NABP
National Association of Boards of Pharmacy
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DURABLE MEDICAL EQUIPMENT PROSTHETICS, ORTHOTICS, AND SUPPLIES ACCREDITATION PROGRAM
Single Facility Letter of Agreement

The National Association of Boards of Pharmacy® (NABP®) is approved by the Centers for Medicare & Medicaid Services (CMS), a division of the United States Department of Health & Human Services, as an accrediting organization for pharmacies that supply durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). NABP's DMEPOS Accreditation Program ("Program") verifies the qualifications of state-licensed pharmacies that provide a Limited Line of DMEPOS under Quality Standards established by CMS and is designed to provide a means by which state and federal regulatory agencies and the public may readily identify pharmacy DMEPOS suppliers that are appropriately licensed, have agreed to adhere to the CMS Quality Standards and the requirements of the Program, and have agreed to comply with the federal and state laws and regulations governing the provision of DMEPOS supplies.

This Letter of Agreement and attachments (hereinafter "Agreement") between the National Association of Boards of Pharmacy ("NABP") located at 1600 Feehanville Drive, Mount Prospect, Illinois 60056 and Custom Care Pharmacy LLC, dba Custom Care Pharmacy LLC ("Pharmacy") located at 20320 Northwest Freeway, Unit 300, Jersey Village, Texas 77065 which supplies a Limited Line of DMEPOS, represents the agreement between the parties regarding Pharmacy's participation in the Program and is effective the date the accreditation is awarded, December 26, 2018.

A. Incorporation by Reference.
The following exhibits and documents are incorporated by reference and made a part of this Agreement.

1. Exhibit A — CMS Quality Standards
2. Exhibit B — Fee Schedule
3. Exhibit C — Appeal Procedure
4. Addendum One — Health Insurance Portability And Accountability Act (HIPAA) Business Associate Agreement executed prior to survey of Pharmacy

B. Definitions.

1. "Limited Line of DMEPOS" is the following durable medical equipment, prosthetics, orthotics, and supplies for which NABP is a CMS-approved accreditation provider:

   i. Diabetic equipment and supplies
   ii. Enteral and parenteral nutrients, equipment, and supplies
   iii. Off-the-shelf, non-custom products and supplies, including:
      1. Orthotics
      2. Mobility aids
      3. Wound care supplies
      4. Medical
      5. Urological aids
      6. Respiratory aids
   iv. Such other DMEPOS products for which CMS, from time to time, may approve NABP as an accreditation provider.

2. "Program" is NABP's DMEPOS accreditation program, which is a voluntary program developed and implemented by NABP, pursuant to Quality Standards established and approved by CMS, that awards accreditation to qualifying pharmacies that have met the Program Requirements.

3. "Program Accreditation" is the recognition NABP awards to qualifying pharmacies that meet the Program Requirements.

4. "CMS Quality Standards" are the quality standards for the provision of DMEPOS as established and as may be modified from time to time by CMS.

5. "Program Requirements" are the requirements pharmacies must meet in order to obtain Program Accreditation, and include documentation and operational compliance with the CMS Quality Standards, valid licensure and provider status, absence of relevant legal or regulatory information as described and requested in the Program application, and this Agreement.

6. "Persons" include individuals, sole proprietors, partnerships, corporations, limited liability companies, and all other entities engaged as pharmacies.

C. Accreditation.

1. Pharmacy agrees that accreditation has been awarded based upon its successful completion of the Program.

2. Pharmacy agrees to cooperate with NABP in the verification of its compliance with this Agreement and for purposes of determining whether to renew accreditation. NABP may itself, or through an independent third party designated by NABP, conduct unannounced

on-site compliance reviews for accreditation renewal purposes, or based upon NABP's own initiative in response to complaints from third parties or information NABP receives indicating Pharmacy may not be in compliance with this Agreement.

a) NABP will perform an annual review to verify Pharmacy's licensure and its pharmacist's-in-charge licensure and evaluate any information received concerning Pharmacy's compliance with this Agreement.

b) Once every three years after initial accreditation, NABP will perform a compliance review, which includes the components of the annual review described herein and an unannounced on-site survey to determine if Pharmacy is qualified for continued participation in the Program and, therefore, renewal of accreditation.

c) Pharmacy agrees to provide NABP and NABP's surveyors with sufficient access to its facility and records for purposes of conducting a compliance review to ensure that Pharmacy is in compliance with this Agreement. Pharmacy also agrees to permit and facilitate interviews with key Pharmacy personnel in order to evaluate compliance with this Agreement.

3. The parties agree that all information in the application documentation, renewal documentation, and information NABP, its employees, contractors, or surveyors obtain through the initial accreditation, compliance review, or accreditation renewal processes will be used for the purpose of evaluating Pharmacy's eligibility for renewal of accreditation or continued participation in the Program, as applicable. Such information shall be deemed confidential and shall not be disclosed, except to the extent that it is in the public domain, is requested by CMS, is legally required to be disclosed, or when NABP, its employees, contractors, or surveyors believe in good faith that the Pharmacy, Pharmacy's owners, or Pharmacy's or Pharmacy's owners' staffs engaged in or are engaging in conduct that violates state or federal law, in which case NABP will notify Pharmacy; however, NABP reserves the right to notify its member boards of pharmacy, CMS, or appropriate state or federal regulatory or law enforcement authorities. If NABP is legally required to disclose such information, NABP agrees to provide Pharmacy with reasonable advance written notice of the pending disclosure so that the Pharmacy can adequately object to or defend against said disclosure. Notwithstanding anything to the contrary herein, NABP reserves the right to share information with its member boards of pharmacy, CMS, or appropriate regulatory or law enforcement authorities concerning Pharmacy's accreditation status, any denial of accreditation, or any suspension or disqualification from the Program.

4. The parties further agree that Pharmacy may request a compliance review audit pursuant to the terms described in the Appeal Procedure.

5. The expenses of any initial accreditation evaluation, surveys, compliance reviews, and the process for renewal of accreditation shall be borne by the Pharmacy. Such expenses are set

forth in Exhibit B.

6. Unless otherwise agreed to by the parties, all fees and expenses for initial accreditation, surveys, compliance reviews, and renewal of accreditation must be paid in advance. Failure to remit payments due may result in NABP's termination of this Agreement and Pharmacy's disqualification from participation in the Program.

7. (a) Within thirty (30) days of any significant change in the application information or documentation provided to NABP, including but not limited to license or registration numbers, compliance officer, etc. Pharmacy agrees to notify NABP via a Program application form or some other suitable writing.

   (b) Pharmacy agrees to notify NABP annually regarding any change in pharmacist-in-charge.

   (c) Pharmacy agrees to notify NABP within ten (10) days of a change in address, change in ownership, any merger with another business organization, or acquisition of another retail pharmacy business. Unless otherwise permitted by NABP, Pharmacy must submit an amended Program application, or other suitable writing permitted by NABP, and any applicable fees in order for it to qualify for continued Program Accreditation. NABP reserves the right to require removal of any Program Accreditation claims from any Pharmacy publication(s) and discontinuation of any use of NABP intellectual property during the period while the amended application or writing is under consideration by NABP. Pharmacy agrees to notify NABP in writing within ten (10) days of cessation of supplying the Limited Line of DMEPOS services described herein or cessation of all operations. On this notification, the Pharmacy shall affirm that all use and any references to its Program Accreditation have been discontinued and removed.

8. Should Pharmacy provide DMEPOS products in addition to the Limited Line of DMEPOS described herein and for which CMS requires accreditation, Pharmacy may seek accreditation for such additional DMEPOS products through another CMS-approved accreditation provider; however, Pharmacy agrees to provide NABP with prompt written notice of such accreditation provider's name, address, and additional DMEPOS products for which Pharmacy is seeking accreditation, within ten (10) days of engaging such provider. Program Accreditation will continue during the time that Pharmacy is seeking such accreditation from the CMS-approved accreditation provider; however, NABP is not responsible for the actions or omissions of the any such accreditation provider.

D. Modification to Program Requirements.

1. The CMS Quality Standards described in Exhibit A may be modified by CMS from time to time, in which case NABP may request and Pharmacy agrees to provide documentation or information demonstrating its compliance with such revised Standards. Pharmacy may also

elect to terminate this Agreement, per the terms and conditions set forth in Paragraph K3.

2. The Program Requirements may be modified by NABP from time to time upon at least thirty (30) days prior written notice to Pharmacy, at which time Pharmacy may terminate this Agreement, per Paragraph K3.

E. Publication of Program Accreditation.

1. Pharmacy acknowledges NABP's sole ownership of the Program documents, materials, and Program logos and all ownership rights thereunder, and agrees not to challenge or engage in any act that would interfere either directly or indirectly with such ownership. Pharmacy will not assert or seek any rights in or protection of any kind, other than those granted under this Agreement.

2. NABP grants Pharmacy a limited, nonexclusive, and non-transferable authorization to publish its accreditation under the Program in such media as press releases, its website, and in general business discussions; however, Pharmacy must properly credit NABP's intellectual property, such as NABP®. Any request to otherwise use NABP's trademarks, such as Program logos, requires NABP's prior written authorization and will be subject to terms and conditions established by NABP.

3. Pharmacy agrees that Program Accreditation does not constitute an endorsement by NABP of Pharmacy, the quality of any products dispensed or supplied by or any services provided by Pharmacy. Pharmacy may not sublicense, transfer, or assign its Program Accreditation or any permission to use NABP's intellectual property without the prior written authorization of NABP.

F. Right of Publicity by NABP.

Pharmacy grants NABP a non-exclusive, royalty-free license during the term of this Agreement to use and distribute the following information about Pharmacy in NABP's current list of DMEPOS-accredited pharmacies located on NABP's website, in Program brochures, NABP's newsletters, and in other NABP publications, which includes but is not limited to:

1. Pharmacy name and address;

2. Date of accreditation;

3. Program Accreditation is valid for three years;

4. Other information agreed to herein, or that may be agreed to by the parties.

G. Loss of Qualification.

In accordance with this Agreement, NABP at its sole discretion may, at any time, disqualify Pharmacy from participation in the Program if:

1. Pharmacy, Pharmacy owners, employees, affiliates, or agents violate any term of this Agreement;

2. Any documentation submitted to NABP on behalf of the Pharmacy, including the initial application and documentation for accreditation, is falsified in any manner;

3. Pharmacy, or any Pharmacy officer, Compliance Officer (CO), pharmacist-in-charge, or any principals or owners who directly or indirectly own greater than ten percent (10%) interest in the Pharmacy (with the exception of publicly held corporations) who are employed by or providing services on behalf of Pharmacy is/are (i) convicted of any felony or violation of any state or federal drug, device, DMEPOS, or fraud statute, or (ii) subject to a final judgment or decree of disciplinary action issued by a board of pharmacy or governmental authority;

4. Pharmacy, or any Pharmacy officer, CO, pharmacist-in-charge, or any principals or owners who directly or indirectly own greater than ten percent (10%) interest in the Pharmacy (with the exception of publicly held corporations) who are employed by or providing services on behalf of Pharmacy engages in any conduct that (i) is a violation of state or federal law, (ii) is not in compliance with this Agreement, or (iii) is found by NABP to be detrimental to the public health or welfare;

5. Pharmacy, or any Pharmacy officer, CO, pharmacist-in-charge, or any principals or owners who directly or indirectly own greater than ten percent (10%) interest in the Pharmacy (with the exception of publicly held corporations) who are employed by or providing services on behalf of the Pharmacy is/are currently or become the subject of an investigation or is/are charged by any board of pharmacy or governmental authority;

6. Pharmacy files for or is currently a party to bankruptcy proceedings;

7. Pharmacy publishes its Program Accreditation or uses NABP intellectual property in a manner that is false, inaccurate, or in violation of this Agreement or the terms or conditions of any NABP authorization to publish or display its Program Accreditation.

