



ACHIEVING ACHC ACCREDITATION

MAY 2018



 DMEPOS

 [AccreditationUniversity.com](https://www.AccreditationUniversity.com)

ACCREDITATION COMMISSION *for* HEALTH CARE



ACHIEVING ACHC ACCREDITATION

TABLE OF CONTENTS

PRESENTATION - ACHIEVING ACHC ACCREDITATION

P. 5

RESOURCES

P. 43

PER INITIAL CHECKLIST

P. 45

PI MADE SIMPLE

P. 47

ACHC DMEPOS STANDARD UPDATE

P. 51

DMEPOS ACCREDITATION APPLICATION ADDENDUM

P. 55

MEDICARE DMEPOS SUPPLIER STANDARDS

P. 57

CMS DMEPOS QUALITY STANDARDS

P. 59

REQUIREMENTS FOR HIGH COST DMEPOS

P. 79

ACHIEVING ACHC ACCREDITATION



NOTES

WELCOME

- Housekeeping Items



Restrooms



No Smoking



Breaks



Lunch



Evaluations

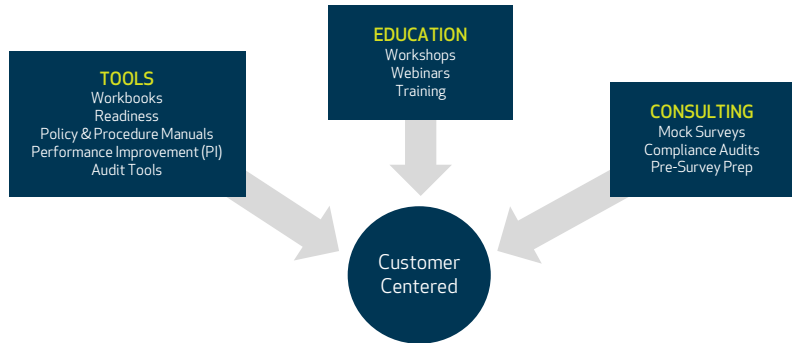


GREG STOWELL

Education & Consulting Manager

NOTES

ACCREDITATION UNIVERSITY



 DMEPOS



TIM SAFLEY, MBA, RRT, RCP

Program Director, DMEPOS
Pharmacy & Sleep

ALSO JOINING OUR TRAINING TODAY

- Suzie Steger: Accreditation University Customer Experience Coordinator
- ACHC Account Advisors

ACHIEVING ACHC ACCREDITATION



JOSÉ DOMINGOS

President & CEO

INTRODUCTIONS

- Name
- Company
- Location
- Years involved in the accreditation process

AGENDA FOR THE DAY

8am-8:30am	Registration/Continental Breakfast
8:30am- 9am	Welcome/Introductions/Review of Agenda
9am-9:30am	ACHC Accreditation Guide to Success - Standards
9:30am-10am	Registration - Application-Programs-PER Submission
10am-10:15am	Break
10:15am-10:30am	DMEPOS Addendum
10:30am-11am	The Survey Day
11am- Noon	Preparing Your Organization

NOTES

AGENDA FOR THE DAY (CONT.)

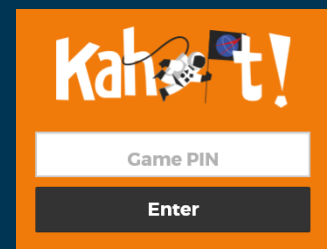
Noon-12:45pm	Lunch Break - Questions
12:45pm-2pm	Review of ACHC Standards
2pm-2:45pm	Top Standard Deficiencies
2:45-3pm	Break
3pm-4pm	PI Program and Group Project
4pm-4:15pm	Post-Survey Process
4:15pm-4:30pm	Maintaining Compliance
4:30pm	Evaluation/Questions

LEARNING OBJECTIVES



- Understand Medicare DMEPOS requirements
- Become familiar with the initial and renewal accreditation process
- Detail the essential components of functional Performance Improvement (PI) and compliance programs
- Learn how to prepare an organization for the accreditation survey
- Establish expectations for survey day and strategies for survey success
- A detailed look at “problem” standards
- Review of the “Top 10” standard deficiencies
- Learn how to utilize the *ACHC Accreditation Guide to Success* workbook to ensure ongoing compliance

TEACHING TOOL: Kahoot!

- Cell phone or laptop
- Go to Kahoot.it
- Enter Game PIN
- Enter your nickname
(Use your creativity)
- See “You’re in”
- You are ready!





ACHIEVING ACHC ACCREDITATION

TODAY'S LEARNING GUIDES

- *ACHC Accreditation Guide to Success* workbook
- Presentation handout

ACCREDITATION COMMISSION *for* HEALTH CARE

13

NOTES

GUIDE TO SUCCESS WORKBOOK



- Any sample policies and procedures provided in the *ACHC Accreditation Guide to Success* workbooks are for example and illustration purposes only
- Each organization is unique in its organizational structure and product offerings and must develop and implement specific policies and procedures that ensure compliance with all ACHC standards
 - Policies and procedures must also meet or exceed state and/or federal regulatory requirements.



ACCREDITATION COMMISSION *for* HEALTH CARE

14

HOW TO USE THIS WORKBOOK

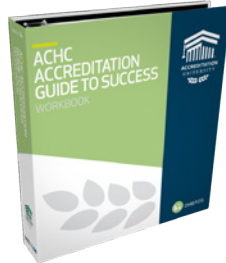
- Essential Components (Sample P&Ps)
 - Each ACHC standard contains "Essential Components" that indicate what needs to be readily identifiable in a policy and procedure.
 - *"Essential Components" are not the standard and are only an example.*
- Other Tools
 - Each section contains a compliance checklist and a self-assessment tool to further guide the preparation process
- Quick Standard Reference
 - Quickly locate important information for successfully completing the ACHC accreditation process



ACCREDITATION COMMISSION *for* HEALTH CARE

15

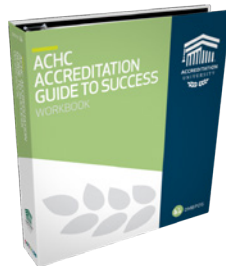
HOW TO USE THE WORKBOOK



Page 9	Table of Contents
Pages 13-16	Quick Standard Reference
Pages 21-26	Accreditation Process
Pages 31-33	Global Staff Interview Questions
Pages 35-39	Practice Run Audit Tool
Page 4.1	Look at Section 4

- Note shaded areas

HOW TO USE THE WORKBOOK



Page 4.18	Tools Available
Page 4.20	Compliance Checklist
Page 4.23	Accreditation Sample Documents
Page 4.28	Audit Tools

- Each section provides the same tools and information



ACHIEVING ACHC ACCREDITATION

ACHC MISSION & VALUES

Our Mission

Accreditation Commission for Health Care (ACHC) is dedicated to delivering the best possible experience and to partnering with organizations and healthcare professionals that seek accreditation and related services.

Our Values

- Committed to successful, collaborative relationships
- Flexibility without compromising quality
- Every employee is accountable for their contribution to providing the best possible experience
- We will conduct ourselves in an ethical manner in everything we do

NOTES

CONSULTATIVE SURVEY APPROACH

- ACHC values drive the survey approach
 - Consultative but not consultants
 - Flexibility without compromise
 - Consistency in interpretation of requirements
 - Accuracy in reporting findings/observations
 - Offering organizations the opportunity to clarify or correct deficiencies

SURVEYOR EXPERTISE

- Surveyor knowledge and expertise drive both the experience and the quality of the survey
- Surveyor success is driven by ACHC processes and tools
 - Surveyor Training
 - Surveyor Annual Evaluations
 - Surveyor Satisfaction Surveys



ENSURING ACHC QUALITY

- CMS deeming authority
- ISO certification
- Customer satisfaction
- Complaint investigation
- Internal audits
- Quality Council
- Surveyor expertise

CUSTOMER SATISFACTION

ACHC is committed to providing the best possible experience.

98%

of our customers regard their experience with ACHC as positive.

"There was time, attention and excellent feedback given by ACHC/PCAB at every point of the process."

– PHARMACY, FOLCROFT, PA

98%

of our customers would recommend ACHC.

"ACHC standards certainly improved our compounding pharmacy in terms of quality and control"

– PHARMACY, HAVERTOWN, PA

Customer Satisfaction Survey data gathered from 7/2015-present.

BRANDING ELEMENTS

- Gold Seal of Accreditation
 - Represents compliance with the most stringent national standards
- ACHC Accredited Logo



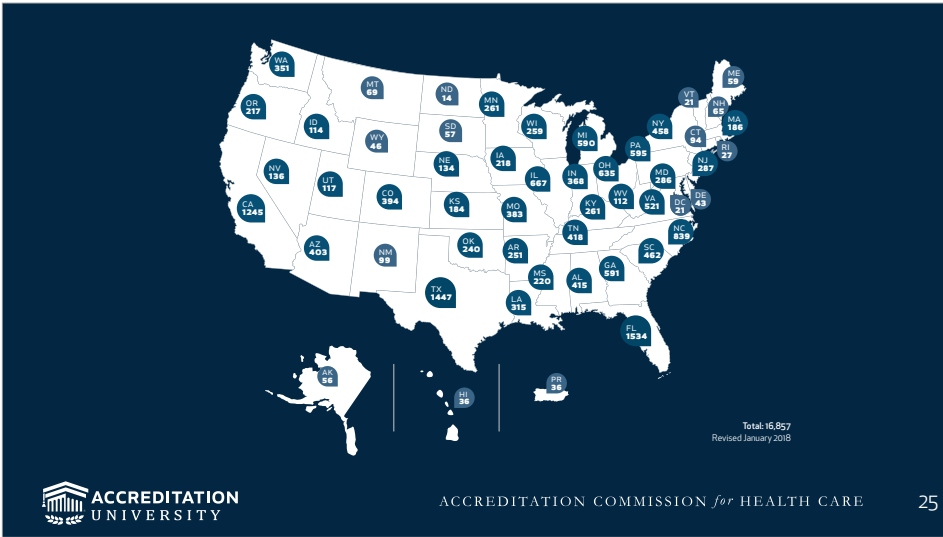
ACHC
ACCREDITED



ACHC
ACCREDITED



ACHIEVING ACHC ACCREDITATION



NOTES

ACHC PROGRAMS & SERVICES

HOME HEALTH

- Home Health Aide
- Medical Social Services
- Occupational Therapy
- Physical Therapy
- Skilled Nursing
- Speech Therapy

HOSPICE

- Hospice Inpatient Care
- Hospice Care

PRIVATE DUTY

- Private Duty Aide
- Private Duty Companion/Homemaker
- Private Duty Infusion Nursing
- Private Duty Nursing
- Private Duty Occupational Therapy
- Private Duty Physical Therapy
- Private Duty Speech Therapy
- Private Duty Social Work

DMEPOS

- Community Retail
- Clinical Respiratory Care Services
- Fitter
- Home/Durable Medical Equipment
- Medical Supply Provider
- Complex Rehabilitation and Assistive Technology Supplier

SLEEP

- Sleep Lab/Center
- Home Sleep Testing

AMBULATORY CARE

- Convenient Care Clinics

BEHAVIORAL HEALTH

- ACHC offers a variety of Behavioral Health services to suit your accreditation needs. Contact ACHC for details or visit achc.org for a complete listing of services available.

PHARMACY

- Ambulatory/Infusion Center
- Infusion Nursing
- Infusion Pharmacy
- Specialty Pharmacy
- > SRX without DMEPOS
- Long Term Care Pharmacy

PCAB Accreditation (A Service of ACHC)

- > Non-Sterile Compounding (Ref. USP <795>)
- > Sterile Compounding (Ref. USP <797>)
- ACHC Inspection Services (AIS)

DISTINCTIONS*

- Distinction in Behavioral Health
- Distinction in Hazardous Drug Handling
- Distinction in Infectious Disease Specific to HIV
- Distinction in Nutrition Support
- Distinction in Oncology
- Distinction in Palliative Care

*The provider must be accredited with ACHC to be eligible for a distinction service.



GETTING STARTED

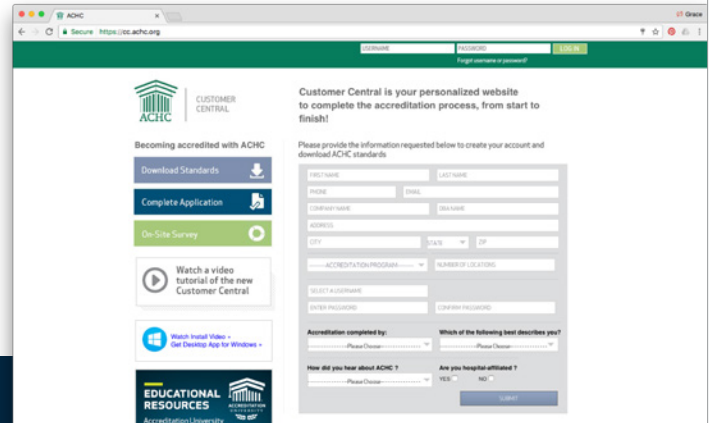
Overview of the 5 steps in the Application, Standards Download, and PER Process

NOTES

STEP 1: REGISTRATION



- Customer Central: cc.achc.org



STEP 2: DOWNLOAD STANDARDS



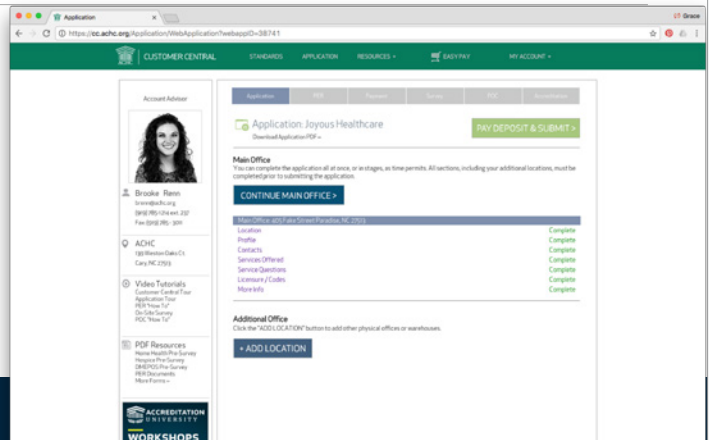
Updates will be posted on Customer Central



ACCREDITATION COMMISSION *for* HEALTH CARE

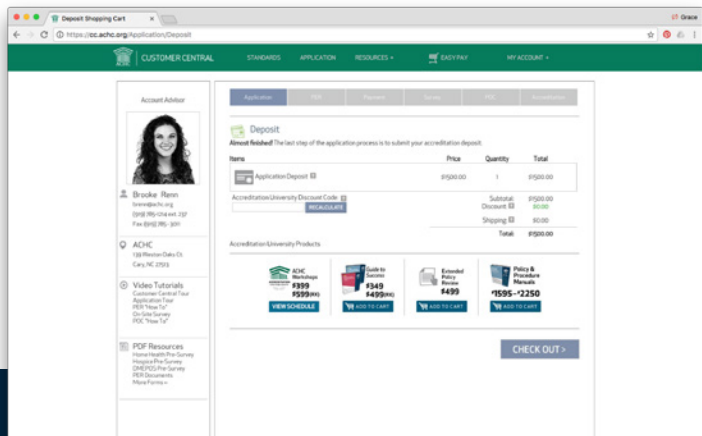
29

STEP 3: APPLICATION



ACHIEVING ACHC ACCREDITATION

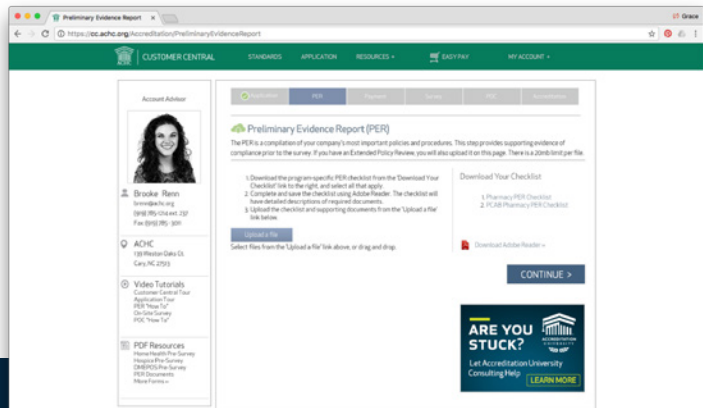
STEP 3: APPLICATION



31

NOTES

STEP 3: APPLICATION



32

STEP 3: PER CHECKLIST

PRELIMINARY EVIDENCE REPORT (PER) INITIAL CHECKLIST



[DMEPOS ACCREDITATION]
 This checklist constitutes the requirements of the PER, which is mandatory for organizations applying for Initial Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Community Retail (CR) accreditation.
 Review and acknowledge that all of the following requirements have been met and submit this signed checklist with the required items listed below.

