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Rule Package #67898 – "Amend, Rescind, Promulgate New Current Rules"

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Chapter 4779-3 Definitions -- Rescind and Enact New (reorganize, amend, add new)

(Current language here: http://66.161.141.185/oac/4779-3-01)

4779-3-01 Definition of terms.

The following definitions shall apply to the language of Chapter 4779. of the Revised Code:

(A) General Definitions

(1) "Board" means the state board of orthotic, prosthetics and pedorthics.

(2) "Temporary license" means a license issued under section 4779.18 of the Revised Code.

(B) Licensing language and educational standards

(1) "Good moral character" as it is used in section 4779.09 and under division (A)(1)(3) in section 4779.18 of the Revised Code, means not having been convicted of a crime of moral turpitude; not having made misstatements or misrepresentation in connection with an application or examination for registration, certification or licensure; and not having willfully violated any of the sections related to conduct required of applicants or licensees and set forth in the statutes or rule.

(2) "License" as it is used under division (A) of section 4779.20 of the Revised Code, means the authority to practice in the noted profession pursuant to an action of the board granting such authority and as represented by the original license wall certificate or an official copy of the license certificate, or the annual renewal card, as issued by the board.

(3) "Licensee" means a person who holds a license issued under Chapter 4779. of the Revised Code.

(4) "Nationally accredited college or university in the U.S." means colleges and universities accredited by an accreditation body recognized by the U.S. department of education, including regional accreditation bodies.

(5) "Provides two semesters or three quarters of instruction" as it is used in subdivisions (B)(1), (C)(1), and (D)(1) of section 4779.26 of the Revised Code means that the certificate program meets those specific traditional education duration standards or meets the standards as developed and implemented by the national commission on orthotic and prosthetic education (NCOPE) in effect at the time the applicant was completing his or her formal education for entrance to the referenced professions. Such instruction may include blended learning that allows for a combination of online distance learning, classroom learning, and on-site clinical learning that meets the standards established by the commission on accreditation of allied health education professions (CAAHEP).

(6) "Provides two semesters or three quarters of instruction" as it is used in subdivisions (B)(1), (B)(2), and (B)(3) of section 4779.27 of the Revised Code means that the residency program requires as a prerequisite for admission the educational equivalent of learning required by section 4779.26 of the Revised Code or residency admission standards as developed and implemented by the national commission on orthotic and prosthetic education (NCOPE) that were in effect at the

time the applicant was completing his or her formal education for entrance to the referenced professions and that meets or met the standards established by the commission on accreditation of allied health education professions (CAAHEP).

(7) "Residency program" approved by the board, as referenced in section 4779.10 of the Revised Code, section 4779.11 of the Revised Code, and section 4779.12 of the Revised Code means a residency requiring nineteen hundred hours under the direct supervision of a practitioner certified in the same discipline, and which meets the requirements of section 4779.27 of the Revised Code.

(8) "Suspended" as used in section 4779.31 of the Revised Code means a license that has lapsed or been placed on inactive or non-renewed status due to non-payment of renewal fees, as well as a license placed under suspension as the result of an adjudication pursuant to section 4779.28, 4779.29, or 4779.30 of the Revised Code, or as the result of an agreement entered into between the board and the license holder in lieu of proceeding to adjudication.

(C) Supervision definitions and requirements

(1) "Physically present" as it is used under division (B) of section 4779.04 of the Revised Code means at the same building, location, or facility as the non-licensed practitioner and patient.

(2) "Under the direct supervision", as it is used under division (B)(5) of section 4779.02 of the Revised Code, means the individual who provides orthotic, prosthetic, or pedorthic services under the supervision of an individual authorized to practice medicine or osteopathic medicine, must perform the evaluation, measurement, design, fitting, adjusting, servicing, or training in a building, facility, or location where the physician or osteopathic physician is present at the time the service is provided and pursuant to a professional arrangement whereby the physician or osteopathic physician takes full clinical and consumer care responsibility for the orthotic, prosthetic, or pedorthic services provided.

(3) "Under the supervision" as it is used under division (B) in section 4779.18 of the Revised Code means the temporary license holder who practices under the supervision of an individual who holds a full practitioner license issued under section 4779.09 of the Revised Code may conduct all activities either at a building, location, or facility where the supervising orthotist, prosthetist, or pedorthist is physically present or at a location where the supervising orthotist, prosthetist, or pedorthist is readily available to the individual through some means of telecommunication and is in a location that under normal circumstances is not more than sixty minutes travel time away from the location where the temporary license holder is practicing.