8. Pharmacy is disqualified from participation in or is denied accreditation or credentialing by any other accreditation or credentialing program, governmental authority, or entity, such as NABP's Verified-Internet Pharmacy Practice Sites® (VIPPS®) or Verified-Accredited Wholesale Distributors® (VAWD®) programs, CMS-approved DMEPOS accreditation provider, etc; or

9. NABP fails to timely receive the Pharmacy's written notice of appeal of the suspension and fee payment.

H. Suspension From the Program.

1. In the event a complaint is filed with NABP concerning Pharmacy, or NABP obtains information indicating the Pharmacy is not in compliance with CMS Quality Standards or the terms or conditions of this Agreement, then:

a) The Accreditation Committee of NABP will review the matter, and will notify Pharmacy in writing of the impending suspension of Program Accreditation, and the basis thereof.

b) Pharmacy may respond to the charge, in which case such response shall be in writing and shall be sent to the Executive Director/Secretary of NABP within twenty-one (21) days of the date of the notice. Within ten (10) days thereafter, the Executive Director/Secretary shall forward copies of the Pharmacy response to the Accreditation Committee. The Accreditation Committee will then review the facts relating to the allegations, including any Pharmacy response, and shall determine if sufficient grounds exist to temporarily suspend Pharmacy from participation in the Program. If no response to the allegations is received or the Accreditation Committee determines that the allegations are true, then Pharmacy will be sent a written notice of the Accreditation Committee's decision that Pharmacy's participation in the Program is temporarily suspended.

c) Pharmacy must remove all claims and references to Pharmacy being accredited under the Program as well as any NABP intellectual property from all displayed locations within ten (10) days of the date on the notice of temporary suspension. NABP reserves the right to display a notice that the Pharmacy's participation in the Program has been suspended, and further reserves the right to share with its member boards of pharmacy, CMS, or regulatory or law enforcement authorities information pertaining to the temporary suspension of Pharmacy from the Program.

I. Appeal From Suspension.

1. In the event that Pharmacy is suspended by the Accreditation Committee of NABP, Pharmacy may appeal the decision, as an Appellant, in accordance with the terms and conditions of the Appeal Procedure attached as Exhibit C.

2. Except as otherwise agreed to by the parties, if all claims and references to Program Accreditation as well as all NABP intellectual property are not removed within the required time frame, as set forth in Exhibit C, or if a written notice of appeal and fee payment are not received by NABP within the required time period as set forth in Exhibit C, the temporary suspension converts to disqualification from the Program with no further rights of internal appeal.

3. Appellant shall have no further rights to internal appeal after either the Appellate Commission has rendered a decision to disqualify Appellant from the Program.

4. If Appellant is disqualified, NABP shall not consider any future requests for accreditation from Pharmacy until all findings and bases for the disqualification are remedied and resolved.

5. NABP reserves the right to share with its member boards of pharmacy, CMS, or regulatory or law enforcement authorities information pertaining to the disqualification of Pharmacy from the Program.

J. Term of This Agreement.

1. The term of this Agreement shall begin upon the date the DMEPOS accreditation was awarded and shall extend through three (3) years (unless earlier terminated under the provisions of paragraph K. Thereafter, the Agreement shall automatically extend for one (1) year periods unless either party notifies the other in writing within sixty (60) days of the expiration of the initial three (3) year term, or any one year extension thereof, of its election to terminate the Agreement.

K. Termination of Agreement.

1. NABP may terminate the Agreement in writing upon the occurrence of any of the following:

a) Pharmacy's failure to appeal a suspension in accordance with the Appeal Procedure set forth in Exhibit C;

b) Pharmacy's failure to timely remove all claims and references to Program Accreditation and any NABP intellectual property from all displayed locations in accordance with the Appeal Procedure set forth in Exhibit C;

c) A determination by the Appellate Commission that Pharmacy is disqualified from participation in the Program;

d) The Pharmacy fails to timely pay to NABP any required fees, or fails to pay the expenses and other fees of the Appellate Commission in accordance with the Appeal Procedure set forth in Exhibit C;

e) Following written notice from NABP, Pharmacy or its owners prohibit NABP from performing one or more on-site surveys, compliance reviews, or accreditation renewals or otherwise refuse to provide sufficient access to Pharmacy's records or facility, or refuse to permit or facilitate interviews with one or more key personnel; or

f) NABP's election upon at least ten (10) days written notice to Pharmacy to discontinue the Program or NABP's participation as a CMS-approved accreditation provider in accordance with any applicable regulations.