Required items to be submitted to the Accreditation Commission for Health Care (ACHC):

- Accreditation application
- Non-refundable deposit
- Organization's information packet that is given to the clients when the client is provided equipment, services or products
 - Medicare providers must demonstrate that they are giving the beneficiaries all of the required information that is outlined in the CMS Quality and Supplier Standards. This would not be applicable to any non-Medicare providers.
 - It is preferred that this information be provided to ACHC in digital format
- Organizational chart by position titles

Confirmation of the following (initial in spaces provided):

- _____ I attest that this organization possesses all policies and procedures as required by the ACHC Accreditation Standards
- _____ Organization has 5 client/patient files, or can provide 5 mock files at the time of survey if equipment or supplies have not been provided
- _____ I acknowledge that this organization was/is/will be in compliance with ACHC Accreditation Standards as of _____ (date)

I, having the authority to represent this organization, verify that _____ (organization's legal name) has met the above requirements for survey. Failure to meet any of the aforementioned requirements when the ACHC Surveyor arrives on site may result in additional charges to the organization for a subsequent survey to be performed when the organization has notified ACHC. It has met all of the above requirements. I agree that during my accreditation with ACHC that if I receive any citation(s) from a federal or state agency that will notify ACHC within ten (10) calendar days.

(Name) _____ (Title) _____
 (Date) _____ (Signature) _____

33

NOTES

STEP 3: ADDENDUM

- We will cover this in detail in just a minute!

Accreditation application addendum

DMEPOS

Legal Name _____ City _____ State _____ Zip _____

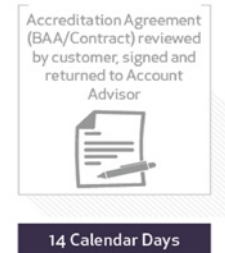
Address _____

All DMEPOS suppliers must complete this addendum. Please select all supply categories provided by your organization. For multiple product code additions, check only the codes that apply. This information is required by CMS. DMEPOS applications that are submitted to ACHC without this information cannot be processed.

<input type="checkbox"/> DM01 Automatic External Defibrillators (AEDs)	<input type="checkbox"/> DM26 Pressure Reducing Beds/Mattresses/Overlays/Pads - Used	<input type="checkbox"/> PD05 Ocular Prostheses
<input type="checkbox"/> DM02 Commodes/Urinals/Bedpans	<input type="checkbox"/> HD01 Home Dialysis Equipment and Supplies	<input type="checkbox"/> PD07 Somatic Prostheses
<input type="checkbox"/> DM03 Continuous Passive Motion (CPM) Devices	<input type="checkbox"/> HD02 Hemodialysis Equipment and Supplies	<input type="checkbox"/> PD08 Tracheostomy Supplies
<input type="checkbox"/> DM04 Contracture Treatment Devices - Dynamic Splint	<input type="checkbox"/> M01 Canes and Crutches	<input type="checkbox"/> PD09 Urological Supplies
<input type="checkbox"/> DM05 Blood Glucose Monitors and Supplies (non-mail order)	<input type="checkbox"/> M02 Patient Lifts	<input type="checkbox"/> PD11 Prosthetic Lenses - Conventional Eyeglasses
<input type="checkbox"/> DM06 Blood Glucose Monitors and Supplies (mail order)	<input type="checkbox"/> M03 Power Operated Vehicles (Scooters)	<input type="checkbox"/> PD12 Prosthetic Lenses - Conventional Contact Lenses
<input type="checkbox"/> DM07 Gastric Suction Pumps	<input type="checkbox"/> M04 Seat Lift Mechanisms	<input type="checkbox"/> PD13 Prosthetic Lenses - Prosthetic Cataract Lenses
<input type="checkbox"/> DM08 Heat & Cold Applications	<input type="checkbox"/> M05 Walkers	<input type="checkbox"/> PE03 Enteral Nutrients
<input type="checkbox"/> DM09 Hospital Beds- Electric	<input type="checkbox"/> M06 Wheelchairs - Standard Manual	<input type="checkbox"/> PE04 Enteral Equipment and/or Supplies
<input type="checkbox"/> DM10 Hospital Beds- Manual	<input type="checkbox"/> M06a Wheelchair - Standard Manual Related Accessories	<input type="checkbox"/> PE05 Parenteral Nutrients
<input type="checkbox"/> DM11 Infrared Heating Pad Systems	<input type="checkbox"/> M07 Wheelchairs - Standard Power	<input type="checkbox"/> PE06 Parenteral Equipment and/or Supplies
<input type="checkbox"/> DM12 External Infusion Pumps	<input type="checkbox"/> M07a Wheelchair - Standard Power Related Accessories	<input type="checkbox"/> PR01 Limb Prostheses
<input type="checkbox"/> DM13 External Ambulatory Insulin Pump	<input type="checkbox"/> M08 Wheelchairs - Complex Rehabilitative Manual Wheelchairs	<input type="checkbox"/> RP01 Continuous Positive Airway Pressure (CPAP) Devices
<input type="checkbox"/> DM14 Implanted Infusion Pumps and Supplies	<input type="checkbox"/> M08a Wheelchair - Complex Rehabilitative Manual Wheelchairs Related Accessories	<input type="checkbox"/> R01 High Frequency Chest Wall Oscillation (HFCWO) Devices
<input type="checkbox"/> DM15 Negative Pressure Wound Therapy Pumps and Supplies	<input type="checkbox"/> M09 Wheelchairs - Complex Rehabilitative Power Wheelchairs	<input type="checkbox"/> R04 Intermittent Positive Pressure Breathing (IPPB) Devices
<input type="checkbox"/> DM16 Neuromuscular Electrical Stimulators (NMES)	<input type="checkbox"/> M09a Wheelchair - Complex Rehabilitative Power Wheelchairs Related Accessories	<input type="checkbox"/> R05 Intermittent/Passive Ventilation Devices
<input type="checkbox"/> DM17 Enticogenesis Stimulators	<input type="checkbox"/> M10 Wheelchair Seating/Cushions	<input type="checkbox"/> R06 Mechanical In-Exsufflation Devices
<input type="checkbox"/> DM18 Pneumatic Compression Devices	<input type="checkbox"/> OR01 Orthoses - Custom Fabricated	<input type="checkbox"/> R07 Nebulizer Equipment and Supplies
<input type="checkbox"/> DM19 Speech Generating Devices	<input type="checkbox"/> OR02 Orthoses - Prefabricated (non-	<input type="checkbox"/> R08 Oxygen Equipment and Supplies
<input type="checkbox"/> DM20 Support Surfaces: Pressure Reducing Beds/Mattresses/Overlays/Pads	<input type="checkbox"/> PD01 Traction Equipment	<input type="checkbox"/> R08a Respiratory Assist Device

STEP 4: FEE ESTIMATE AND AGREEMENT

- Determination of fees
 - Number of locations
 - Number of Surveyors required
 - Number of days required
- Accreditation Agreement
 - Obligations of each party
 - Signed and returned within 14 calendar days
 - You are not scheduled until all steps are completed



STEP 5: SCHEDULING THE SURVEY

- Surveys are scheduled approximately 3-6 months from the date the accreditation agreement was signed (or as needed by expiration date)
- Surveys are unannounced
- Surveys are conducted during normal business hours
- Blackout dates are honored
- Surveys may include multiple Surveyors and multiple days

ACHIEVING ACHC ACCREDITATION

SO WHEN AM I OFFICIALLY “IN PROCESS?”

- Completed application (online)
- Deposit (online)
- Completion and return of PER (online)
- Signed and returned Accreditation Agreement
- When will your survey be conducted?
 - New application – Some point after “date of readiness” (minus blackout dates)
 - Renewal – Based on when you apply, and when accreditation expires

NOTES



PRE-SURVEY REVIEW DMEPOS ADDENDUM

A critical document that impacts your accreditation, ability to bill Medicare, and participation in Competitive Bidding

DMEPOS ADDENDUM

- Did you know that if you bill Medicare for an item not included on your accreditation addendum you will be denied payment for that submitted claim?
- Did you know that if your accreditation addendum does not match your 855S Medicare may deny submitted claims?
- Did you know that many DMEPOS providers had their Competitive Bid submissions rejected during previous rounds of bidding because they were not accredited for all product codes listed under a bidding category?

NOTES

DMEPOS ADDENDUM

- It is very important that this information is completed accurately for each location
- You will be asked to verify if each branch location will bill Medicare and will have a Medicare number
- Only select the codes that each location is actually providing
 - You should not select codes for items you hope to provide in the future
- If you are looking to add a code for the purposes of submitting a Competitive Bid to the CBIC, you must demonstrate your ability to provide those products and services before that code will be added
- Your application addendum guides ACHC to ensure we have the proper accreditation programs and tools selected for your survey and that we send a Surveyor with the needed expertise

ADDENDUM

- During your survey your Surveyor will fill out and ask you to sign a new DMEPOS Addendum
- The Surveyor can only include items for which your organization can fill an order the day of the survey
- You cannot add codes on your survey day that were not included in your application, as those additions may require additional standards, P&Ps or specially trained/licensed personnel, and could move you into a new accreditation category, e.g. OR01, S02-S03, M08-9A, PE05
- Make sure your application includes all addendum items you provide



SURVEY ADDENDUM
DMEPOS PHARMACY

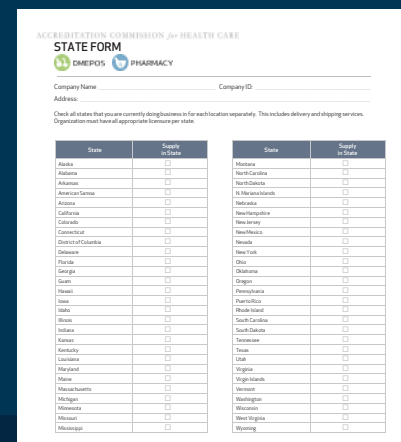
Company ID: _____ Survey Date: _____

Survey Attention
For the ACHC Surveyor conducting the on-site survey that this company has been surveyed for the above product codes. These addendums are a condition of the Surveyor's report to the Accreditation Commission.

Category Attention
I hereby affirm the accuracy of the information provided. And, my company is required to provide all of the identified above addendum codes to staff for their use during the survey. Failure to do so will result in a surveyor being notified and a surveyor being notified by the ACHC Surveyor regarding the significance of the information provided.

ADDENDUM

- ACHC must know which products you are providing and in which states
- Many states require license to ship or deliver products into their state
 - It is your responsibility to have the appropriate license or documentation as to why you believe you do not need one
- An addendum item cannot be included without the proper state license



STATE FORM
DMEPOS PHARMACY

Company Name: _____ Company ID: _____
Address: _____

Check all states that you are currently doing business in for each location separately. This includes delivery and shipping services. Organization must have all appropriate licenses per state.

State	Supply to State	State	Supply to State
Alabama	<input type="checkbox"/>	Missouri	<input type="checkbox"/>
Alaska	<input type="checkbox"/>	North Carolina	<input type="checkbox"/>
Arizona	<input type="checkbox"/>	North Dakota	<input type="checkbox"/>
Arkansas	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
California	<input type="checkbox"/>	OK	<input type="checkbox"/>
Colorado	<input type="checkbox"/>	Northwest Territories	<input type="checkbox"/>
Connecticut	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Delaware	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
District of Columbia	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Florida	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Georgia	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Idaho	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Illinois	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Indiana	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Iowa	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Kansas	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Kentucky	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Louisiana	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Maine	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Maryland	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Massachusetts	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Michigan	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Minnesota	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Mississippi	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Missouri	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Montana	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Nebraska	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Nevada	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
New Hampshire	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
New Jersey	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
New Mexico	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
New York	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
North Carolina	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
North Dakota	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Ohio	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Oklahoma	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Oregon	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Pennsylvania	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Rhode Island	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
South Carolina	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
South Dakota	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Tennessee	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Texas	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Utah	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Vermont	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Virginia	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Washington	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
West Virginia	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Wisconsin	<input type="checkbox"/>	Ohio	<input type="checkbox"/>
Wyoming	<input type="checkbox"/>	Ohio	<input type="checkbox"/>

ACHIEVING ACHC ACCREDITATION

DMEPOS ADDENDUM

- What happens if I need to add a product or service at some time after my accreditation visit?
 - Changes to product codes is common, and ACHC has provided you with the ability to add product codes by submitting a simple form found on Customer Central: My Account, Edit Company Info, Add/Remove Product Codes and download the “DMEPOS Product Addition Packet”
 - Just complete the required information and submit to your Account Advisor

DMEPOS ADDENDUM

In closing:

- You must also be able to produce license(s) (as required) for each state to which you are providing products and services
- The Surveyor cannot include an item on the addendum unless you are able to provide any required state licenses and demonstrate the ability to provide that product the day of the survey
- Before you participate in competitive bidding, make sure you are accredited for each product code listed under the category you are bidding (see Categories Listed)



ACHC ACCREDITATION VISITS TO DMEPOS PROVIDERS

Overview of the ACHC Accreditation survey day for DMEPOS providers

NOTES

ON-SITE SURVEY PROCESS

- On-site survey process
 - Pages 24-25
- Practice run audit tool
 - Pages 35
- Survey “what ifs”
 - What if other key personnel are gone?
 - What if we don’t have a required document?
 - What if we don’t know an answer?

SURVEY DAY

- If you have multiple locations, help the Surveyor know where items needed for review are located:
 - Personnel records
 - Training records
 - QI/PI records
 - Insurance/Surety Bonds
 - Logs
- Not everything needs to be at every location. Access to some records may be required.

SURVEY DAY

- Your unannounced survey date is selected with several factors in mind:
 - The date you apply and submit all required information (should be 6-9 months or more)
 - The date your accreditation expires (for renewals)
 - A date of readiness selected by new organizations
 - Your selected blackout dates
 - ACHC listed holidays
- On your survey day, the Surveyor call the main number listed on your application
 - They will not leave a call-back number but will state their name and that they will be arriving today for your survey
- When the Surveyor arrives you are welcome to ask to see identification
 - The Surveyor should have a name badge with a picture ID
- The Surveyor may show up any time during standard hours of operation

ACHIEVING ACHC ACCREDITATION

SURVEY DAY/SURVEYOR

- Who is your Surveyor?
 - Expert in DMEPOS
 - 20+ years of experience
 - Industry experience and knowledge
 - Completed comprehensive ACHC training
 - Completed required field training (precept)
 - Background checks and completed BAA
 - Selected for your survey based on experience
 - Most are contracted staff; some are full-time employees
 - Asked to verify that survey does not create a conflict of interest
 - You will not know the name of your Surveyor in advance

INITIAL SURVEYS

- Initial surveys can be “complicated”
- The Surveyor is assessing your level of compliance with a set of standards by looking for evidence of compliance
- Evidence is limited because ACHC can only hold you accountable back to a “date of readiness” (the date that you represent that you were in full compliance with ACHC requirements)
- As an example, let’s assume that was 90 days before survey
- ACHC cannot hold you accountable for compliance prior to that date (but when you represent that you are in compliance you must be fully in compliance)

INITIAL SURVEYS

- Example:
 - Personnel record for someone hired 3 years ago
 - You did not do reference checks, background checks, or initial orientation or training
 - You can’t go backwards and do it now, however:
 - The Surveyor will expect to see a background check completed since your date of compliance
 - They will expect to see trainings and competencies since the date of compliance

NOTES

FOCUS ON CMS REQUIREMENTS

- Addendum
- Supplier Standards
- Quality Standards

MEDICARE DMEPOS SUPPLIER STANDARDS

Note: This is an abbreviated version of the supplier standards; every Medicare DMEPOS supplier must meet in order to obtain and retain their billing privileges. These standards, in their entirety, are found in 42 CFR 424.57(a).

1. A supplier must be in compliance with all applicable Federal and State licensure and regulatory requirements.
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 Uniform Claiming System within 30 days.
3. A supplier must have an authorized individual (whose signature is binding) sign the enrollment application for billing privileges.
4. A supplier must file orders from its own inventory, or contract with other companies for the purchase of items necessary to fill orders. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care program, or any other Federal government or non-government program.
5. A supplier must advise beneficiaries that they may need to purchase equipment or routinely purchased durable medical equipment, and of the purchase options for rugged rental equipment.
6. A supplier must advise beneficiaries of warranty coverage and honor all warranties under applicable State law, and repair or replace the date of change Medicare covered items that are under warranty.
7. A supplier must maintain a physical facility on its appropriate site and must maintain a visible sign with posted hours of operation. The location must be accessible to the public and staffed during posted hours of business. The location must be at least 200 square feet and contain space for storage needs.
8. A supplier must permit CMS or its agents to conduct on-site inspections to ascertain the supplier's compliance with these standards.
9. A supplier must maintain a primary business telephone listed under the name of the beneficiary in a local directory or a toll-free number accessible through directory assistance. The exclusive use of a pager, answering machine, answering service or call-center 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 is prohibited from direct solicitations to Medicare beneficiaries. For complete details on this prohibition see 42 CFR § 424.57 (d) (1)(i).
12. A supplier is responsible for delivery of all items (except beneficiaries on the use of Medicare covered items), and maintain good of delivery and beneficiary instructions.
13. A supplier must receive, question and respond to complaints of beneficiaries, and maintain documentation of such contacts.
14. A supplier must maintain and replace or as change or repair cost either directly or through a service contract with another company, any Medicare-covered items in its owned or leased facilities.
15. A supplier must accept returns of unreturned items that fill orders for the particular item or reasonable items (appropriate for the beneficiary or the item it was filled and issued as well). Item beneficiaries.
16. A supplier must disclose these standards to each beneficiary it supplies a Medicare-covered item.
17. A supplier must disclose any person having ownership, financial, or control interest in the supplier.
18. A supplier must not carry or through a supplier affiliate, 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 process 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 claims and regulations.
22. All suppliers must be accredited by a CMS-approved accreditation organization in order to receive and receive a supplier billing number. The accreditation must address the specific products and services for which the supplier is accredited (either for the supplier to receive payment for those specific products and services through its various managed pharmacy contracts).
23. All suppliers must notify their accreditation organization when a new DMEPOS location is opened.
24. All suppliers must disclose upon application all products and services, including the address of any product lines for which they are seeking accreditation.
25. A supplier must meet the survey head requirements, specified in 42 CFR § 424.57 (d).
26. A supplier must obtain orders from a state-licensed prescriber.
27. A supplier must maintain relevant and supporting documentation consistent with provisions found in 42 CFR § 424.57(d).

SURVEY DAY

- The Surveyor is only a data collector
- The Surveyor does not play any role in the ultimate review decision or the status of your accreditation
- You will be given the opportunity to correct deficiencies during the survey day (if reasonable)
- Correcting deficiencies as you go eliminates the need to submit a Plan of Correction for those items, although the item is still recorded as a “no”
- If requested items cannot be located in a “reasonable time frame,” the item must be marked as a deficiency
- Management is welcome and encouraged to be a part of the entire accreditation process

SURVEY DAY (CONTINUED)

- Try to keep your staff relaxed and focused
- Customers come first! (Just keep us in the loop)
- Perfection is not the goal of the day
- Almost everything can be “fixed”
- There is nothing your staff can say in an interview that will sink the ship, so relax!
- Deficiencies are common...and expected
- Don't get sidetracked by “What's my score?”
- Ask questions/clarification
- The Surveyor is not always correct, so challenge him/her

ACHIEVING ACHC ACCREDITATION

SURVEY DAY (CONTINUED)

- Opening conference (set the schedule for the day)
- Tour of facilities
- Staff interviews
- Personnel record review
- Patient record review
- Patient visits/Interviews
- Review of logs & Medicare-required documents
- Review of PI/QI data
- Exit conference



NOTES

OPENING CONFERENCE

- Begins shortly after arrival of Surveyor
- Management may invite all staff members
- Good time to gather information needed by the Surveyor
 - Logs, inspections, reports
 - Licenses, bonds, insurance as required
 - Personnel list
 - Staff schedules
 - HR records
 - PI/QI data
- The Surveyor will use this time to set the schedule for the day



PERSONNEL RECORD REVIEW

- Surveyor will review personnel records for key staff and contract staff
- Must be selected randomly by the Surveyor
- May include all staff members or only select ones
- Preferable for someone from your organization to review charts with us
- Looking for items to include:
 - Application, tax forms, I-9 (as applicable)
 - Job descriptions and evaluations
 - Verification of qualifications/Licenses
 - Orientation records, trainings, competencies, ongoing education
 - Medical information (TB/HepB as applicable)
 - Background checks

For a complete listing of items required in the personnel record, review DRX4-1C of the ACHC Accreditation Standards



CLIENT RECORD REVIEWS

- Client records must be selected randomly by the Surveyor
 - Preferable to choose from a list/printout of payments (EOB)
 - Preferable for someone from your organization to review with us
- May include current patients and discharged patients
- Both billing and medical records
 - Representative of the care/services provided
- Review of patient paperwork and education provided
- Review of Plan of Service/Plan of Care and updates

DRX5-1A details the requirements of the client record

PATIENT VISITS/INTERVIEWS

- ACHC Surveyors will expect for you to arrange for us to visit patients/customers as part of your accreditation visit
- Please provide the Surveyor with a list of potential customers (who are within a reasonable driving distance)
- The Surveyor may also call some recent customers for a phone interview
- If you have a location that customers may come to for products and/or services, the Surveyor may ask to speak with some of those customers as well
- The customer needs to give you permission for us to visit or interview them (we do not require that to be in writing)

REVIEW OF LOGS & MEDICARE-REQUIRED DOCUMENTS

- | | |
|---|---|
| <ul style="list-style-type: none"> ▪ Training/in-service logs ▪ Referral Logs ▪ On-call schedule/logs ▪ Infection control tracking logs ▪ Temperature logs ▪ Fire and disaster drill logs ▪ Maintenance, repair, and cleaning logs | <ul style="list-style-type: none"> ▪ Complaint logs ▪ Oxygen complaint log ▪ Surety bond, liability and vehicle insurance, org chart, budget, contracts/BAA's, required licenses |
|---|---|

ACHIEVING ACHC ACCREDITATION

REVIEW OF PI/QI DATA

- Your Surveyor will expect to see evidence of ongoing PI/QI activities for the previous three years (if a renewal)
 - PI/QI meeting notes alone do not meet these requirements
 - PI/QI must document the following required PI study indicators/activities:
 - Adverse events
 - Client/patient complaints
 - Client/patient records
 - Satisfaction surveys (clients, referral source, personnel)
 - Billing and coding errors
 - At least one important aspect related to service/care provided
 - Ongoing monitoring of processes that involve risks including infections and communicable diseases, if applicable
- Refer to the Performance Improvement Made Simple Document located on Customer Central

REVIEW OF PI/QI DATA

- Each performance improvement activity/study listed above needs to include the following items:
 - A description of indicator(s) to be monitored/activities to be conducted
 - Frequency of activities
 - Designation of who is responsible for conducting the activities
 - Methods of data collection
 - Acceptable limits for findings
 - Who will receive the reports
 - Plans to re-evaluate if findings fail to meet acceptable limits
 - Any other activities required under state or federal laws or regulations

CLOSING CONFERENCE

- The ACHC Surveyor conducts a closing conference with the organization's representatives
- Management may decide which staff members attend
- Can provide a scheduled time for closing to accommodate phone participation by remote staff
- Surveyor covers all areas of noncompliance with reference to the standard requirement
- Great opportunity for you provide missing items or seek clarification
- The Surveyor cannot answer the question "How did we do?" as they only collect and submit the data
- The Surveyor should complete the closing conference by the end of the business day

NOTES

POST-SURVEY PROCESS

- ACHC accreditation review staff review all the data submitted by the Surveyor and provides the accreditation decision
- Summary of Findings (SOF) is prepared describing all ACHC Accreditation Standards that were marked as a deficiency during the survey
 - Each deficiency will detail the “Action Required” to bring that deficiency into compliance
- The organization then completes the provided POC document, detailing how it will meet and maintain compliance with that ACHC requirement

POST-SURVEY PROCESS

- The POC template will be sent electronically from your Account Advisor
- All documentation must be on the POC template
- The POC is provided for you to document the plan to correct each deficiency noted on the SOF as well as your plan to prevent a recurrence
 - Make sure to provide exactly what is required on the POC
 - You will only provide “evidence” when requested on the Summary of Findings document
 - POC will be reviewed and separately approved once all required information and evidence has been submitted
 - Once your POC has been approved, your certificate of accreditation is sent to you

PLAN OF CORRECTION (POC)

ONCE COMPLETED, PLEASE EMAIL THIS FORM TO THE ATTENTION OF YOUR ACCOUNT ADVISOR



Organization: Greg's Pharmacy

Standard	Plan of Correction <small>(Specify action taken to bring standard into compliance)</small>	Date of Compliance <small>(Date correction to be completed)</small>	Title <small>(Individual responsible for correction)</small>	Process to Prevent Recurrence <small>(Describe monitoring of corrective actions to ensure they effectively prevent recurrence)</small>	POC Compliant <small>(ACHC internal use only)</small>	Comments <small>(POC internal use only)</small>
TCR03-B	What would be a proper POC for this deficiency?	What's a reasonable time frame?		How do you prevent this from happening again?		

ACHIEVING ACHC ACCREDITATION

ACHC ACCREDITATION DECISION DEFINITIONS



ACCREDITED
 Provider meets all requirements for full accreditation status. Accreditation is granted but Plan of Correction (POC) may still be required.*



ACCREDITATION PENDING
 Provider meets basic accreditation requirements but accredited status is granted upon submission of an approved POC.



DEPENDENT
 Provider has significant deficiencies to achieve accreditation. An additional on-site visit will be necessary to be eligible for accreditation.



DENIED
 Accreditation is denied. Provider must start process from the beginning once deficiencies are addressed.



NOTES

SURVEY REPORT FOR SURVEY ON 03/2017 SERVICES: HME



Deficiency Category - Interviews/Observations		Deficient
Standard	Comments	
DRX7-12D Personnel implement the organization's policies and procedures for the cleaning, storage, safe transportation, delivery, and setup of equipment used in the provision of care/service. Implementation in home environmental and electrical safety assessment.	The safety and adequacy of electrical outlets was not being assessed by some delivery personnel. Corrective Action: Obtain an electrical outlet safety tester and document the testing results for any electrical equipment set up in the patient's residence (see tester example and policy copied during the survey). Best Practice: Note that staff were not able to show how a volt meter could identify any of the following conditions: open ground; open neutral; hot and neutral reversed; hot and ground reversed.	X



SURVEY REPORT FOR SURVEY ON 08/2016 SERVICES: HME



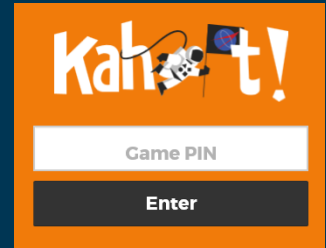
Deficiency Category - Quality & Supplier with ** Evidence Required on POC**		Deficient
Standard	Comments	
DRX6-1D There is an annual Performance Improvement (PI) report written.	The Performance Improvement (PI) program did not include an annual evaluation for 2015 / 2016 detailing the organization PI outcomes. Corrective Action: In order to be in compliance with this standard complete an annual Performance Improvement report. As PI data is collected throughout the year complete a comprehensive, annual report that summarizes all the years PI activities and outcomes. The findings and corrective actions will indicate if goals were met or what action was taken to improve company performance as they relate to the care/service provided (example provided).	X



NOTES

TEACHING TOOL: Kahoot!

- Cell phone or laptop
- Go to Kahoot.it
- Enter Game PIN
- Enter your Nickname
(Use your initials + zip code, e.g. CR27513)
- See “You’re in”
- You’re ready!



KEY PREPARATION TIPS



Strategies for a successful survey
A look at common deficiencies and survey pitfalls

PREPARING YOUR ORGANIZATION

- Perform your own survey
- Interview staff
- Review records/logs
- Observe warehouses, drivers, and shipping

ACHIEVING ACHC ACCREDITATION

PRE-SURVEY WORKGROUP GROUP ACTIVITY

- Preparing Your Organization
 - Turn to the bottom of page 22
 - Looking at the steps listed in "Preparing Your Organization," share ideas and strategies you have used to address each of the listed activities
 - Education of staff
 - Field visits
 - Auditing
 - Practice run
 (reference audit tools for additional information)

PRE-SURVEY AUDITS: HOW TO KNOW YOU'RE READY

- Preparing your Organization
 - Pre-survey audit tools in the back of each section
 - Use the audit tools to involve your staff
 - Do random audits to ensure ongoing compliance
 - Think like a Surveyor

STANDARDS UPDATE

On February 1, 2018, ACHC released revisions to program standards. Generally, the revisions are minor and include additions, deletions, and clarifications. All deletions became effective February 1, 2018. All other changes are effective June 1, 2018.

Among the updates:

- One of the major revisions changes pharmacy care plans and medication profile reviews from 'every 30 days' to 'prior to dispensing and based on therapy protocols.'
- Specialty pharmacies will see reduced requirements for PI committee members and personnel drug testing.
- There are clarifications regarding what items do not need to be placed in the personnel file of 1099 personnel.

NOTES

NOTES

Standards

SECTION 1

ORGANIZATION AND ADMINISTRATION

The standards in this section apply to the leadership and organizational structure of the company. All items referring to business licensure including federal, state and local licenses which affect the day-to-day operations of the business should be addressed. This section includes the leadership structure including board of directors, advisory committees, management and employees. Also included are the leadership responsibilities, conflicts of interest, chain of command, program goals, and regulatory compliance.

Standards

SECTION 2

PROGRAM/SERVICE OPERATIONS

The standards in this section apply to the specific programs and services an organization is supplying. This section addresses rights and responsibilities, complaints, protected health information, cultural diversity, and compliance with fraud and abuse prevention laws.

Standards

SECTION 3

FISCAL MANAGEMENT

The standards in this section apply to the financial operations of the company. These standards will address the annual budgeting process, business practices, accounting procedures, and the company's financial processes.

ACHIEVING ACHC ACCREDITATION

NOTES

Standards

SECTION 4

HUMAN RESOURCE MANAGEMENT

The standards in this section apply to all categories of personnel in the organization unless otherwise specified. Personnel may include, but are not limited to, support personnel, licensed clinical personnel, unlicensed clinical personnel, administrative and/or supervisory employees, contract personnel, independent contractors, volunteers, and students completing clinical internships. This section includes requirements for personnel records including skill assessments and competencies.



Standards

SECTION 5

PROVISION OF CARE AND RECORD MANAGEMENT

The standards in this section apply to documentation and requirements for the service recipient /client/ patient record. These standards also address the specifics surrounding the operational aspects of care/service provided.



Standards

SECTION 6

QUALITY OUTCOMES/PERFORMANCE IMPROVEMENT

The standards in this section apply to the organization's plan and implementation of a Performance Improvement (PI) Program. Items addressed in these standards include who is responsible for the program, activities being monitored, how data is compiled, and corrective measures being developed from the data and outcomes.



NOTES

Standards

SECTION 7

RISK MANAGEMENT: INFECTION AND SAFETY CONTROL

The standards in this section apply to the surveillance, identification, prevention, control, and investigation of infections and safety risks. The standards also address environmental issues such as fire safety, hazardous materials, and disaster and crisis preparation.




TOP STANDARD DEFICIENCIES

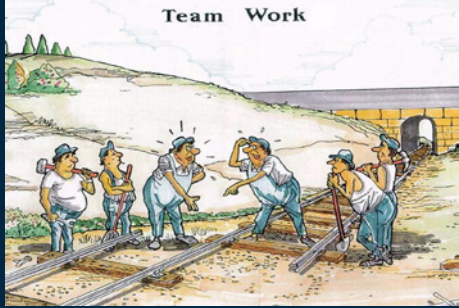
- Key Element
- Documentation (or lack thereof)
- Personnel records (orientation, training, competencies)
 - Also includes staff interviews!
- Client/Patient Records (demographics, complete order, signatures, POS)
- Warehouse, vehicles
- Equipment (cleaning, function testing, maintenance, repair)
- Performance Improvement




ACHIEVING ACHC ACCREDITATION


DMEPOS

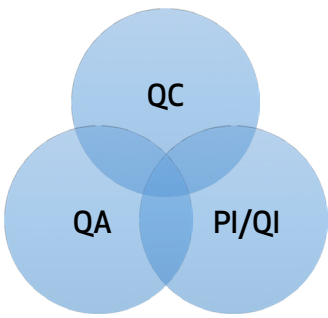
OVERVIEW OF PI STANDARDS





ACCREDITATION COMMISSION *for* HEALTH CARE
85

NOTES

WHAT IS PI?



PI: Performance Improvement
 QA: Quality Improvement
 QC: Quality Control
 QI: Quality Improvement


ACCREDITATION COMMISSION *for* HEALTH CARE
86

AMERICAN SOCIETY FOR QUALITY DEFINITIONS

- Quality Improvement is “an ongoing effort to improve products, services or processes. These efforts can seek ‘incremental’ improvement over time or ‘breakthrough’ improvement all at once”
- Audience: Give some examples of QI in the typical HME


ACCREDITATION COMMISSION *for* HEALTH CARE
87

KEY POINTS

- Only you know what your organization needs to improve
- Your PI is effective when you can answer this question

“As a result of your Performance Improvement activities, what did you improve?”

PI STANDARDS

- DRX6-1A: Requires a written PI Plan that uses your QA and QC data to identify opportunities for improvement and when necessary, act upon them
- DRX6-1B: Who leads your PI Program?
- DRX6-1C: PI involves everyone, and they get training in it
- DRX6-1D: “As a result of your Performance Improvement activities, what did you improve?” (Annual Report)

DRX6-2A, PI REQUIREMENTS

- A description of the indicator(s) to be monitored/activities to be conducted
- Frequency of activities
- Designation of who is responsible for conducting the activities
- Methods of data collection
- Acceptable limits for findings
- Who will receive the reports
- Plans to re-evaluate if findings fail to meet acceptable limits
- Any other activities required under state or federal laws or regulations

ACHIEVING ACHC ACCREDITATION

PI ACTIVITIES SHOULD INCLUDE ASSESSING AND MONITORING

- Standard DRX 6-1A
 - Adverse events
 - Client/patient complaints
 - Client/patient records
 - Satisfaction surveys
 - Billing and coding errors
 - At least one important aspect related to care/service provided

(DRX 6-3A-G provides details for the above)

PI ACTIVITIES SHOULD INCLUDE ASSESSING AND MONITORING

- Standard DRX6-3B: Performance Improvement (PI) activities include ongoing monitoring of at least one important aspect related to the care provided.
- Standard DRX6-3C: Performance Improvement (PI) activities include satisfaction surveys.
- Standard DRX6-3D: Performance Improvement (PI) activities include a review of the client/patient records.
- Standard DRX6-3E: Performance Improvement (PI) activities include the ongoing monitoring of client/patient grievances/complaints.

PI ACTIVITIES SHOULD INCLUDE ASSESSING AND MONITORING

- Standard DRX6-3F: Written policies and procedures are established and implemented by the organization to identify, monitor, report, investigate, and document all adverse events, incidents, accidents, variances, or unusual occurrences that involve client/patient care/service.
- Standard DRX6-3G: Performance Improvement (PI) activities include ongoing monitoring of billing and coding errors.

NOTES

NOTES



PI AUDIT TOOL

PI AUDIT DESCRIPTIONS

PI Activity/Audit Descriptions

Description of Audit/Activities: _____ Conducted By: _____

Frequency of Activities: _____

Data Collected From: _____

Threshold/Goal: _____

Plan for re-evaluation if threshold/goal is not met: _____

All Programs will be presented to the PI Committee and the Governing Body/Board. In the event an audit fails to meet a threshold/goal, a written plan of correction will be created that indicates plans to re-evaluate.

Creation Date: _____ Form #1

© Accreditation Commission for Health Care, Inc. 2017 | 8.16


ACCREDITATION UNIVERSITY ACCREDITATION COMMISSION *for* HEALTH CARE

PI WORKGROUP ACTIVITY

- Discuss common areas of concern/challenge
- Establish a PI study for your group addressing the concern
- Follow the outline on the sheet provided

ACCREDITATION UNIVERSITY ACCREDITATION COMMISSION *for* HEALTH CARE 95

KEEP IT SUPER SIMPLE (KISS)



K KEEP
i IT
S SUPER
S SIMPLE

ACCREDITATION UNIVERSITY ACCREDITATION COMMISSION *for* HEALTH CARE

ACHIEVING ACHC ACCREDITATION

KEEP IT RELEVANT

- Within the required categories, monitor what is important to you
- Involve entire staff
- Get results that you understand and can use
- Document activities and use results to drive quality and efficiencies



NOTES

PERFORMANCE IMPROVEMENT

- Great ROI
- $ROI (\%) = \frac{\text{Net Monetary Benefits}}{\text{Program Costs}} \times 100$
- One of few activities that can increase customer and referral source satisfaction and employee performance, and save you money through efficiencies
- Can greatly reduce
 - Waste, complaints, conflicts, and stress
- Can help build
 - Teamwork, customer service, commitment, job satisfaction, and engagement

HAD ENOUGH?



NOTES



MARKETING ADVANTAGE

- ACHC Accreditation is a noteworthy and distinguishing accomplishment that your pharmacy should be proud to display
 - It shows the organization's dedication and adherence to a rigorous set of standards
 - It demonstrates a commitment to providing the highest quality of health care to those served
 - It provides assurance for key constituents: providers, payors, physicians, and patients
 - It builds TRUST

ACHIEVING ACHC ACCREDITATION

MARKETING TOOLS

- ACHC provides the tools to leverage your accredited status
- All accredited organizations receive the ACHC Branding Kit
 - Brand guidelines
 - ACHC Accredited logos
 - Window cling



NOTES

BRANDING ELEMENTS

- Gold Seal of Accreditation
 - Represents compliance with the most stringent national standards
- ACHC Accredited Logo



ACHC
ACCREDITED



ACHC
ACCREDITED



ACHC RESOURCES

- A few basic places to promote ACHC Accredited status:
 - Website – home page or landing page
 - Marketing materials – any marketing piece that is seen by the public
 - Press releases – in the “boilerplate” of the press release or the footer
 - Social media – profile image, home page, banner image
 - Promotional items – tradeshow displays, giveaways
 - Email – email signature
 - Voicemail – voicemail message

ACHC RESOURCES

- ACHC's Marketing Department is available to help with your marketing needs
- Feel free to contact them at marketing@achc.org or (855) 937-2242



WORKSHOP EVALUATION

- Please help us know what we can do better
- What additional education or resources would be helpful?
- Would additional workshops be helpful?
- Would on-site, pre-survey audits be helpful?
- How would you like us to communicate updates or changes?

ACHIEVING ACHC ACCREDITATION



 **THANK YOU**
Accreditation Commission for Health Care
139 Weston Oaks Ct., Cary, NC 27513
855-937-2242

Greg Stowell
Education & Consulting Manager
gstowell@achc.org

Timothy Safley
Program Director, DMEPOS, Pharmacy & Sleep
tsafley@achc.org

NOTES

RESOURCES



 DMEPOS

PRELIMINARY EVIDENCE REPORT (PER) INITIAL CHECKLIST



FOR PROVIDERS.
BY PROVIDERS.™

[ DMEPOS ACCREDITATION]

This checklist constitutes the requirements of the PER, which is mandatory for organizations applying for initial Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS/Community Retail (CR)) accreditation.

Review and acknowledge that all of the following requirements have been met and submit this signed checklist with the required items listed below.

Required items to be submitted to the Accreditation Commission for Health Care (ACHC):

- Accreditation application
- Non-refundable deposit
- Organization's information packet that is given to the clients when the client is provided equipment, services or products
 - Medicare providers must demonstrate that they are giving the beneficiaries all of the required information that is outlined in the CMS Quality and Supplier Standards. This would be not applicable to any non-Medicare providers.
 - It is preferred that this information be provided to ACHC in digital format
- Organizational chart by position titles

Confirmation of the following (initial in spaces provided):

_____ I attest that this organization possesses all policies and procedures as required by the ACHC Accreditation Standards

_____ Organization has 5 client/patient files, or can provide 5 mock files at the time of survey if equipment or supplies have not been provided

_____ I acknowledge that this organization was/is/will be in compliance with ACHC Accreditation Standards as of _____ (date)

I, having the authority to represent this organization, verify that _____ (organization's legal name) has met the above requirements for survey. Failure to meet any of the aforementioned requirements when the ACHC Surveyor arrives on site may result in additional charges to the organization for a subsequent survey to be performed when the organization has notified ACHC it has met all of the above requirements. I agree that during my accreditation with ACHC that if I receive any citation(s) from a federal or state agency that I will notify ACHC within ten (10) calendar days.

(Name)

(Title)

(Date)

(Signature)

PERFORMANCE IMPROVEMENT MADE SIMPLE



FOR PROVIDERS.
BY PROVIDERS.™

[ DMEPOS]

Statistical data would tell us that Quality Improvement (QI)/Performance Improvement (PI) is anything but simple. In fact, QI/PI continues to be among the most commonly missed standards. By following the steps detailed below, you can minimize your PI confusion and maximize the organizational benefits from your efforts.

General PI/QI Principles

- Keep it simple (KIS) and specifically focused to your organization
- Know what you want to get out of it (Centers for Medicare & Medicaid Services [CMS] compliance only or more?)
- Pick a place to store data (makes it easier to review)
- Pick a time each month to review (set a date on your calendar)
- Develop a plan to address any identified negative trends (trends are what we are looking for)
- Document activities

Purpose of PI/QI

- Because CMS tells you to! (Since you have no choice, let's add some value!)
- QI/PI will enable the organization to assess processes of care, services, and operations
- Organization-wide PI efforts address priorities for improved quality of care/service, client/patient/staff safety, operational efficiencies, and regulatory compliance
- PI helps you identify potential issues before they turn into problems, problems that could lead to patient issues, payment refunds, etc.

Required study indicators

You must select one ongoing PI/QI study indicator for each of these listed categories (total of 8)

1. Adverse events – including correction plans and assessment to prevent future safety risks
2. Client/patient complaints
3. Client/patient records
4. Satisfaction surveys – clients, personnel, and referral sources
5. Billing and coding errors
6. At least one important aspect related to service/care provided - include examples
7. Audits of the Compliance Program – Standard DRX2-9A

Each PI activity/study listed above must include the following items (these items must be defined and documented for each activity/audit)

- A description of indicator(s) to be monitored/activities to be conducted
 - List items that will be looked for during the activity/audit
- Frequency of activities
- Designation of who is responsible for conducting the activities
- Data collection methods
 - List all files, forms, documents, etc., that will be reviewed
- Acceptable limits for findings/goals

- Set goals that are attainable but that allow room for improvement
- Remember that your goal may not always be a number
 - For example, if you are doing an audit to determine if there is an issue, then your goal is to gather data; once you have gathered your data, you can set a finite
 - For items such as complaints and incidents, it may be hard to put a number or percentage as a goal; in this case, your goal may be “no development of a negative trend”
- Who will receive the reports?
- Plans to re-evaluate if findings fail to meet acceptable limits
- Any other activities required under state or federal laws or regulations

Example PI/QI study indicator

Study indicator: **client/patient records**

- A description of indicator(s) to be monitored/activities to be conducted (audit of client/patient records looking at completeness and accuracy of documentation)
- Frequency of activities (quarterly audit)
- Designation of who is responsible for conducting the activities (manager and biller)
- Methods of data collection (random selection of high-risk and high-volume items; minimum of 10 charts per product category)
- Acceptable limits for findings (90%)
- Recipient of reports (owner)

Plans to re-evaluate if findings fail to meet acceptable limits (*plan of correction is to be completed and implemented immediately; effectiveness of plan of correction will be monitored for three months*)

- Any other activities required under state or federal laws and regulations
(none required)

Hint:

Make a form to use for each activity/audit and compile your activities/make a form to outline each activity/audit

- Description of indicator(s) to be monitored/activities to be conducted _____
- Frequency of activities _____
- Designation of who is responsible for conducting the activities _____
- Methods of data collection _____
- Acceptable limits for findings _____
- Who will receive the reports _____
- Plans to re-evaluate if findings fail to meet acceptable limits _____
- Any other activities required under state or federal laws or regulations _____
- Plan of correction: _____

Create an audit tool or form to tabulate your data

- Tabulate your data and compare the results to your acceptable limits for findings/goals

ACCREDITATION COMMISSION *for* HEALTH CARE

Consider a graph with each month/quarter across the top and each activity/audit going down the left side; fill in the results of each audit and see if any trends develop

	Q1	Q2	Q3	Q4
Complaints	1	1	3	5
Incidents	0	0	1	0
Client Files	76%	82%	96%	97%

- If your goal is met, great job!
 - If your goal is not met, create a plan of correction to improve performance

Keep the forms in a in a three-ring binder and

- Tab each section for each study indicator
- Use the binder to collect data throughout the month/quarter/year
- Use your form to summarize your findings
- Keep plans of correction in the same section
- Summarize all findings for the year on an annual basis

Now when your Surveyor shows up for your survey and asks for your three years of PI/QI data, (yes we will) you have it all organized and in one place - very impressive to your Surveyor!!!

Remember: Keep it simple (KIS) and focused on what is important to your organization

STANDARDS UPDATE REFERENCE GUIDE



FOR PROVIDERS.
BY PROVIDERS.™



PHARMACY



DMEPOS

UPDATE OVERVIEW

Listed below is a summary of the updates that have been made for 2018.
Please review these changes and compare them to the standards that you have downloaded.

MULTIPLE

Removed reference to standards that had been deleted or combined with other standards

SECTION 1

Standard DRX1-2A

– Removed requirement of governing body to review annual program evaluation

Standard DRX1-7A

+ Added compliance with organization policies and procedures and ACHC accreditation process

– Removed compliance with professional licensure/certification

SECTION 3

Standard DRX3-1A

– Removed requirement for budget to be reflective of the organization strategic plan

Standard DRX3-4B

+ Added clarification that organization is to notify Medicare beneficiaries when assignment is not accepted

SECTION 4

Standard DRX4-1C

+ Added clarification for information that does not need to be readily available for contracted personnel

Standard DRX4-2C

+ Added that TB testing could include a blood test

Standard DRX4-2K

+ Added drug testing for cause

– Removed requirement for random drug testing

Standard DRX4-7A

+ Added requirement for a competency assessment for personnel who educate on the use of medications

– Removed the requirement for an annual observation of personnel performing job duties; Annual competencies are still required

Standard DRX4-7C

+ Added requirement for a competency assessment for personnel overseeing sterile compounding

+ Added clarification that gloved fingertip/thumb sampling should occur after gloving and garbing, resulting in zero colony forming units on no less than 3 occasions prior to performing/overseeing sterile compounding

+ Added clarification that competency assessments may need to be completed semi-annually based on risk levels



Please sign into your Customer Central Account to download the latest standards.



Contact your Account Advisor for any additional questions at **855-937-2242**.

STANDARDS UPDATE REFERENCE GUIDE



FOR PROVIDERS.
BY PROVIDERS.™



PHARMACY



DMEPOS

SECTION 4

- + Added clarification that annual/semi-annual competency assessments should include media-fill tests that represent the most challenging or stressful conditions the compounder may encounter, and gloved fingertip/thumb sampling should occur upon completion of media-fill tests. If the total cfu of both gloves exceed 3, there is documentation that the compounder is immediately re-instructed and re-evaluated by compounding personnel to ensure correction

Standard DRX4-8A

- + Added that annual workplace safety training includes components of DRX7-2A

Standard DRX4-11C

- + Added that contracts for the use of outside personnel include compliance with organization policies for orientation, competencies, and required background checks

Standard DRX4-11D *Now DRX6-3I*

Standard DRX4-11E *Now DRX6-3J*

SECTION 5

Standard DRX5-2I

- + Added clarification that the care plan is reviewed prior to dispensing medication and based on therapy protocols instead of reviewing every 30 days

Standard DRX5-3H

- Removed anticipated length of need from elements of the initial evaluation/assessment and plan of service

Standard DRX5-7A

- + Added clarification that the medication profile is reviewed prior to dispensing medication and based on therapy protocols instead of reviewing every 30 days

Standard DRX5-7A.01

- + Added clarification that the medication profile is reviewed prior to dispensing medication and based on therapy protocols instead of reviewing every 30 days

Standard DRX5-7B

- + Added that the route of administration is to be documented as part of the medication profile

Standard DRX5-7C

- + Added that the route of administration is to be documented as part of the medication profile

SECTION 6

Standard DRX6-1F

- Removed requirement of PI committee to include personnel from all departments and at least one member from outside the organization



Please sign into your Customer Central Account to download the latest standards.



Contact your Account Advisor for any additional questions at **855-937-2242**.

STANDARDS UPDATE REFERENCE GUIDE



FOR PROVIDERS.
BY PROVIDERS.™



PHARMACY



DMEPOS

SECTION 7

Standard DRX7-8F

- + Added requirement to monitor humidity in storage areas
- + Added clarification that temperatures in storage areas are to be monitored and documented at least daily and that storage conditions be in compliance with USP<659>
- + Added clarification that hazardous and non-hazardous drugs are to be stored separately
- + Added that cleaning and disinfecting of compounding facilities is to be documented
- + Added clarification that cleaning processes are documented, including the cleaning or disinfection agent used

Standard DRX7-8G

- + Added requirement for calibration of temperature-sensing devices to conform to National Institute of Standards and Technology (NIST) standards

Standard DRX7-80

- + Clarified situations described in USP <797>
 - » Clarified the environment necessary for low-risk nonhazardous or radiopharmaceutical CSPs with a 12-hour or less BUD.
 - » Defined the ISO class for a PEC and expands the PEC options to include a BSC
 - » Added the presence of rust in the buffer area as a deficiency

Standard DRX7-80.01

- + Added compliance with current NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings
- + Added clarification that pre-sterilization procedures occur in an ISO class-8 area
- + Added requirement for facility protocols for decontamination of work surfaces that may come in contact with hazardous drugs

Standard DRX7-8P

- + Clarified that procedures must also address monitoring of controlled air environments

**Not all standards apply to all organizations. Consult your copy of standards to determine which are applicable to your organization.*



Please sign into your Customer Central Account to download the latest standards.



Contact your Account Advisor for any additional questions at **855-937-2242**.



DMEPOS Accreditation Application Addendum

****Fax to 919-785-3011****

Legal Name: _____ **Company ID#:** _____

- | | |
|---|--|
| <input type="checkbox"/> DM01 Automatic External Defibrillators (AEDs) | <input type="checkbox"/> M09 Wheelchairs-Complex Rehabilitative Power Wheelchairs |
| <input type="checkbox"/> DM02 Commodes/Urinals/Bedpans | <input type="checkbox"/> M09a Wheelchairs-Complex Rehabilitative Power Wheelchairs Related Accessories |
| <input type="checkbox"/> DM03 Continuous Passive Motion (CPM) Devices | <input type="checkbox"/> M10 Wheelchair Seating/Cushions |
| <input type="checkbox"/> DM04 Contracture Treatment Devices: Dynamic Splint | <input type="checkbox"/> OR01 Orthoses: Custom Fabricated |
| <input type="checkbox"/> DM05 Blood Glucose Monitors and Supplies (non-mail order) | <input type="checkbox"/> OR02 Orthoses: Prefabricated (non-custom fabricated) |
| <input type="checkbox"/> DM06 Blood Glucose Monitors and Supplies (mail order) | <input type="checkbox"/> OR03 Orthoses: Off-The-Shelf |
| <input type="checkbox"/> DM07 Gastric Suction Pumps | <input type="checkbox"/> OR04 Penile Pumps |
| <input type="checkbox"/> DM08 Heat & Cold Applications | <input type="checkbox"/> PD01 Breast Prostheses and Accessories |
| <input type="checkbox"/> DM09 Hospital Beds-Electric | <input type="checkbox"/> PD02 Cochlear Implants |
| <input type="checkbox"/> DM10 Hospital Beds-Manual | <input type="checkbox"/> PD03 Facial Prostheses |
| <input type="checkbox"/> DM11 Infrared Heating Pad Systems | <input type="checkbox"/> PD04 Neurostimulators |
| <input type="checkbox"/> DM12 External Infusion Pumps and Supplies | <input type="checkbox"/> PD05 Ocular Prostheses |
| <input type="checkbox"/> DM13 Insulin Infusion Pumps and Supplies | <input type="checkbox"/> PD06 Ostomy Supplies |
| <input type="checkbox"/> DM14 Implanted Infusion Pumps and Supplies | <input type="checkbox"/> PD07 Somatic Prostheses |
| <input type="checkbox"/> DM15 Negative Pressure Wound Therapy Pumps and Supplies | <input type="checkbox"/> PD08 Tracheostomy Supplies |
| <input type="checkbox"/> DM16 Neuromuscular Electrical Stimulators (NMES) | <input type="checkbox"/> PD09 Urological Supplies |
| <input type="checkbox"/> DM17 Osteogenesis Stimulators | <input type="checkbox"/> PD10 Voice Prosthetics |
| <input type="checkbox"/> DM18 Pneumatic Compression Devices | <input type="checkbox"/> PD11 Prosthetic Lenses: Conventional Eyeglasses |
| <input type="checkbox"/> DM19 Speech Generating Devices | <input type="checkbox"/> PD12 Prosthetic Lenses: Conventional Contact Lenses |
| <input type="checkbox"/> DM20 Support Surfaces: Pressure Reducing Beds/Mattresses/Overlays/Pads | <input type="checkbox"/> PD13 Prosthetic Lenses: Prosthetic Cataract Lenses |
| <input type="checkbox"/> DM21 Traction Equipment | <input type="checkbox"/> PE03 Enteral Nutrients |
| <input type="checkbox"/> DM22 Transcutaneous Electrical Nerve Stimulators (TENS) | <input type="checkbox"/> PE04 Enteral Equipment and/or Supplies |
| <input type="checkbox"/> DM23 Ultraviolet Light Devices | <input type="checkbox"/> PE05 Parenteral Nutrients |
| <input type="checkbox"/> HD01 Home Dialysis Equipment and Supplies | <input type="checkbox"/> PE06 Parenteral Equipment and/or Supplies |
| <input type="checkbox"/> HD02 Hemodialysis Equipment and Supplies | <input type="checkbox"/> PR01 Limb Prostheses |
| <input type="checkbox"/> M01 Canes and Crutches | <input type="checkbox"/> PR02 Eye Prostheses |
| <input type="checkbox"/> M02 Patient Lifts | <input type="checkbox"/> R01 Continuous Positive Airway Pressure (CPAP) Devices |
| <input type="checkbox"/> M03 Power Operated Vehicles (Scooters) | <input type="checkbox"/> R02 High Frequency Chest Wall Oscillation (HFCWO) Devices |
| <input type="checkbox"/> M04 Seat Lift Mechanisms | <input type="checkbox"/> R03 Invasive Mechanical Ventilation Devices |
| <input type="checkbox"/> M05 Walkers | <input type="checkbox"/> R04 Intermittent Positive Pressure Breathing (IPPB) Devices |
| <input type="checkbox"/> M06 Wheelchairs-Standard Manual | <input type="checkbox"/> R05 Intrapulmonary Percussive Ventilation Devices |
| <input type="checkbox"/> M06a Wheelchairs-Standard Manual Related Accessories | <input type="checkbox"/> R06 Mechanical In-Exsufflation Devices |
| <input type="checkbox"/> M07 Wheelchairs-Standard Power | <input type="checkbox"/> R07 Nebulizer Equipment and Supplies |
| <input type="checkbox"/> M07a Wheelchairs-Standard Power Related Accessories | <input type="checkbox"/> R08 Oxygen Equipment and Supplies |
| <input type="checkbox"/> M08 Wheelchairs-Complex Rehabilitative Manual Wheelchairs | <input type="checkbox"/> R09 Respiratory Assist Devices |
| <input type="checkbox"/> M08a Wheelchairs-Complex Rehabilitative Manual Wheelchairs Related Accessories | <input type="checkbox"/> R10 Respiratory Suction Pumps |
| | <input type="checkbox"/> R12 Ventilators Accessories/Supplies |
| | <input type="checkbox"/> S01 Surgical Dressings |
| | <input type="checkbox"/> S02 Diabetic Shoes/Inserts-Off-the-Shelf |
| | <input type="checkbox"/> S03 Diabetic Shoes/Inserts-custom |

This DMEPOS Accreditation Addendum was completed by the organization's owner (or designated representative) and was reviewed with the ACHC Surveyor on _____ (DATE). The organization's owner/designee and the ACHC Surveyor agree that the products selected in this addendum accurately represent the products offered by the organization. The organization is aware that any changes from the products indicated in this addendum must be submitted to ACHC for approval.

