from sharing a practice location with certain other Medicare providers and suppliers.

30. DMEPOS suppliers must remain open to the public for a minimum of 30 hours per week with certain exceptions.

Prescription Change Recommendation Form

Physician's name: _____ Date: _____

Patient's name: _____

Prescribed item/ service: _____

[SUPPLIER NAME] recommends the following type of change to this prescription:

Change Type	Reason/Description
☐ Necessary change	_____
☐ Refinement	_____
☐ Additional evaluations	_____

Please contact [EMPLOYEE NAME] at (800) 555-5555 with any questions.
Thank you for your attention.

Sample Care and Maintenance Guidelines Ankle/Foot Orthosis

Wearing

To put on your orthosis, either:

— Put on your orthosis followed by your shoe.

— Slide your orthosis into your shoe and then slip your foot into your shoe.

Schedule:

— Days 2–3: Begin wearing your orthosis in a non-weight-bearing situation for 15–30 minutes several times each day (e.g., watching television or sitting down to eat.

— Days 4–7: Add 15–30 minutes of functional walking around the house.

— Days 8–14: Increase wearing time daily.

Cautions

— **Never wear your orthosis without a shoe; you could slip and fall.**

— **Wear ONLY the heel height for which your orthosis was made.**

— **Only increase wearing time if you are able to wear it fairly comfortably.**

— **Wear a sock or stocking underneath your orthosis, making sure there are no wrinkles and that it comes up higher on your leg than the top of the orthosis.**

Phsyical Care and Maintenance

— Your skin may become red under some pressure areas of your orthosis, but this nothing to worry about if the redness disappears shortly after you remove the orthosis.

— Wash your feet thoroughly every day.

— Inspect your feet with a mirror or have someone check them for you. Check for redness on ankle bones, top of toes, bunions, arch, back of heel, top of calf, and all other areas of brace contact.

Cautions

— **If your skin is sore and irritated, or if redness persists long after removing the orthosis (more than 10 minutes), call for an adjustment IMMEDIATELY.**

Orthosis Care and Maintenance:
Plastic Orthosis

Check for:

— Loose screws.

— Stirrup detaching from shoe.

— Loose or weak buckles and Velcro closures.

— Worn leather work and loose or worn rivets.

Metal Orthosis

Check for:

— Cracks in the plastic.

— Loose straps or weak Velcro closures.

— Gaping or increased room in the brace.

— Stress or white marks in the plastic.

Sample Beneficiary Instruction Checklist
Splints and Special Instructions

Patient's name: _____ Date:_____

Your splint is a device designed especially for you. It is to help your arm and hand feel better.

Purpose

- ☐ Keep from moving and allow to heal
- ☐ Protection
- ☐ Increase movement
- ☐ Other (specify below):

  _____

Schedule for Wearing

- ☐ All the time (except when bathing)
- ☐ All the time
- ☐ At night
- ☐ Most of the time
- ☐ As needed

Precautions

Call the therapist/take splint off/adjust straps immediately if you notice a change in any of the following:

- — Feeling like pins and needles/burning
- — Redness/blisters
- — Fingers feeling cold
- — Change of color
- — Pain
- — Swelling

Warnings

- — Do not leave splint in the sun, near a heater, or in a hot car.
- — Do not put splint in a dishwasher or microwave.
- — Be careful near stove or open flame.

Cleaning

Clean with warm (not hot) water and washcloth using hand soap or dish detergent. Rinse well with warm water. Pat dry with towel.

Instructions

Call [SUPPLIER'S PHONE NUMBER] with any questions.

The above has been read by and a written copy given to the beneficiary.

Patient signature:_____ Date:_____

Therapist signature: Date: