ACCREDITATION UNIVERSITY

# ACHIEVING ACHC ACCREDITATION

MARCH 2018

DMEPOS

AccreditationUniversity.com

ACCREDITATION COMMISSION *for* HEALTH CARE

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# ACHIEVING ACHC ACCREDITATION

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GREG STOWELL
Education & Consulting Manager
ACCREDITATION UNIVERSITY
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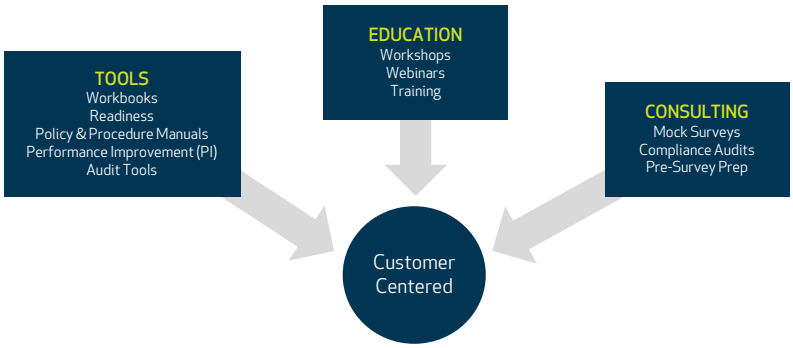


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DMEPOS

## TIM SAFLEY, MBA, RRT, RCP

Program Director, DMEPOS
Pharmacy & Sleep

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## ALSO JOINING OUR TRAINING TODAY

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

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DMEPOS

## JOSÉ DOMINGOS

President & CEO

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## INTRODUCTIONS

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

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## 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 |

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## 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 |

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## 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

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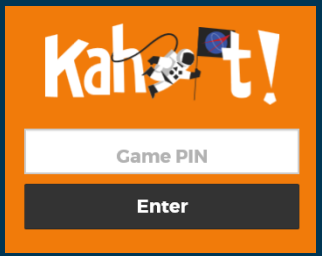
## TEACHING TOOL: Kahoot!

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

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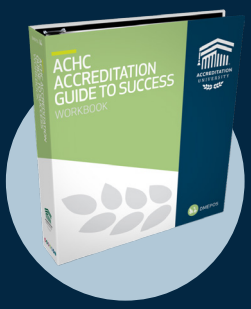
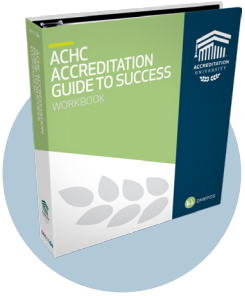
## TODAY'S LEARNING GUIDES

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






## GUIDE TO SUCCESS WORKBOOK

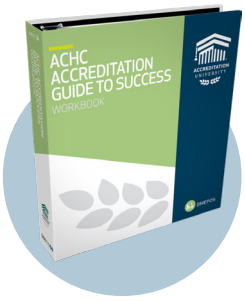



- Any sample policies and procedures provided in the *ACHC Accreditation Guide to Success* workbooks are for example and illustration purposes only
- Each organization is unique in its organizational structure and product offerings and must develop and implement specific policies and procedures that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



## 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



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## 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

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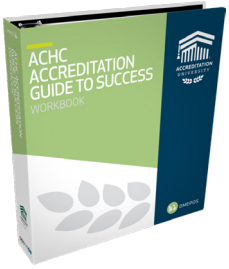
## HOW TO USE THE WORKBOOK




| | |
|---|---|
| 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

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## 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

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## 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

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## 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

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## 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