Effective:
R.C. 119.032 review dates: 01/02/2012
Promulgated Under: 119.03
Statutory Authority: 4779.08
Rule Amplifies: Chapter 4779
Prior Effective Dates: 08/09/02; 04/09/07; 11/01/2008

Custom fab and fit proposed 2010 show changes

(E) "Custom fabricated or fitted medical device" as referenced in division (E) of section 4779.01 of the Revised Code means an orthotic, prosthetic or pedorthic device that is individually made (custom fabricated) or fitted (custom fitted) for a specific patient. Further, it is a device the provision of which requires access to a facility with the equipment necessary to fulfill the ongoing consumer-care responsibility to provide follow-up treatment, including modification, adjustment, maintenance and repair of the item(s).

(1) A custom fabricated item is defined as a device which 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.

(a) A molded-to-patient-model item is a particular type of custom fabricated device in which either:

(i) 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

(ii) A digital image of the patient's body part is made using computer-aided design-computer aided manufacture (CAD-CAM) systems software. This technology includes specialized probe/digitizers and scanners that create a computerized positive model and then direct milling equipment to carve a positive model. The device is then individually fabricated and molded over the positive model of the patient.

(2) A custom fitted item is defined as 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.

(a) A custom fitted item/device as referenced in division (E) of section 4779.01 of the Revised Code does not include:

(i) Upper extremity adaptive equipment used to facilitate the activities of daily living;

(ii) Finger splints or wrist splints;

(iii) Prefabricated elastic or fabric abdominal supports with or without metal or plastic reinforcing stays requiring minimal fitting;

(iv) Other prefabricated soft goods requiring minimal fitting;

(v) Nontherapeutic accommodative inlays;

(vi) Nontherapeutic shoes that are not manufactured or modified for a particular individual;

(vii) Prefabricated foot care products;

(viii) Other durable medical equipment that is not categorized as an orthotic, prosthetic, or pedorthic device; dental appliances; or devices implanted into the body by a physician.

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(E) "Custom fabricated or fitted medical device" as referenced in division (E) of section 4779.01 of the Revised Code means an orthotic, prosthetic or pedorthic device that is individually made (custom fabricated) or fitted (custom fitted) for a specific patient. Further, it is a device the provision of which requires access to a facility with the equipment necessary to fulfill the ongoing consumer-care responsibility to provide follow-up treatment, including modification, adjustment, maintenance and repair of the item(s).

(1) A custom fabricated item is defined as a device which 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.

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(ii) A digital image of the patient's body part is made using computer-aided design-computer aided manufacture (CAD-CAM) systems software. This technology includes specialized probe/digitizers and scanners that create a computerized positive model and then direct milling equipment to carve a positive model. The device is then individually fabricated and molded over the positive model of the patient.

(2) A custom fitted item is defined as 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.

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(iii) Prefabricated elastic or fabric abdominal supports with or without metal or plastic reinforcing stays requiring minimal fitting;

(iv) Other prefabricated soft goods requiring minimal fitting;

(v) Nontherapeutic accommodative inlays;

(*vi*) Nontherapeutic shoes that are not manufactured or modified for a particular individual;

(vii) Prefabricated foot care products;

(viii) Other durable medical equipment that is not categorized as an orthotic, prosthetic, or pedorthic device; dental appliances; or devices implanted into the body by a physician.

(K) "Custom fabricated or fitted medical device" as referenced in division (E) of section 4779.01 of the Revised Code means an orthotic, prosthetic or pedorthic device that is individually made (custom fabricated) or fitted (custom fitted) for a specific patient. No other patient would be able to use this item after fabrication or fitting.

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

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(2) A custom fitted item is defined as a prefabricated device which is manufactured in quantity without a specific patient in mind. The device may be supplied as a kit of prefabricated parts that require some assembly and/or fitting and adjustment, or a device that must be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific patient.

(a) A custom fitted item/device as referenced in division (E) of section 4779.01 of the Revised Code does not include:

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(ii) Finger splints;

(iii) Wrist splints;

(iv) Prefabricated elastic or fabric abdominal supports with or without metal or plastic reinforcing stays;

(v) Other prefabricated soft goods requiring minimal fitting;

(vi) Nontherapeutic accomodative inlays;

(vii) Shoes that are not manufactured or modified for a particular individual;

(viii) Prefabricated foot care products;

(ix) Other durable medical equipment;

(x) Dental applicances;

(xi) Pedorthic devices;

(xii) Devices implanted into the body by a physician.