2. If this Agreement is terminated pursuant to paragraphs K.1.f) or K.3, then Pharmacy shall be entitled to a prorated refund of the unused portion of any prepaid store or annual participation fee; however, if NABP has commenced licensure verification work for Pharmacy, then Pharmacy will not be entitled to such a refund. In the event that Pharmacy has prepaid any survey fee(s)

and termination of this Agreement occurs pursuant to paragraph K.1.f) or K.3, then Pharmacy is entitled to receive a refund of such survey fee(s), so long as travel arrangements have not been completed for the performance of such survey. NABP may withhold from the refund any costs or fees owed to NABP for such things as administrative fees, reviewing an appeal, convening the Appellate Commission, performing a compliance survey, performing accreditation renewal activities, etc.

3. Termination by Pharmacy.
Pharmacy may terminate the Agreement upon thirty (30) days written notice to NABP. No prorated refund of the unused portion of any prepaid store or annual participation fee will be paid to Pharmacy, unless NABP implements new or revised DMEPOS Criteria and Pharmacy wishes to terminate the Agreement. In the event that Pharmacy has prepaid survey fee(s), then the Pharmacy is entitled to receive a refund of such survey fee(s), so long as travel arrangements have not been completed for the performance of such survey.

Unless otherwise permitted by NABP, Pharmacy may not terminate this Agreement once NABP has initiated a suspension action as described herein.

4. Effect of Termination on Rights.
Upon termination, all rights and benefits granted to Pharmacy under this Agreement shall terminate and Pharmacy shall immediately cease using any NABP intellectual property authorized under this Agreement and representing itself as being Program Accredited. NABP shall immediately cease using Pharmacy's name and related information on its web page and other materials.

L. Fees.

1. Pharmacy shall timely pay all fees, including survey and yearly participation fees, computed in accordance with Exhibit B.

2. Unless otherwise agreed, any survey fees must be paid in advance of the initial award of Program Accreditation or before any triennial compliance review is performed as applicable, including any survey fees related to compliance verification or other reviews performed to allow NABP to retain confidence in Pharmacy's continued participation in the Program.

3. NABP will prepare an invoice describing the services to be provided to the Pharmacy and the fees that are due. Pharmacy agrees to pay to all NABP-invoiced fee amounts in accordance with the terms specified on the invoice. Pharmacy agrees all payments shall be in United States dollars and in the form of a check, money order, ACH transfer, wire transfer or credit card payments. NABP does not accept credit card payments for any invoices or fees over $10,000. If Pharmacy pays any fee through an ACH or wire transfer or similar process, Pharmacy agrees not to perform a reverse ACH or wire transfer without the prior written approval of NABP.

4. NABP shall submit to Pharmacy and Pharmacy shall accept all invoices sent through regular mail, facsimile, or email. Pharmacy will not require NABP to use a vendor registration, invoicing, or purchase order system or similar process for any purpose under this Agreement. Pharmacy agrees that the submission of any invoice or the receipt of any payment under this Agreement shall not be conditioned upon NABP accepting terms or conditions that are not already set forth in this Agreement. Pharmacy shall not impose any fees upon NABP in connection with any particular method of providing an invoice to the Pharmacy or receiving payment from Pharmacy.

M. Pharmacy Representations and Warranties.

Pharmacy represents and warrants the following:

1. All of the information in Pharmacy's completed Program application and the documentation submitted with the application is accurate and truthful to the best of Pharmacy's knowledge, and all information and documentation subsequently submitted:

a) in support of the initial application

b) in any accreditation renewal process

OR

c) in support of any compliance review or survey process will be accurate and truthful to the best of Pharmacy's knowledge.