REVIEWED ON SITE BY:

_____ ACHC Surveyor – Print Name

_____ ACHC Surveyor - Signature

_____ Organization Representative – Print Name

_____ Organization Representative - Signature

Company Name _____
 Address _____

******Check all states that you are currently doing business in for each location separately. (This includes delivery and shipping services.)
 Organization must have all appropriate licensure per state.
 This applies to DMEPOS/RX providers**

STATE	Currently doing business	STATE	Currently doing business
Alaska		Montana	
Alabama		North Carolina	
Arkansas		North Dakota	
American Samoa		N. Mariana Islands	
Arizona		Nebraska	
California		New Hampshire	
Colorado		New Jersey	
Connecticut		New Mexico	
District of Columbia		Nevada	
Delaware		New York	
Florida		Ohio	
Georgia		Oklahoma	
Guam		Oregon	
Hawaii		Pennsylvania	
Iowa		Puerto Rico	
Idaho		Rhode Island	
Illinois		South Carolina	
Indiana		South Dakota	
Kansas		Tennessee	
Kentucky		Texas	
Louisiana		Utah	
Maryland		Virginia	
Maine		Virgin Islands	
Massachusetts		Vermont	
Michigan		Washington	
Minnesota		Wisconsin	
Missouri		West Virginia	
Mississippi		Wyoming	

MEDICARE DMEPOS SUPPLIER STANDARDS

Note: This is an abbreviated version of the supplier standards every Medicare DMEPOS supplier must meet in order to obtain and retain their billing privileges. These standards, in their entirety, are listed in 42 C.F.R. 424.57(c).

1. A supplier must be in compliance with all applicable Federal and State licensure and regulatory requirements.
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. A supplier must have an authorized individual (whose signature is binding) sign the enrollment application for billing privileges.
4. A supplier must fill orders from its own inventory, or contract with other companies for the purchase of items necessary to fill orders. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or 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 and must maintain a visible sign with posted hours of operation. The location must be 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.
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 is prohibited from direct solicitation to Medicare beneficiaries. For complete details on this prohibition see 42 CFR § 424.57 (c) (11).
12. A supplier is responsible for delivery of and must instruct beneficiaries on the use of Medicare covered items, and maintain proof of delivery and beneficiary instruction.
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 cost either directly, or through a service contract with another company, any 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 standards to each beneficiary it supplies a Medicare-covered item.
17. A supplier must disclose 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 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 for those specific products and services (except for certain exempt pharmaceuticals).
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. A supplier must meet the surety bond requirements specified in 42 CFR § 424.57 (d).
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 CFR § 424.516(f).
29. A supplier is prohibited from sharing a practice location with other Medicare providers and suppliers.
30. A supplier must remain open to the public for a minimum of 30 hours per week except physicians (as defined in section 1848(j) (3) of the Act) or physical and occupational therapists or a DMEPOS supplier working with custom made orthotics and prosthetics.

MEDICARE DMEPOS SUPPLIER STANDARDS

DMEPOS suppliers have the option to disclose the following statement to satisfy the requirement outlined in Supplier Standard 16 in lieu of providing a copy of the standards to the beneficiary.

The products and/or services provided to you by (supplier legal business name or DBA) are subject to the supplier standards contained in the Federal regulations shown at 42 Code of Federal Regulations Section 424.57(c). These standards concern business professional and operational matters (e.g. honoring warranties and hours of operation). The full text of these standards can be obtained at <http://ecfr.gpoaccess.gov>. Upon request we will furnish you a written copy of the standards.



DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS,
and SUPPLIES (DMEPOS) QUALITY STANDARDS

FINAL
October 2008

DMEPOS Quality Standards

Table of Contents

Section I: Supplier Business Services Requirements -----	3
A. Administration -----	3
B. Financial Management -----	4
C. Human Resources Management -----	4
D. Consumer Services -----	5
E. Performance Management -----	5
F. Product Safety -----	6
G. Information Management -----	7
Section II: Supplier Product-Specific Service Requirements-----	8
A. Intake & Assessment -----	8
B. Delivery & Set-up-----	8
C. Training/Instructions to Beneficiary and/or Caregiver(s) -----	9
D. Follow-up -----	9
Appendices-----	10
A. Respiratory Equipment, Supplies, and Services -----	10
B. Manual Wheelchairs, Power Mobility Devices, and Complex Rehabilitative Wheelchairs and Assistive Technology-----	12
C. Custom Fabricated and Custom Fitted Orthoses, Prosthetic Devices, External Breast Prostheses, Therapeutic Shoes and Inserts, and their Accessories and Supplies; Custom-Made Somatic, Ocular and Facial Prostheses -----	15

DMEPOS Quality Standards

Section I: Supplier Business Services Requirements

A. Administration

1. The supplier shall have one or more individuals who perform leadership functions, with the authority, responsibility, and accountability to direct the organization and its key activities and operations.

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 organization's structure, examples of leadership positions may include the owners, governing body, chief executive officer, and other individuals responsible for managing services provided by the organization.

2. The supplier shall govern its business so that it obtains and provides appropriate quality equipment, item(s), and service(s) to beneficiaries.
3. The supplier shall have a physical location and display all licenses, certificates, and permits to operate. The licenses, certificates and permits must be displayed in an area accessible to customers and patients. The supplier shall provide copies, upon request, to government officials or their authorized agents.
4. The supplier shall provide only durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) and other items that meet applicable Food and Drug Administration (FDA) regulations and medical device effectiveness and safety standards. The supplier shall obtain from the manufacturer copies of the features, warranties, and instructions for each type of non-custom fabricated item.
5. The supplier shall comply with all Medicare statutes, regulations (including the disclosure of ownership and control information requirements at 42 CFR §420.201 through §420.206), manuals, program instructions, and contractor policies and articles.
6. The supplier shall implement business practices to prevent and control fraud, waste, and abuse by:
 - Using procedures that articulate standards of conduct to ensure the organization's compliance with applicable laws and regulations; and
 - Designating one or more individuals in leadership positions to address compliance issues.

DMEPOS Quality Standards

B. Financial Management

1. The supplier shall implement financial management practices that ensure accurate accounting and billing to beneficiaries and the Medicare program. Financial records shall be accurate, complete, current, and reflect cash or accrual base accounting practices.
2. The supplier shall maintain accounts that link equipment and item(s) to the beneficiary and manage revenues and expenses on an ongoing basis, as they relate to beneficiary services, including the following:
 - Reconciling charges to beneficiaries for equipment, supplies, and services with invoices, receipts, and deposits;
 - Planning to meet the needs of beneficiaries and maintain business operations by having an operating budget, as appropriate to the business's size and scope of services; and
 - Having a mechanism to track actual revenues and expenses

C. Human Resources Management

1. The supplier shall:

- Implement policies and issue job descriptions that specify personnel qualifications, training, certifications/licensures where applicable, experience, and continuing education requirements consistent with the specialized equipment, items, and services it provides to beneficiaries;
- Provide copies of such policies, job descriptions and certifications/licensures (where applicable) upon request to accreditation organizations and government officials or their authorized agents; and

Verify and maintain copies of licenses, registrations, certifications, and competencies for personnel who provide beneficiary services.

2. Technical personnel shall be competent to deliver and set-up equipment, item(s) and service(s) and train beneficiaries and/or caregiver(s).
3. Professional personnel shall be licensed, certified, or registered and function within their scope of practice as required by the State standards under which the professional is licensed, certified or registered.

DMEPOS Quality Standards

October 2008

D. Consumer Services

1. When providing equipment, item(s), and service(s) to beneficiaries and/or caregiver(s), the supplier shall:

- Provide clear, written or pictorial, and oral instructions related to the use, maintenance, infection control practices for, and potential hazards of equipment and/or item(s) as appropriate;
- Provide information regarding expected time frames for receipt of delivered items;
- Verify that the equipment, item(s), and service(s) were received;

Document in the beneficiary's record the make and model number or any other identifier of any non-custom equipment and/or item(s) provided;

- Provide essential contact information for rental equipment and options for beneficiaries and/or caregiver(s) to rent or purchase equipment and/or item(s), when applicable; and
 - Provide information and telephone number(s) for customer service, regular business hours, after-hours access, equipment and/or item(s) repair, and emergency coverage.
2. If the supplier cannot or will not provide the equipment, item(s) or service(s) that are prescribed for a beneficiary, the supplier shall notify the prescribing physician (for purpose of these standards, we are using this term to include other practitioners who can prescribe DMEPOS under Medicare laws and regulations) or other health care team member(s) promptly within 5 calendar days.
3. Within 5 calendar days of receiving a beneficiary's complaint, the supplier shall notify the beneficiary, using either oral, telephone, e-mail, fax, or letter format, that it has received the complaint and is investigating. Within 14 calendar days, the supplier shall provide written notification to the beneficiary of the results of its investigation. The supplier shall maintain documentation of all complaints received, copies of the investigations, and responses to beneficiaries.

E. Performance Management

1. The supplier shall implement a performance management plan that measures: outcomes of consumer services, billing practices, and adverse events. The data collection may target certain aspects of services that have a potential to cause harm or injury; occur frequently (creating a greater than expected number of adjustment(s), repair(s), or replacement(s)); or require significant instruction to assure safe use and benefit of the equipment and/or item(s).
2. At a minimum, each supplier shall measure:
- Beneficiary satisfaction with and complaints about product(s) and service(s);

DMEPOS Quality Standards

October 2008

- Timeliness of response to beneficiary question(s), problem(s), and concern(s);
 - Impact of the supplier's business practices on the adequacy of beneficiary access to equipment, item(s), service(s), and information;
 - Frequency of billing and coding errors (e.g., number of Medicare claims denied, errors the supplier finds in its own records after it has been notified of a claims denial); and
 - Adverse events to beneficiaries due to inadequate service(s) or malfunctioning equipment and/or item(s) (e.g., injuries, accidents, signs and symptoms of infection, hospitalizations). This may be identified through follow-up with the prescribing physician, other healthcare team member(s), or the beneficiary and/or caregiver(s).
3. The supplier shall seek input from employees, customers, and referral sources when assessing the quality of its operations and services.

F. Product Safety

1. The supplier shall:

- Implement a program that promotes the safe use of equipment and item(s) and minimizes safety risks, infections, and hazards both for its staff and for beneficiaries;
- Implement and maintain a plan for identifying, monitoring, and reporting (where indicated) equipment and item(s) failure, repair, and preventive maintenance provided to beneficiaries;
- Investigate any incident, injury or infection in which DMEPOS may have contributed to the incident, injury or infection, when the supplier becomes aware. The investigation should be initiated within 24 hours after the supplier becomes aware of an incident, injury or infection resulting in a beneficiary's hospitalization or death. For other occurrences, the supplier shall investigate within 72 hours after being made aware of the incident, injury or infection. The investigation includes all necessary information, pertinent conclusions about what happened, and whether changes in system(s) or processes are needed. The supplier should consider possible links between the equipment, item(s) and service(s) furnished and the adverse event;
- Have a contingency plan that enables it to respond to emergencies and disasters or to have arrangements with alternative suppliers in the event that the supplier cannot service its own customers as the result of an emergency or disaster; and

Verify, authenticate, and document the following prior to distributing, dispensing, or delivering products to an end-user:

The products are not adulterated, counterfeit, suspected of being counterfeit, and have not been obtained by fraud or deceit; and

DMEPOS Quality Standards

October 2008

The products are not misbranded and are appropriately labeled for their intended distribution channels.

G. Information Management

The supplier shall maintain accurate, pertinent, accessible, confidential, and secure beneficiary records, in accordance with privacy and security standards of the Health Insurance Portability and Accountability Act (HIPAA) and other applicable State standards.

DMEPOS Quality Standards

October 2008

Section II: Supplier Product-Specific Service Requirements

1. All DMEPOS must serve a medical purpose to be covered under the Medicare program and may require the prescribing physician to collaborate and coordinate clinical services with other healthcare professionals (e.g., orthotists; prosthetists; occupational, physical, respiratory therapists; pedorthists; etc.).
2. In addition to the supplier product-specific service requirements in this section, the DMEPOS supplier shall implement the requirements stated in Appendices A through C, as applicable to its business.

A. Intake & Assessment

1. The supplier shall consult with the prescribing physician as needed to confirm the order and to recommend any necessary changes, refinements, or additional evaluations to the prescribed equipment, item(s), and/or service(s).

Beneficiary's Record

2. The supplier shall:
 - Review the beneficiary's record as appropriate and incorporate any pertinent information, related to the beneficiary's condition(s) which affect the provision of the DMEPOS and related services, or to the actual equipment, item(s) and service(s) provided, in collaboration with the prescribing physician; and
 - The DMEPOS prescription, any certificates of medical necessity (CMNs), and pertinent documentation from the beneficiary's prescribing physician shall be kept unaltered in the beneficiary's record.

B. Delivery & Set-up

I. The supplier shall:

- Deliver and set-up, or coordinate set-up with another supplier, all equipment and item(s) in a timely manner as agreed upon by the beneficiary and/or caregiver, supplier, and prescribing physician;
- Provide all equipment and item(s) that are necessary to operate the equipment or item(s) and perform any further adjustments as applicable;
- Provide, or arrange for, loaner equipment equivalent to the original equipment during any repair period except for orthotics and prosthetics; and

DMEPOS Quality Standards

October 2008

- Assure that all equipment and item(s) delivered to the beneficiary is consistent with the prescribing physician's order and identified beneficiary needs, risks, and limitations of which the supplier is aware.

C. Training/Instruction to Beneficiary and/or Caregiver(s)

1. The supplier shall, as applicable:

- Provide, or coordinate the provision of, appropriate information related to the set-up (including preparation of enteral/parenteral nutrients), features, routine use, troubleshooting, cleaning, infection control practices, and maintenance of all equipment and item(s) provided;
- Provide relevant information and/or instructions about infection control issues related to the use of all equipment and item(s) provided;
- For initial equipment and/or item(s) provided by mail order delivery: Verify and document in the beneficiary's record that the beneficiary and/or caregiver(s) has received training and written instructions on the use of the equipment and item(s); and

Ensure that the beneficiary and/or caregiver(s) can use all equipment and item(s) provided safely and effectively in the settings of anticipated use.

2. Beneficiary and/or caregiver(s) training and instructions shall be commensurate with the risks, complexity, and manufacturer's instructions and/or specifications for the equipment and item(s). The supplier shall tailor training and instruction materials and approaches to the needs, abilities, learning preferences, and language of the beneficiary and/or caregiver(s).

D. Followup

The supplier shall provide follow-up services to the beneficiary and/or caregiver(s), consistent with the type(s) of equipment, item(s) and service(s) provided, and recommendations from the prescribing physician or healthcare team member(s).