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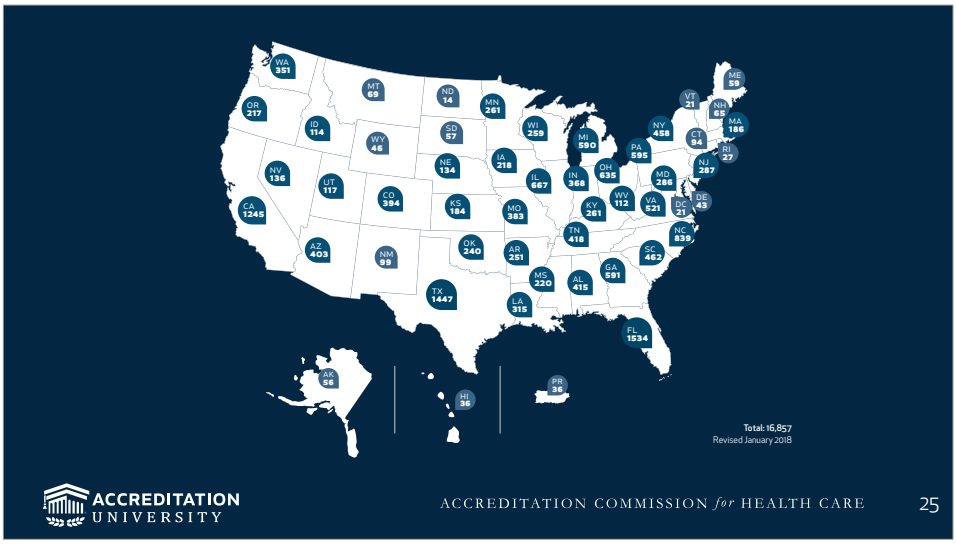


## ACHC PROGRAMS & SERVICES

**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.

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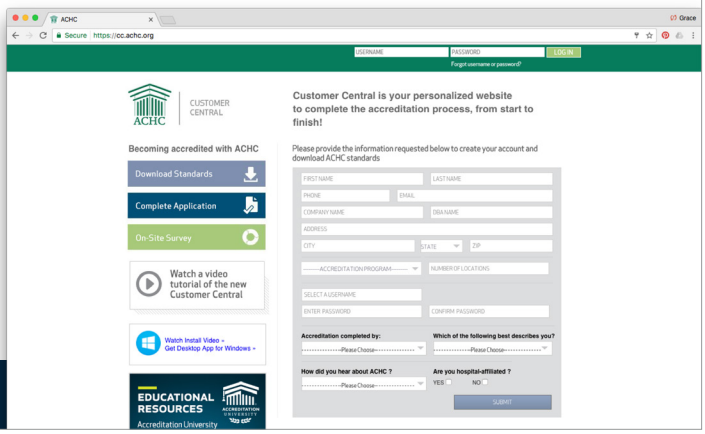
## STEP 1: REGISTRATION

CUSTOMER CENTRAL

- Customer Central: cc.achc.org

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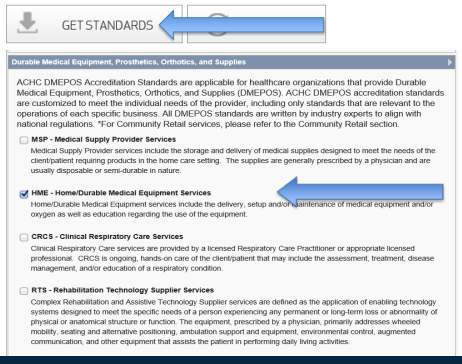
## STEP 2: DOWNLOAD STANDARDS

CUSTOMER CENTRAL

cc.achc.org

Updates will be posted on Customer Central

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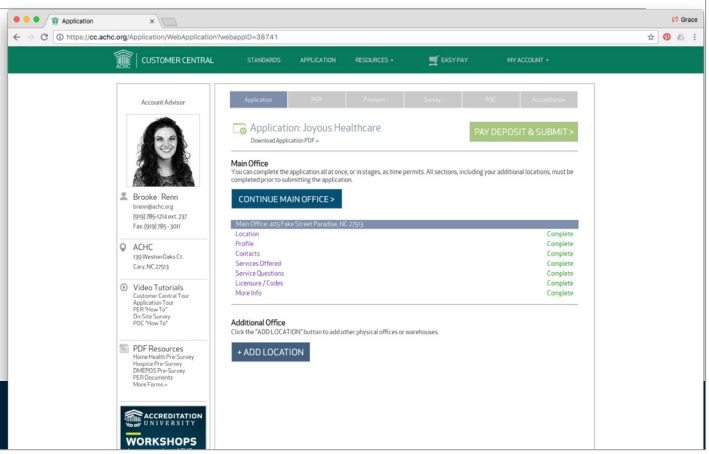
## STEP 3: APPLICATION