2. Pharmacy owners, Pharmacy, Pharmacy staff and Pharmacy owners' staff are not currently individually and/or collectively under formal investigation, indictment, prosecution and have not been convicted or had a license, registration, or provider number or status denied, disqualified, excluded, fined, placed on probation, suspended, revoked, or otherwise disciplined or sanctioned over the past five (5) years by any governmental entity or self-regulation program in any country, for violation of any governmental statutes, rules or regulations under or related to the drug laws or criminal laws of any such jurisdiction.

a) Pharmacy will inform the Executive Director/Secretary of NABP in writing in a format to be agreed to by the parties, if the Pharmacy owners, Pharmacy, Pharmacy staff, or Pharmacy owners' staff become the subject of such an investigation, indictment or charges, prosecution, conviction regardless of plea, or disciplinary order or sanction as described herein, within thirty (30) days of learning of same;

b) Pharmacy shall not be required to report any investigations that do not constitute public information under local, state, or federal securities laws, rules, or regulations.

3. Pharmacy is and will remain in compliance with this Agreement; and

4. The individual signing on behalf of the Pharmacy has the authority to bind Pharmacy to the terms of this Agreement.

N. Warranty Disclaimer/Indemnification.

1. All grants of the right to claim Program Accreditation or to use NABP's intellectual property under this Agreement are made with no express or implied warranty by NABP.

2. Pharmacy agrees to indemnify and hold NABP harmless against any claim, loss, lawsuit, damage, or expense, including, without limitation, reasonable attorney's fees, arising out of:

a) Any failure on the part of the Pharmacy or its owners to comply with any term of this Agreement;

b) Any content in any advertisement, brochure, or other publication released to the public and any content on any internet site or any other site substantially owned or controlled by Pharmacy or its owners including, but not limited to, any claim related to infringement, misappropriation or other violation of a right of another person (including, without limitation, a copyright, right of privacy or publicity, or trade secret claim), or a claim for defamation or obscenity;

c) The offering, performance, sale, or distribution of any drug, product, or service by Pharmacy or its owners; or

d) The actions or omissions of any third party accreditation provider engaged by Pharmacy.

O. Consequential Damages Waiver, Limitation of Liability.

1. Neither party shall be liable to the other for any indirect, incidental, or consequential damage or damages from lost profits or lost use.

2. The maximum aggregate liability of NABP for all claims arising out of or relating to this Agreement, regardless of the form or cause of action, shall be total fees paid by Pharmacy to obtain Program Accreditation for the first year under this Agreement, as set forth in Exhibit B.

P. Pharmacy Responsibility for Other Entities.

Any act or omission by any Pharmacy owners, subsidiary, outlet, partnership, or other pharmacy or organization in Pharmacy's network that involves the distribution of DMEPOS and that is contrary to any of the terms or conditions of this Agreement may be deemed by NABP as the act or omission of the Pharmacy.

Q. Notices/Modification.

All notices under this Agreement shall be in writing and shall be sent to the addresses indicated in this Agreement or at such other addresses as a party may indicate in a written notice to the other party to this Agreement. The terms of this Agreement cannot be amended or modified except upon a prior written agreement signed by Pharmacy and the Executive Director of NABP.

R. Entire Agreement/No Third Party Beneficiaries.

This Agreement embodies the whole agreement and supersedes any prior agreements, understandings, and obligations between the parties.

Nothing in this Agreement is intended, nor will be deemed, to confer rights or remedies upon any person or legal entity not a party to this Agreement.

S. Force Majeure.

The parties shall not be liable for any delay or failure of performance of this Agreement if such failure is caused by acts of God, war, governmental decree, power failure, judgment or order, strike, terrorism, communications failure, equipment or software malfunction, or other circumstances, whether or not similar to the foregoing, which are beyond the reasonable control of such party.

T. Severability.

The provisions of the Agreement are severable. If any provision is determined by a court of competent jurisdiction or a governmental regulatory entity to be invalid or unenforceable, in whole or in part, that provision shall be construed or limited in such a way as to make it enforceable and consistent with the manifest intentions of the parties. If such construction or limitation is impossible, the unenforceable provision will be stricken, and the remaining provisions of this Agreement will remain valid and enforceable.

U. Waiver.

The failure of either party to exercise any of its rights regarding a breach of this Agreement shall not be deemed to be a waiver of such rights nor shall the same be deemed to be a waiver of any subsequent breach.

V. Surviving Paragraphs.

The terms and conditions of this Agreement shall survive the expiration or termination of this Agreement.