DMEPOS Quality Standards

October 2008

Appendix A: Respiratory Equipment, Supplies, and Services

1. Respiratory Services encompass the provision of home medical equipment and supplies (described below) that require technical and professional services.
2. The supplier shall provide respiratory services 24 hours a day, 7 days a week as needed by the beneficiary and/or caregiver(s).
3. Home medical equipment and supplies covered in this appendix include:
 - Oxygen concentrators, reservoirs, high-pressure cylinders, oxygen accessories and supplies, and oxygen conserving devices;
 - Home Invasive Mechanical Ventilators;
 - Continuous Positive Airway Pressure (CPAP) Devices;
 - Respiratory Assist Devices (RAD);
 - Intermittent Positive Pressure Breathing (IPPB) Devices; and
 - Nebulizers.

A. Intake & Assessment

Refer to Section II: Supplier Product-Specific Service Requirements.

B. Delivery & Setup

1. In addition to the requirements described in Section II: Supplier Product-Specific Service Requirements, the supplier shall comply with the current version of the *American Association for Respiratory Care Practice Guidelines* listed below:
 - Oxygen Therapy in the Home or Extended Care Facility;
 - Long Term Invasive Mechanical Ventilation in the Home; and
 - IPPB.

DMEPOS Quality Standards

October 2008

C. Training/Instruction to Beneficiary and/or Caregivers)

1. In addition to the requirements described in Section II: Supplier Product-Specific Service Requirements, the supplier shall comply and provide training to the beneficiary and/or caregiver(s) consistent with the current version of the *American Association for Respiratory Care Practice Guidelines* listed below:

- Long Term Invasive Mechanical Ventilation in the Home;
- Oxygen Therapy in the Home or Extended Care Facility;
- IPPI3;
- Providing Patient and Caregiver Training; and
- Suctioning of the Patient in the Home.

D. Followup

Refer to Section II: Supplier Product-Specific Service Requirements.

DMEPOS Quality Standards

October 2008

Appendix B: Manual Wheelchairs, Power Mobility Devices, and Complex Rehabilitative Wheelchairs and Assistive Technology

This appendix applies to Manual Wheelchairs, Power Mobility Devices (PMDs), and Complex Rehabilitative Wheelchairs and Assistive Technology. Manual wheelchairs include standard recliners, heavy-duty wheelchairs, standard lightweight wheelchairs, and hemi wheelchairs, armrests, legrests/footplates, anti-tipping devices, and other Medicare approved accessories. PMDs include power wheelchairs and power operated vehicles (POVs) and accessories. 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).

I. Manual Wheelchairs

A. Intake & Assessment

In addition to Section II: Supplier Product-Specific Service Requirements, the supplier shall verify that seating, positioning and specialty assistive technology have been evaluated and documented in the beneficiary's record.

B. Delivery & Set-up

Refer to Section II: Supplier Product Specific Service Requirements.

C. Training/Instruction to Beneficiary and/or Caregiver(s) Refer

to Section II: Supplier Product Specific Service Requirements.

D. Follow-up

Refer to Section II: Supplier Product Specific Service Requirements.

II. Power Mobility Devices

A. Intake & Assessment

In addition to Section II: Supplier Product-Specific Service Requirements, the supplier shall verify that seating, positioning and specialty assistive technology have been evaluated and documented in the beneficiary's record.

B. Delivery & Set-up Refer to Section II: Supplier Product-Specific

Service Requirements.

DMEPOS Quality Standards

C. Training/Instruction to Beneficiary and/or Caregiver(s) Refer

to Section II: Supplier Product Specific Service Requirements.

D. Followup

Refer to Section II: Supplier Product Specific Service Requirements.

III. Complex Rehabilitative Wheelchairs and Assistive Technology

In addition to Section II: Supplier Product-Specific Service Requirements, the supplier shall:

1. Employ (W-2 employee) at least one qualified individual as a Rehabilitative Technology Supplier (RTS) per location. A qualified RTS is an individual that has one of the following credentials:

- Certified Rehabilitative Technology Supplier (CRTS);
Assistive Technology Supplier (ATS) (discontinued 12/31/2008);
Assistive Technology Practitioner (ATP) (discontinued 12/31/2008);
Assistive Technology Professional (AT) (effective 1/1/2009).

2. The RTS shall have at least one or more *trained technicians* available to service each location appropriately depending on the size and scope of its business. A trained technician is identified by the following:

- Factory trained by manufacturers of the products supplied by the company;
- Experienced in the field of Rehabilitative Technology, (e.g., on the job training, familiarity with rehabilitative clients, products and services);
- Completed at least 10 hours annually of continuing education specific to Rehabilitative Technology; and
- Able to program and repair sophisticated electronics associated with power wheelchairs, alternative drive controls, and power seating systems.

3. The RTS shall:

- Coordinate services with the prescribing physician to conduct face-to-face evaluations of the beneficiary in an appropriate setting and include input from other members of the health care team (i.e., PT, OT, etc.);

DMEPOS Quality Standards

October 2008

- Provide the beneficiary with appropriate equipment for trial and simulation, when necessary;
 - Maintain in the beneficiary's record all of the information obtained during the assessment; and
 - Implement procedures for assembly and set-up of equipment as well as a process to verify that the final product meets the specifications of the original product recommendation approved by the prescribing physician.
4. If beneficiaries are evaluated in the supplier's facility, the supplier shall:
- Provide the beneficiary private, clean, and safe rooms appropriate for fittings and evaluations; and
 - Maintain a repair shop located in the facility or in close proximity or easily accessible from another location of the supplier, as well as an area appropriate for assembly and modification of products.

A. Intake & Assessment

In addition to Section II: Supplier Product-Specific Service Requirements, the supplier shall verify that seating, positioning and specialty assistive technology have been evaluated and documented in the beneficiary's record.

B. Delivery & Setup

Refer to Section II: Supplier Product Specific Service Requirements.

C. Training/Instruction to Beneficiary and/or Caregiver(s) Refer

to Section II: Supplier Product Specific Service Requirements.

D. Followup

Refer to Section II: Supplier Product-Specific Service Requirements.

DMEPOS Quality Standards

October 2008

Appendix C: Custom Fabricated and Custom Fitted Orthoses, Prosthetic Devices, External Breast Prostheses, Therapeutic Shoes and Inserts, and their Accessories and Supplies; Custom-Made Somatic, Ocular and Facial Prostheses

The supplier shall be trained in a broad range of treatment options to ensure that the item(s) prescribed is/are optimal for the beneficiary's condition. The provision of custom fabricated or custom fitted devices (i.e., other than off-the-shelf items) requires access to a facility with the equipment necessary to fulfill the supplier's responsibility to provide follow-up treatment, including modification, adjustment, maintenance and repair of the item(s). Individuals supplying the item(s) set out in this appendix must possess specialized education, training, and experience in fitting, and certification and/or licensing.

Definition of Terms

The terms below are used to describe the types of devices referred to in this appendix.

1. Custom Fabricated: A custom fabricated item is one that is individually made for a specific patient. No other patient would be able to use this item. A custom fabricated item is a device which is fabricated based on clinically derived and rectified castings, tracings, measurements, and/or other images (such as x-rays) of the body part. The fabrication may involve using calculations, templates and components. This process requires the use of basic materials including, but not limited to plastic, metal, leather or cloth in the form of uncut or unshaped sheets, bars, or other basic forms and involves substantial work such as vacuum forming, cutting, bending, molding, sewing, drilling and finishing prior to fitting on the patient.
2. Molded to Patient Model: 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 computer-aided design-computer aided manufacturing (CAD-CAM) systems software. This technology includes specialized probes/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.
3. Positive Model of the Patient:
 - a) Molded to patient model is a negative impression taken of the patient's body member and a positive model rectification is constructed; or
 - b) 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 is electronically transmitted to a commercial milling machine that carves the rectified model; or
 - c) 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.

DMEPOS Quality Standards

October 2008

4. Custom Fitted: A prefabricated device, which 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, or a device that must be trimmed, bent, molded (with or without heat), or otherwise modified by an individual with expertise in customizing the item to fit and be used by a specific patient.
5. Prosthetic Devices: Devices (other than dental) which replace all or part of an internal body organ (including contiguous tissue), or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ. 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 the condition is of long and indefinite duration, the test of permanence is considered met. (Refer to Section 120 of Chapter 15 of the Medicare Benefit Policy Manual)
6. Orthotic Devices: Rigid and 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.
7. Ocular Prostheses: Custom-fabricated ocular prostheses that replace the globe of the eye or cover the existing unsightly eye as a result of traumatic injury, disease and/or ablative surgery, or congenital malformation. Custom-made eye prostheses include conformers, scleral shells, and ocular prostheses that fit within the natural socket tissue and eyelids, as well as the custom-made ocular prosthesis component that is integrated into an orbital, upper facial, or hemifacial prosthesis.
8. Facial Prostheses: Custom-fabricated prosthetic restoration of the face including auricular, nasal, mid-facial, orbital (including ocular), upper facial, hemi-facial, partial facial, nasal septal, and other areas of the face disfigured by traumatic injury, disease and/or ablative surgery, or congenital malformation.
9. 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 and/or ablative surgery, or congenital malformation.
10. External Breast Prostheses: Prefabricated or custom fabricated forms, bras, and sleeves. (Refer to Section 120 of Chapter 15 of the Medicare Benefit Policy Manual)
11. Off-The-Shelf Orthoses: Orthoses which requires minimal self adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit the beneficiary. Appendix C does not apply to off-the-shelf orthotics. (Refer to 42 CFR, section §414.402)

DMEPOS Quality Standards

October 2008

12. Therapeutic Shoes and Inserts: Includes depth or custom-molded shoes along with inserts for individuals with diabetes (Refer to Section 140 of Chapter 15 of the Medicare Benefit Policy Manual)

a. 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; and

- Have some form of shoe closure.

b. Depth Shoes:

- Have a full length, heel-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; and

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.

Inserts:

- Are total contact, multiple density, removable inlays that are directly molded to the patient's foot or a model of the patient's foot and that are made of a suitable material with regard to the patient's condition.

A. Intake & Assessment

In addition to Section II: Supplier Product-Specific Service Requirements, the supplier shall:

Assess the beneficiary's need for and use of the orthoses/prostheses (e.g., comprehensive history, pertinent medical history (including allergies to materials), skin condition, diagnosis, previous use of an orthoses/prostheses, results of diagnostic evaluations, beneficiary expectations, pre-treatment photographic documentation (when appropriate);

DMEPOS Quality Standards

Determine the appropriate orthoses/prostheses and specifications based on beneficiary need for use of the orthoses/prostheses to ensure optimum therapeutic benefits and appropriate strength, durability, and function as required for the beneficiary;

Formulate a treatment plan that is consistent with the prescribing physician's dispensing order and/or the written plan of care, in accordance with Medicare rules, and consult the physician when appropriate;

Perform an in person diagnosis-specific functional clinical examination as related to the beneficiary's use and need of the orthoses/prostheses (e.g., 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);

- Establish goals and expected outcomes of the beneficiary's use of the orthoses/prostheses (e.g., reduce pain, increase comfort, enhance function and independence, provide joint stability, prevent deformity, increase range of motion, address cosmetic issues and/or promote healing) with feedback from the beneficiary and/or prescribing physician as necessary to determine the appropriateness of the orthoses/prostheses;
- Communicate to the beneficiary and/or caregiver(s), and prescribing physician the recommended treatment plan, including disclosure of potential risk, benefits, precautions, the procedures for repairing, replacing, and/or adjusting the device or item(s), and the estimated time involved in the process;
- Assess the orthoses/prostheses for structural safety and ensure that manufacturer guidelines are followed prior to face-to-face fitting/delivery (e.g., beneficiary weight limits, ensuring that closures work properly and do not demonstrate defects); and
- Ensure the treatment plan is consistent with the prescribing physician's dispensing order.

B. Delivery & Setup

Not applicable to this appendix.

C. Training/Instruction to Beneficiary and/or Caregiver(s)

In addition to Section II: Supplier Product-Specific Service Requirements, the supplier shall:

- Provide instructions to the beneficiary and/or caregiver(s) for the specific orthoses, prostheses, or therapeutic shoe/inserts as follows:

How to use, maintain, and clean the orthoses/prostheses (e.g., wearing schedules, therapy, residual limb hygiene, other pertinent instructions);
How to don and doff the orthoses/prostheses, including how to adjust closures for proper fit;

DMEPOS Quality Standards

How to inspect the skin for pressure areas, redness, irritation, skin breakdown, pain, or edema;

- How to utilize an appropriate interface (e.g., stockinettes, socks, gloves, shoes) to accommodate the orthoses/prostheses where appropriate;
How to report any problems related to the orthoses/prostheses to the supplier or the prescribing physician if changes are noted (e.g., changes in skin condition, heightened pain, increase in edema, wound concerns, changes in general health, height, weight, or intolerance to wearing the orthoses/prostheses as applicable);
- How to schedule follow-up appointments as necessary; and
- How to establish an appropriate "wear schedule" and schedule for tolerance of the orthoses/prostheses.

- Provide necessary supplies (e.g., adhesives, solvents, lubricants) to attach, maintain, and clean the items, as applicable, and information about how to subsequently obtain necessary supplies; and
- Refer the beneficiary back to the prescribing physician as necessary for intervention beyond the supplier's scope of practice.

D. Follow-up

In addition to Section II: Supplier Product-Specific Service Requirements, the supplier shall:

- Have access to a facility with the equipment necessary to provide follow-up treatment and fabrication/modification of the specific orthoses/prostheses;
- Review recommended maintenance with the beneficiary and/or caregiver(s); Solicit feedback from the beneficiary and/or caregiver and prescribing physician as necessary to determine the effectiveness of the orthoses/prostheses (e.g., wear schedule/tolerance, comfort, perceived benefits/detriments, ability to don and doff, proper usage and function, overall beneficiary satisfaction);

Review and make changes to the treatment plan based on the beneficiary's current medical condition;

Continue to assist the beneficiary until the orthoses/prostheses reaches the optimal level of fit and function consistent with the treatment plan; and

- Provide appropriate beneficiary follow-up treatment consistent with the types of orthoses/prostheses or therapeutic shoe/inserts provided, the beneficiary's diagnosis, specific care rendered, and recommendations.

A CMS Medicare Administrative Contractor
<http://www.NGSMedicare.com>

Re: Face-to-Face and Written Order Requirements for High Cost DME

Dear Physician,

For certain specified items of durable medical equipment the Affordable Care Act requires that an in-person, face-to-face examination (F2F) documenting the need for the item must have occurred sometime during the six (6) months prior to the order for and delivery of the item. The purpose of this letter is to provide a summary of these requirements.

A F2F examination meeting the requirements discussed below is required each time a new prescription for one of the specified items is required. A new prescription is required by Medicare:

- For all claims for purchases or initial rentals
- When there is a change in the order for the accessory, supply, drug, etc.
- On a regular basis (even if there is no change in the order) only if it is so specified in the documentation section of a particular medical policy
- When an item is replaced
- When there is a change in the supplier
- When required by state law

These requirements are effective for all new orders (prescriptions) for the specified items created on or after July 1, 2013.