CUSTOMER CENTRAL

Submit completed electronic application, PER and $1,500 deposit

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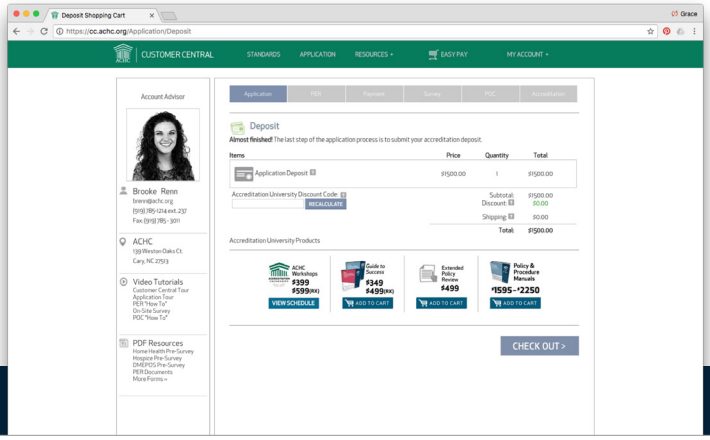
## STEP 3: APPLICATION

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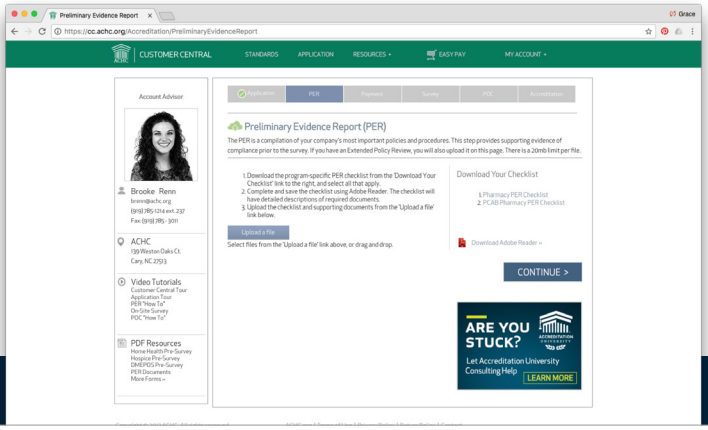
## STEP 3: APPLICATION

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## 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 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)

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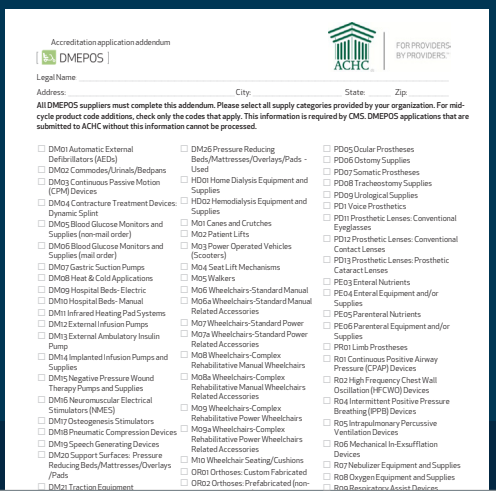
## STEP 3: ADDENDUM

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


Accreditation application addendum

DMEPOS

ACHC

FOR PROVIDERS. BY PROVIDERS.

Legal Name

Address: City: State: Zip:

**All DMEPOS suppliers must complete this addendum. Please select all supply categories provided by your organization. For mid-cycle 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.**