W. Governing Law.

This Agreement shall be governed by and interpreted under the laws of the State of Illinois in the United States of America, without regard to its conflict of laws provisions. For any legal proceeding, lawsuit, action, dispute, or claim in connection with this Agreement, the parties hereby consent and submit to the exclusive jurisdiction of a state or federal court, or alternative dispute resolution forum, located in Cook County, Illinois (collectively "Court"), agree to commence any action in the Court, and waive any objection to the laying of venue of any such action in the Court. Should the parties agree to resolve any dispute arising out of or in connection with this Agreement through arbitration, arbitration shall be conducted in Illinois by a reputable arbitration organization agreed to by the parties and in accordance with Illinois law. Notwithstanding anything herein to the contrary, all matters pertaining to CMS provider/supplier numbers or participation or status, CMS competitive bidding, and the like shall be governed and interpreted under applicable federal laws and rules.

X. Assignability.

1. This Agreement may not be assigned by either party without the written consent of the other.

2. The terms and conditions of this Agreement shall be binding upon the heirs, personal representatives, assignees, and successors of the parties.

This Letter of Agreement is executed by the parties as of the date and year appearing below.

Y. Federal Law.

In the event any provision of this Agreement shall be contrary to the law of the United States of America in regard to Pharmacy's participation in the Program, federal law shall be deemed applicable and this Agreement shall be deemed modified but only to the extent necessary to meet the requirements of such law.

Z. Insurance.

The parties agree to maintain current and sufficient liability, property, worker's compensation and other applicable insurance policies through a reputable insurance agency(s) to protect themselves against any claims that may arise pursuant to the services or activities that may be performed pursuant to this Agreement.

AA. Headings.

The headings contained in this Agreement are for the purpose of convenience only and are not intended to define or limit the contents of the provisions contained therein.

This Letter of Agreement is executed by the parties as of the date and year appearing below.

National Association of Boards of Pharmacy
1600 Feehanville Drive
Mount Prospect, IL 60056

Custom Care Pharmacy LLC
dba Custom Care Pharmacy LLC

and on behalf of its owners
20320 Northwest Freeway, Unit 300
Jersey Village, TX 77065

_____ **_____**
Signature **Signature**

_____ **_____**
Date **Date**

Printed Name: Carmen A. Catizone **Printed Name: _____**

Title: Executive Director/Secretary **Title: _____**

Exhibit A

Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

QUALITY STANDARDS

FINAL - October 2008

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. <u>Consumer Services</u>

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

- Provide clear, written or pictorial, and oral instructions related to the use, maintenance, infection control practices for, and potential hazards of equipment and/or item(s) as appropriate;

- Provide information regarding expected time frames for receipt of delivered items;

- Verify that the equipment, item(s), and service(s) were received;

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

- Provide essential contact information for rental equipment and options for beneficiaries and/or caregiver(s) to rent or purchase equipment and/or item(s), when applicable; and

- Provide information and telephone number(s) for customer service, regular business hours, after-hours access, equipment and/or item(s) repair, and emergency coverage.

2. If the supplier cannot or will not provide the equipment, item(s) or service(s) that are prescribed for a beneficiary, the supplier shall notify the prescribing physician (for purpose of these standards, we are using this term to include other practitioners who can prescribe DMEPOS under Medicare laws and regulations) or other health care team member(s) promptly within 5 calendar days.

3. Within 5 calendar days of receiving a beneficiary's complaint, the supplier shall notify the beneficiary, using either oral, telephone, email, 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 (eg, 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) (eg, injuries, accidents, signs and symptoms of infection, hospitalizations). This may be identified through follow-up with the prescribing physician, other health care 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. <u>Information Management</u>

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 health care professionals (eg, orthotists; prosthetists; occupational, physical, respiratory therapists; pedorthists).

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

1. 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. <u>Follow-up</u>

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 health care 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 & Set-up

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 Caregiver(s)**

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;
    - IPPB;
    - Providing Patient and Caregiver Training; and
    - Suctioning of the Patient in the Home.

D. Follow-up

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 (eg, 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 (ATP) (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, (eg, 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 (eg, PT, OT);

   - 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 & 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.