Face-To-Face Examination Requirements

The physician must have a face-to-face examination with the beneficiary in the six (6) months prior to the date of the written order for the specified items of DME.

This face-to-face requirement includes examinations conducted via the Centers for Medicare & Medicaid Services (CMS)-approved use of telehealth examinations (as described in Chapter 15 of the CMS Internet-Only Manual [IOM] Publication 100-02, *Medicare Benefit Policy Manual* and Chapter 12 of the CMS IOM Publication 100-04, *Medicare Claims Processing Manual*).

For the physician prescribing a specified DME item:

The face-to-face examination with the beneficiary must be conducted within the six (6) months prior to the date of the prescription.

The face-to-face examination must document that the beneficiary was evaluated and/or treated for a condition that supports the need for the item(s) of DME ordered.

Remember that all Medicare coverage and documentation requirements for DMEPOS also apply. There must be sufficient medical information included in the medical record to demonstrate that the applicable coverage criteria are met. Refer to the applicable Local Coverage Determination for information about the medical necessity criteria for the item(s) being ordered.

The prescriber must provide a copy of the face-to-face examination and the prescription for the item(s) to the DMEPOS supplier before the item can be delivered.

Prescription (Order) Requirements

These items require a written order prior to delivery (WOPD). A WOPD is the standard Medicare detailed written order, which must be completed and in the DMEPOS supplier's possession BEFORE the item can be delivered. The prescription (order) for the DME must meet all requirements for a WOPD and include all of the items below:

- Beneficiary's name,
- Physician's Name
- Date of the order and the start date, if start date is different from the date of the order
- Detailed description of the item
- The prescribing practitioner's National Provider Identifier (NPI),
- The signature of the ordering practitioner
- Signature date

For any of the specified items provided on a periodic basis, including drugs, the written order must include:

- Item(s) to be dispensed
- Dosage or concentration, if applicable
- Route of Administration, if applicable
- Frequency of use
- Duration of infusion, if applicable
- Quantity to be dispensed
- Number of refills, if applicable

Note that prescriptions for these specified DME items require the National Provider Identifier to be included on the prescription. Prescriptions for other DME items do not have this NPI requirement.

Date and Timing Requirements

There are specific date and timing issues:

- The date of the F2F must be on or before the date of the written order (prescription) and may be no older than 6 months prior to the prescription date.
- The date of the F2F must be on or before the date of delivery for the item(s) prescribed.
- The date of the written order must be before the date of delivery (date of service [DOS]).
- The DMEPOS supplier must have documentation of both the face-to-face visit and the completed WOPD in their file prior to the delivery of these items.

This letter is intended to be a general summary. It is not intended to take the place of the law, regulations, or national and local coverage determinations. Detailed information about these requirements can be found on the CMS Web site <http://www.cms.gov> or on the [DME contractors' Web site](#).

Sincerely,

Paul J. Hughes, MD Medical Director, DME MAC, Jurisdiction A NHIC, Corp.	Robert D. Hoover, Jr., MD, MPH, FACP Medical Director, DME MAC, Jurisdiction C CGS Administrators, LLC
Stacey V. Brennan, MD, FAAFP Medical Director, DME MAC, Jurisdiction B National Government Services	Eileen Moynihan, MD Medical Director, DME MAC, Jurisdiction D Noridian Healthcare Solutions

TABLE A: DME List of Specified Covered Items

The DME list of Specified Covered Items is as follows. The original list was at 77 *Federal Register* 44798. This original list contains some codes that have been deleted or that were made not valid for Medicare (*) in the interim while some other codes have had narrative changes (**). Updates to the list will be made as CMS releases revisions.

Refer to the Pricing, Data Analysis, and Coding Contractor Web site for information on coding at <http://www.dmepdac.com>.

Table Name

HCPCS Code	Description
E0185	Gel or gel-like pressure mattress pad
E0188	Synthetic sheepskin pad
E0189	Lamb's wool sheepskin pad
E0194	Air fluidized bed
E0197	Air pressure pad for mattress standard length and width
E0198	Water pressure pad for mattress standard length and width
E0199	Dry pressure pad for mattress standard length and width
E0250	Hospital bed fixed height with any type of side rails, mattress
E0251	Hospital bed fixed height with any type side rails without mattress
E0255	Hospital bed variable height with any type side rails with mattress
E0256	Hospital bed variable height with any type side rails without mattress
E0260	Hospital bed semi-electric (Head and foot adjustment) with any type side rails with mattress
E0261	Hospital bed semi-electric (head and foot adjustment) with any type side rails without mattress
E0265	Hospital bed total electric (head, foot and height adjustments) with any type side rails with mattress
E0266	Hospital bed total electric (head, foot and height adjustments) with any type side rails without mattress
E0290	Hospital bed fixed height without rails with mattress

HCPCS Code	Description
E0291	Hospital bed fixed height without rail without mattress
E0292	Hospital bed variable height without rail without mattress
E0293	Hospital bed variable height without rail with mattress
E0294	Hospital bed semi-electric (head and foot adjustment) without rail with mattress
E0295	Hospital bed semi-electric (head and foot adjustment) without rail without mattress
E0296	Hospital bed total electric (head, foot and height adjustments) without rail with mattress
E0297	Hospital bed total electric (head, foot and height adjustments) without rail without mattress
E0300	Pediatric crib, hospital grade, fully enclosed
E0301	Hospital bed Heavy Duty extra wide, with weight capacity 350-600 lbs with any type of rail, without mattress
E0302	Hospital bed Heavy Duty extra wide, with weight capacity greater than 600 lbs with any type of rail, without mattress
E0303	Hospital bed Heavy Duty extra wide, with weight capacity 350-600 lbs with any type of rail, with mattress
E0304	Hospital bed Heavy Duty extra wide, with weight capacity greater than 600 lbs with any type of rail, with mattress
E0424	Stationary compressed gas Oxygen System rental; includes contents, regulator, nebulizer, cannula or mask and tubing
E0431	Portable gaseous oxygen system rental includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing
E0433	Portable liquid oxygen system
E0434	Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, content gauge, cannula or mask, and tubing
E0439	Stationary liquid oxygen system rental, includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
E0441	Oxygen contents, gaseous (1 months' supply)
E0442	Oxygen contents, liquid (1 months' supply)
E0443	Portable Oxygen contents, gas (1 months' supply)
E0444	Portable oxygen contents, liquid (1 months' supply)
E0450	Volume control ventilator without pressure support used with invasive interface
E0457	Chest shell
E0459	Chest wrap
E0460	Negative pressure ventilator portable or stationary
E0461	Volume control ventilator without pressure support node for a noninvasive interface
E0462	Rocking bed with or without side rail
E0463	Pressure support ventilator with volume control mode used for invasive surfaces
E0464	Pressure support vent with volume control mode used for noninvasive surfaces
E0470	Respiratory Assist Device, bi-level pressure capability, without backup rate used non-invasive interface
E0471	Respiratory Assist Device, bi-level pressure capability, with backup rate for a non-invasive interface
E0472	Respiratory Assist Device, bi-level pressure capability, with backup rate for invasive interface
E0480	Percussor electric/pneumatic home model
E0482	Cough stimulating device, alternating positive and negative airway pressure
E0483	High Frequency chest wall oscillation air pulse generator system

HCPCS Code	Description
E0484	Oscillatory positive expiratory device, non-electric
E0570	Nebulizer with compressor
E0575	Nebulizer, ultrasonic, large volume
E0580	Nebulizer, durable, glass or autoclavable plastic, bottle type for use with regulator or flowmeter
E0585	Nebulizer with compressor & heater
E0601	Continuous airway pressure device
E0607	Home blood glucose monitor
E0627	Seat lift mechanism incorporated lift-chair
E0628	Separate Seat lift mechanism for patient owned furniture electric
E0629	Separate seat lift mechanism for patient owned furniture non-electric
E0636	Multi positional patient support system, with integrated lift, patient accessible controls
E0650	Pneumatic compressor non-segmental home model
E0651	Pneumatic compressor segmental home model without calibrated gradient pressure
E0652	Pneumatic compressor segmental home model with calibrated gradient pressure
E0655	Non- segmental pneumatic appliance for use with pneumatic compressor on half arm
E0656	Non- segmental pneumatic appliance for use with pneumatic compressor on trunk
E0657	Non- segmental pneumatic appliance for use with pneumatic compressor chest
E0660	Non- segmental pneumatic appliance for use with pneumatic compressor on full leg
E0665	Non- segmental pneumatic appliance for use with pneumatic compressor on full arm
E0666	Non- segmental pneumatic appliance for use with pneumatic compressor on half leg
E0667	Segmental pneumatic appliance for use with pneumatic compressor on full-leg
E0668	Segmental pneumatic appliance for use with pneumatic compressor on full arm
E0669	Segmental pneumatic appliance for use with pneumatic compressor on half leg
E0671	Segmental gradient pressure pneumatic appliance full leg
E0672	Segmental gradient pressure pneumatic appliance full arm
E0673	Segmental gradient pressure pneumatic appliance half leg
E0675	Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency
E0692	Ultraviolet light therapy system panel treatment 4 foot panel
E0693	Ultraviolet light therapy system panel treatment 6 foot panel
E0694	Ultraviolet multidirectional light therapy system in 6 foot cabinet
E0720	Transcutaneous electrical nerve stimulation, two lead, local stimulation
E0730	Transcutaneous electrical nerve stimulation, four or more leads, for multiple nerve stimulation
E0731	Form fitting conductive garment for delivery of TENS or NMES
E0740	Incontinence treatment system, Pelvic floor stimulator, monitor, sensor, and/or trainer
E0744	Neuromuscular stimulator for scoliosis
E0745	Neuromuscular stimulator electric shock unit
E0747	Osteogenesis stimulator, electrical, non-invasive, other than spine application.
E0748	Osteogenesis stimulator, electrical, non-invasive, spinal application
E0749	Osteogenesis stimulator, electrical, surgically implanted
E0760	Osteogenesis stimulator, low intensity ultrasound, non-invasive
E0762	Transcutaneous electrical joint stimulation system including all accessories
E0764	Functional neuromuscular stimulator, transcutaneous stimulations of muscles of ambulation with computer controls

HCPCS Code	Description
E0765	FDA approved nerve stimulator for treatment of nausea & vomiting
E0782	Infusion pumps, implantable, Non-programmable
E0783	Infusion pump, implantable, Programmable
E0784	External ambulatory infusion pump
E0786	Implantable programmable infusion pump, replacement
E0840	Tract frame attach to headboard, cervical traction
E0849	Traction equipment cervical, free-standing stand/frame, pneumatic, applying traction force to other than mandible
E0850	Traction stand, free standing, cervical traction
E0855	Cervical traction equipment not requiring additional stand or frame
E0856	Cervical traction device, cervical collar with inflatable air bladder
E0958**	Manual wheelchair accessory, one-arm drive attachment
E0959**	Manual wheelchair accessory-adapter for Amputee
E0960**	Manual wheelchair accessory, shoulder harness/strap
E0961**	Manual wheelchair accessory wheel lock brake extension handle
E0966**	Manual wheelchair accessory, headrest extension
E0967**	Manual wheelchair accessory, hand rim with projections
E0968*	Commode seat, wheelchair
E0969*	Narrowing device wheelchair
E0971**	Manual wheelchair accessory anti-tipping device
E0973**	Manual wheelchair accessory, adjustable height, detachable armrest
E0974**	Manual wheelchair accessory anti-rollback device
E0978*	Manual wheelchair accessory positioning belt/safety belt/ pelvic strap
E0980*	Manual wheelchair accessory safety vest
E0981**	Manual wheelchair accessory Seat upholstery, replacement only
E0982**	Manual wheelchair accessory, back upholstery, replacement only
E0983**	Manual wheelchair accessory power add on to convert manual wheelchair to motorized wheelchair, joystick control
E0984**	Manual wheelchair accessory power add on to convert manual wheelchair to motorized wheelchair, Tiller control
E0985	Wheelchair accessory, seat lift mechanism
E0986**	Manual wheelchair accessory, push activated power assist
E0990**	Manual wheelchair accessory, elevating leg rest
E0992**	Manual wheelchair accessory, elevating leg rest solid seat insert
E0994*	Arm rest
E1014	Reclining back, addition to pediatric size wheelchair
E1015	Shock absorber for manual wheelchair
E1020	Residual limb support system for wheelchair
E1028**	Wheelchair accessory, manual swing away, retractable or removable mounting hardware for joystick, other control interface or positioning accessory
E1029**	Wheelchair accessory, ventilator tray
E1030**	Wheelchair accessory, ventilator tray, gimbaled
E1031	Rollabout chair, any and all types with castors 5" or greater
E1035**	Multi-positional patient transfer system with integrated seat operated by care giver
E1036**	Patient transfer system
E1037	Transport chair, pediatric size

HCPCS Code	Description
E1038**	Transport chair, adult size up to 300lb
E1039**	Transport chair, adult size heavy duty >300lb
E1161	Manual Adult size wheelchair includes tilt in space
E1227*	Special height arm for wheelchair
E1228*	Special back height for wheelchair
E1232	Wheelchair, pediatric size, tilt-in-space, folding, adjustable with seating system
E1233**	Wheelchair, pediatric size, tilt-in-space, folding, adjustable without seating system
E1234	Wheelchair, pediatric size, tilt-in-space, folding, adjustable without seating system
E1235	Wheelchair, pediatric size, rigid, adjustable, with seating system
E1236	Wheelchair, pediatric size, folding, adjustable, with seating system
E1237	Wheelchair, pediatric size, rigid, adjustable, without seating system
E1238	Wheelchair, pediatric size, folding, adjustable, without seating system
E1296*	Special sized wheelchair seat height
E1297*	Special sized wheelchair seat depth by upholstery
E1298*	Special sized wheelchair seat depth and/or width by construction
E1310**	Whirlpool non-portable
E2502**	Speech Generating Devices prerecord messages between 8 and 20 Minutes
E2506**	Speech Generating Devices prerecord messages over 40 minutes
E2508**	Speech Generating Devices message through spelling, manual type
E2510**	Speech Generating Devices synthesized with multiple message methods
E2227**	Rigid pediatric wheelchair adjustable
K0001	Standard wheelchair
K0002	Standard hemi (low seat) wheelchair
K0003	Lightweight wheelchair
K0004	High strength ltwt wheelchair
K0005	Ultra Lightweight wheelchair
K0006	Heavy duty wheelchair
K0007	Extra heavy duty wheelchair
K0009	Other manual wheelchair/base
K0606**	AED garment with electronic analysis
K0730	Controlled dose inhalation drug delivery system



[AccreditationUniversity.com](https://www.AccreditationUniversity.com)

T (919) 228-6559

F (919) 785-3011

139 Weston Oaks Ct., Cary, NC 27513

ACCREDITATION COMMISSION *for* HEALTH CARE