- ☐ DM01 Automatic External Defibrillators (AEDs)
- ☐ DM02 Commodes/Urinals/Bedpans
- ☐ DM03 Continuous Passive Motion (CPM) Devices
- ☐ DM04 Contracture Treatment Devices: Dynamic Splint
- ☐ DM05 Blood Glucose Monitors and Supplies (non-mail order)
- ☐ DM06 Blood Glucose Monitors and Supplies (mail order)
- ☐ DM07 Gastric Suction Pumps
- ☐ DM08 Heat & Cold Applications
- ☐ DM09 Hospital Beds- Electric
- ☐ DM10 Hospital Beds- Manual
- ☐ DM11 Infrared Heating Pad Systems
- ☐ DM12 External Infusion Pumps
- ☐ DM13 External Ambulatory Insulin Pump
- ☐ DM14 Implanted Infusion Pumps and Supplies
- ☐ DM15 Negative Pressure Wound Therapy Pumps and Supplies
- ☐ DM16 Neuromuscular Electrical Stimulators (NMES)
- ☐ DM17 Osteogenesis Stimulators
- ☐ DM18 Pneumatic Compression Devices
- ☐ DM19 Speech Generating Devices
- ☐ DM20 Support Surfaces: Pressure Reducing Beds/Mattresses/Overlays /Pads
- ☐ DM21 Traction Equipment
- ☐ DM26 Pressure Reducing Beds/Mattresses/Overlays/Pads - Used
- ☐ HD01 Home Dialysis Equipment and Supplies
- ☐ HD02 Hemodialysis Equipment and Supplies
- ☐ M01 Canes and Crutches
- ☐ M02 Patient Lifts
- ☐ M03 Power Operated Vehicles (Scooters)
- ☐ M04 Seat Lift Mechanisms
- ☐ M05 Walkers
- ☐ M06 Wheelchairs-Standard Manual
- ☐ M06a Wheelchairs-Standard Manual Related Accessories
- ☐ M07 Wheelchairs-Standard Power
- ☐ M07a Wheelchairs-Standard Power Related Accessories
- ☐ M08 Wheelchairs-Complex Rehabilitative Manual Wheelchairs
- ☐ M08a Wheelchairs-Complex Rehabilitative Manual Wheelchairs Related Accessories
- ☐ M09 Wheelchairs-Complex Rehabilitative Power Wheelchairs
- ☐ M09a Wheelchairs-Complex Rehabilitative Power Wheelchairs Related Accessories
- ☐ M10 Wheelchair Seating/Cushions
- ☐ OR01 Orthoses: Custom Fabricated
- ☐ OR02 Orthoses: Prefabricated (non-
- ☐ PD05 Ocular Prostheses
- ☐ PD06 Ostomy Supplies
- ☐ PD07 Somatic Prostheses
- ☐ PD08 Tracheostomy Supplies
- ☐ PD09 Urological Supplies
- ☐ PD1 Voice Prosthetics
- ☐ PD11 Prosthetic Lenses: Conventional Eyeglasses
- ☐ PD12 Prosthetic Lenses: Conventional Contact Lenses
- ☐ PD13 Prosthetic Lenses: Prosthetic Cataract Lenses
- ☐ PE03 Enteral Nutrients
- ☐ PE04 Enteral Equipment and/or Supplies
- ☐ PE05 Parenteral Nutrients
- ☐ PE06 Parenteral Equipment and/or Supplies
- ☐ PR01 Limb Prostheses
- ☐ R01 Continuous Positive Airway Pressure (CPAP) Devices
- ☐ R02 High Frequency Chest Wall Oscillation (HFCWO) Devices
- ☐ R04 Intermittent Positive Pressure Breathing (IPPB) Devices
- ☐ R05 Intrapulmonary Percussive Ventilation Devices
- ☐ R06 Mechanical In-Exsufflation Devices
- ☐ R07 Nebulizer Equipment and Supplies
- ☐ R08 Oxygen Equipment and Supplies
- ☐ R09 Respiratory Assist Devices

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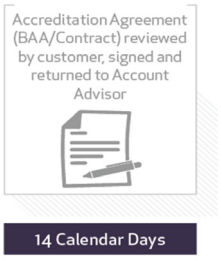
## STEP 4: FEE ESTIMATE AND AGREEMENT

- 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

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## 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

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## 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




## DMEPOS ADDENDUM

- Did you know that if you bill Medicare for an item not included on you 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 where not accredited for all product codes listed under a bidding categories?



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# 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

ACHC

Legal Name

Company ID:

Survey Date:

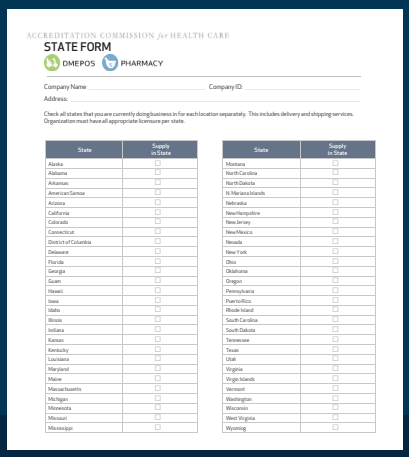
Surveyor Attestation

Company Attestation



# 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



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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 licensure per state.