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 (ie, 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 and 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 hemi-facial 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.)

c. 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. <u>Intake & Assessment</u>

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 (eg, 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 (eg, 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 (eg, 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 (eg, 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. <u>Delivery & Set-up</u>

Not applicable to this appendix.

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

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 (eg, 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 (eg, 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 (eg, 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 (eg, 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. <u>Follow-up</u>

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 (eg, 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.

Exhibit B

Fee Schedule

Single Pharmacy	
Application Submittal Fee	$1,250
NABP Survey Fee	$1,500
NABP Survey Travel Fee	$500
Annual Accreditation Participation Fee (Year 1)	$125
Annual Accreditation Participation Fee (Year 2)	$125
Annual Accreditation Participation Fee (Year 3)	$125
Total 3-year cost	$3,625

Exhibit C

Appeal Procedure

Purpose

This procedure sets forth the process for DMEPOS suppliers to appeal the NABP decision to either deny or remove accreditation.

Procedure

1. In the event that NABP shall deny initial accreditation to a DMEPOS supplier or shall remove such accreditation from a DMEPOS supplier, the DMEPOS supplier may appeal the decision of NABP.

2. In the case of removal, the DMEPOS accredited supplier shall not retain its DMEPOS accreditation, and shall be deemed unaccredited while the matter is under appeal.

3. Provided all fees and expenses invoiced by NABP have been paid, the DMEPOS supplier may file a written Notice of Appeal with the Executive Director/Secretary of NABP within 21 days of the date of the notice of denial or removal. Such Notice of Appeal shall set forth the specific facts supporting the grounds on which the appeal is based.

4. Payment must be submitted with the Notice of Appeal to be applied to the costs incurred by convening the DMEPOS Appellate Commission, which will hear the appeal.

5. NABP shall immediately convene the DMEPOS Appellate Commission; this consists of three independent panelists knowledgeable in DMEPOS activities and appointed by NABP.

6. The appealing party may request an audit of its compliance with the DMEPOS Accreditation Program Criteria. If the appealing party requests an audit an additional fee, equivalent to the then existing survey fee, shall be submitted and will be applied to the costs of performing the audit. The audit shall be conducted by surveyors who were not involved in the initial survey and at the appealing party's expense. A written report of the audit findings will be provided to: 1) the appealing party; 2) NABP; and 3) members of the Appellate Commission. The time requirements hereinafter set forth shall be deemed to commence after the requested audit has been concluded.

7. Unless otherwise agreed by the parties, the Appellate Commission shall set a date, time, and place for a hearing on the appeal not more than 60 days from the date of the receipt of the notice of appeal, or the date after the audit is concluded under paragraph (6) above, whichever may be applicable.

8. The NABP and the appealing party shall have the right to representation by counsel throughout the appeal procedure.

9. All reasonable expenses incurred by the Appellate Commission including, but not limited to travel expenses (ie, transportation, accommodations, and meals) shall be paid by the appealing party.

10. Failure of the appealing party to pay the Appellate Commission's reasonable expenses, in full, within 7 days of the date of the bill or invoice, shall result in termination of the appeals procedure.

11. In the event that any person designated as a member of the Appellate Commission shall be disqualified or shall refuse or be unable to serve for any reason at any time, an alternate member shall be selected by NABP. The member's service and affiliation with NABP, the NABP Executive Committee, and the Appellate Commission shall not be grounds for disqualification based upon claims of conflict-of-interest, bias, or the like.

12. Unless otherwise agreed to by the parties not less than 10 days before the hearing, the appealing party and NABP shall present written statements of their respective positions to the Appellate Commission.

13. Each party may present evidence at the hearing.

14. Unless otherwise agreed to by the parties, closing arguments shall be submitted to the Appellate Commission in writing at such addresses as the Appellate Commission shall indicate with copies to NABP and the appealing party within 14 days of the conclusion of the hearing.

15. Within an additional 30 days thereafter, the Appellate Commission shall render a decision:

a. to affirm the decision of NABP; or
b. to reverse the decision of NABP and grant or restore DMEPOS accreditation.

16. A written report of the Appellate Commission's findings and decision shall be submitted to the Executive Director/Secretary of NABP and the appealing party. The decision of the Appellate Commission to deny or grant accreditation is final.