| State | Supply in State |
|---|---|
| Alaska | ☐ |
| Alabama | ☐ |
| Arkansas | ☐ |
| American Samoa | ☐ |
| Arizona | ☐ |
| California | ☐ |
| Colorado | ☐ |
| Connecticut | ☐ |
| District of Columbia | ☐ |
| Delaware | ☐ |
| Florida | ☐ |
| Georgia | ☐ |
| Guam | ☐ |
| Hawaii | ☐ |
| Iowa | ☐ |
| Idaho | ☐ |
| Illinois | ☐ |
| Indiana | ☐ |
| Kansas | ☐ |
| Kentucky | ☐ |
| Louisiana | ☐ |
| Maryland | ☐ |
| Maine | ☐ |
| Massachusetts | ☐ |
| Michigan | ☐ |
| Minnesota | ☐ |
| Missouri | ☐ |
| Mississippi | ☐ |

| State | Supply in State |
|---|---|
| Montana | ☐ |
| North Carolina | ☐ |
| North Dakota | ☐ |
| N. Mariana Islands | ☐ |
| Nebraska | ☐ |
| New Hampshire | ☐ |
| New Jersey | ☐ |
| New Mexico | ☐ |
| Nevada | ☐ |
| New York | ☐ |
| Ohio | ☐ |
| Oklahoma | ☐ |
| Oregon | ☐ |
| Pennsylvania | ☐ |
| Puerto Rico | ☐ |
| Rhode Island | ☐ |
| South Carolina | ☐ |
| South Dakota | ☐ |
| Tennessee | ☐ |
| Texas | ☐ |
| Utah | ☐ |
| Virginia | ☐ |
| Virgin Islands | ☐ |
| Vermont | ☐ |
| Washington | ☐ |
| Wisconsin | ☐ |
| West Virginia | ☐ |
| Wyoming | ☐ |

## 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

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## 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)

ACCREDITATION UNIVERSITY ACCREDITATION COMMISSION *for* HEALTH CARE 44


NOTES

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

## 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

ACCREDITATION UNIVERSITY ACCREDITATION COMMISSION *for* HEALTH CARE 49

## 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 your are in compliance you must be fully in compliance)

ACCREDITATION UNIVERSITY ACCREDITATION COMMISSION *for* HEALTH CARE 50

## 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

ACCREDITATION UNIVERSITY ACCREDITATION COMMISSION *for* HEALTH CARE 51

NOTES

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 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 rub/unabused (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).

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## 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 recoded 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

ACCREDITATION UNIVERSITY ACCREDITATION COMMISSION *for* HEALTH CARE 53

## 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 every thing 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

ACCREDITATION UNIVERSITY ACCREDITATION COMMISSION *for* HEALTH CARE 54

## 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

ACCREDITATION UNIVERSITY ACCREDITATION COMMISSION *for* HEALTH CARE 55

## 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

ACCREDITATION UNIVERSITY ACCREDITATION COMMISSION *for* HEALTH CARE 56

## 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**

ACCREDITATION UNIVERSITY ACCREDITATION COMMISSION *for* HEALTH CARE 57

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## 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

- 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
- Complaint logs
- Oxygen complaint log
- Surety bond, liability and vehicle insurance, org chart, budget, contracts/BAAs, required licenses

## 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

ACCREDITATION UNIVERSITY ACCREDITATION COMMISSION *for* HEALTH CARE 61

## 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

ACCREDITATION UNIVERSITY ACCREDITATION COMMISSION *for* HEALTH CARE 62

## 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

ACCREDITATION UNIVERSITY ACCREDITATION COMMISSION *for* HEALTH CARE 63

NOTES

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## 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

ACHC FOR PROVIDERS. BY PROVIDERS.™

Organization: Greg's Pharmacy

| Standard | Plan of Correction (Specific action taken to bring standard into compliance) | Date of Compliance (Date correction to be completed) | Title (Individual responsible for correction) | Process to Prevent Recurrence (Describe monitoring of corrective actions to ensure they effectively prevent recurrence) | POC Compliant (ACHC internal use only) | Comments (ACHC internal use only) |
|---|---|---|---|---|---|---|
| TCRX3-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.

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## SURVEY REPORT FOR SURVEY ON 03/2017 SERVICES: HME

| Deficiency Category - Interviews/Observations | | | Defi-cient |
|---|---|---|---|
| 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 the home environmental and electrical safety assessment.** | The safety and adequacy of electrical outlets was not being assessed by some delivery personnel.<br><br>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).<br><br>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 |

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## SURVEY REPORT FOR SURVEY ON 08/2016 SERVICES: HME

| Deficiency Category - Quality & Supplier with ** Evidence Required on POC** | | | Defi-cient |
|---|---|---|---|
| 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.<br><br>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 |

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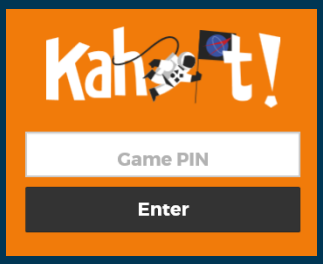
## TEACHING TOOL: Kahoot!

- 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

## 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)

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## 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

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## 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.

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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

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

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

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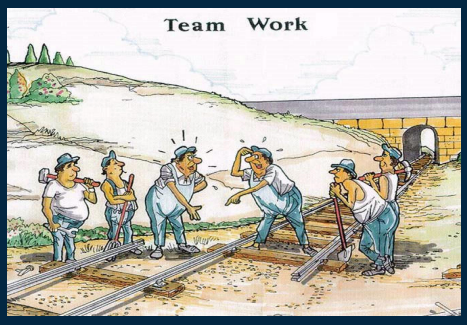
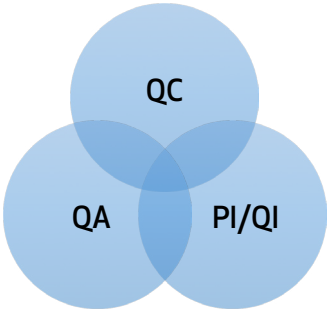
DMEPOS

## OVERVIEW OF PI STANDARDS






## WHAT IS PI?




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



## 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



NOTES

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## 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

## 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.



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## PI AUDIT TOOL

PI AUDIT DESCRIPTIONS

PI Activity/Audit Descriptions

Description of Audit/Indicators: Conducted By:

Frequency of Activities:

Data Collected From:

Threshold/Goal:

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

All PI reports will be presented to the PI committee and the Governing Body/owner.
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 # X



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## 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

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## KEEP IT SUPER SIMPLE (KISS)


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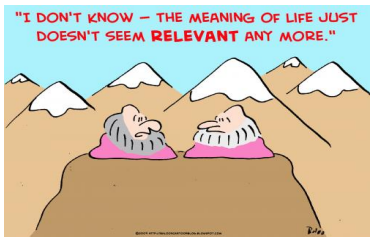
## KEEP IT RELEVANT

- 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




ACCREDITATION UNIVERSITY ACCREDITATION COMMISSION *for* HEALTH CARE 97

## PERFORMANCE IMPROVEMENT

- Great ROI
- ROI (%) = Net Monetary Benefits X 100
  Program Costs
- 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

ACCREDITATION UNIVERSITY ACCREDITATION COMMISSION *for* HEALTH CARE 98

## HAD ENOUGH?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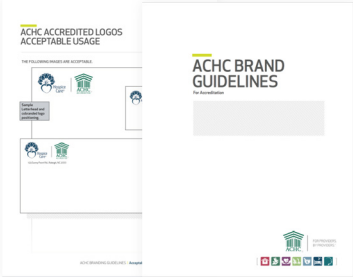
## MARKETING ADVANTAGE

- 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

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## BRANDING ELEMENTS

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

ACHC ACCREDITED

ACHC ACCREDITED

ACCREDITATION COMMISSION FOR HEALTH CARE — ACHC

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## 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

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NOTES

NOTES

## 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


NOTES

ACCREDITATION UNIVERSITY

# RESOURCES

DMEPOS

# PRELIMINARY EVIDENCE REPORT (PER) INITIAL CHECKLIST

[ DMEPOS ACCREDITATION ]

FOR PROVIDERS. BY PROVIDERS.™

**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

[ DMEPOS ]

FOR PROVIDERS. BY PROVIDERS.™

**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

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

PHARMACY DMEPOS

FOR PROVIDERS. BY PROVIDERS.™

## 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

PHARMACY DMEPOS

ACHC

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## 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

PHARMACY DMEPOS

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**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#:** _____

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

### 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.

## 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.

**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 theses 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);

- 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

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.

## 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

- 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).

## 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.

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.

## 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.

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.

## 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.);

- 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. Follow up

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

## 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.

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)

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);

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;

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.

National Government Services

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<br>Medical Director, DME MAC, Jurisdiction A<br>NHIC, Corp. | Robert D. Hoover, Jr., MD, MPH, FACP<br>Medical Director, DME MAC, Jurisdiction C<br>CGS Administrators, LLC |
| Stacey V. Brennan, MD, FAAFP<br>Medical Director, DME MAC, Jurisdiction B<br>National Government Services | Eileen Moynihan, MD<br>Medical Director, DME MAC, Jurisdiction D<br>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 |


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