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

FINAL
October 2008

DMEPOS Quality Standards
October 2008

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NOTE: ALL HIGHLIGHTING IS FROM ORIGINAL DOCUMENT AS POSTED ON CMS WEBSITE.

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. <u>Product Safety</u>

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

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. Follow-up

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 & 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 (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 & 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 (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.)

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. 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 & Set-up

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. <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 (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.

From: Levy, Mark B
To: "MHouskaMRL@aol.com"

Subject: July 14th public hearing
Date: Thursday, June 17, 2010 2:58:00 PM
Attachments: Custom fab and fit mark-up - proposed 2010- current 2008.pdf

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Your email today, shown below, asks the following regarding the public hearing scheduled July 14, 2010, to receive testimony regarding proposed rule amendments, rescissions and enactments.

> "I would like for you to clarify your planned discussion of section 4779-3-02, is this to determine who can fit custom product vs off the shelf products / custom fit vs custom fabricated? If so, have you included all manufactures, as well as representatives from the ABC & BOC in the disbursement of the notice of this meeting? If there are changes or new criteria that you will be proposing at this meeting I would appreciate a copy to review prior to this meeting."

First, please let me advise that the scheduled public hearing is a requirement under state law that governs agencies' responsibility/authority to enact or amend rules pursuant to the statutes under which they operate. We have a fairly detailed document discussing what the process entails and what the requirements are posted on the page with the rules packages; it is available specifically at this link: http://opp.ohio.gov/pdf/OPPrulemaking.pdf .

Second, the full text of the section (ORC § 119.03) of the Ohio Revised Code that prescribes these requirements is available online at this link: http://codes.ohio.gov/orc/119.03 . Paragraph C sets forth the requirements for the manner in which the hearing should be conducted:

> *(C) On the date and at the time and place designated in the notice, the agency shall conduct a public hearing at which any person affected by the proposed action of the agency may appear and be heard in person, by the person's attorney, or both, may present the person's position, arguments, or contentions, orally or in writing, offer and examine witnesses, and present evidence tending to show that the proposed rule, amendment, or rescission, if adopted or effectuated, will be unreasonable or unlawful. An agency may permit persons affected by the proposed rule, amendment, or rescission to present their positions, arguments, or contentions in writing, not only at the hearing, but also for a reasonable period before, after, or both before and after the hearing. A person who presents a position or arguments or contentions in writing before or after the hearing is not required to appear at the hearing.*
> *At the hearing, the testimony shall be recorded. Such record shall be made at the expense of the agency. The agency is required to transcribe a record that is not sight readable only if a person requests transcription of all or part of the record and agrees to reimburse the agency for the costs of the transcription. An agency may require the person to pay in advance all or part of the cost of the transcription.*
> *In any hearing under this section the agency may administer oaths or affirmations.*

As to your specific questions as I understand them.

Question 1. " … clarify your planned discussion of section 4779-3-02, is this to determine who can fit custom product vs off the shelf products / custom fit vs custom fabricated?"

Answer: Proposed OAC 4779-3-01 and OAC 4779-3-02 are being put forward as proposed revisions and updates to the current rule OAC 4779-3-01. Find current rule language at this link: http://codes.ohio.gov/oac/4779-3-01 .

The language of proposed 4779-3-02 is described in the "reader friendly" document at the website this

way:

> Language updated from former/current rule 4779-3-01 (K) -- custom fabrication and custom fit definitions. **Changes reflect the most recent CMS Quality Standards descriptions** and further refine the unique Ohio statutory delineations under the "does not include" clauses. New language provides further clarification of the difference under the Practice Act as regards use of the terms **"accommodative" compared to "custom fabricated and fitted;"** and defines "arch support," "non-therapeutic," and "therapeutic."

Please note the link to the CMS Quality Standards document. The language about custom fabrication and custom fit in the current version of the rule was largely based on a draft of the Quality Standards in circulation at the time that language was proposed. Note the effective date of the current rule language is November 2008. The most recent Quality Standards document was finalized/adopted by CMS in October 2008, around the time the Board was approving our rule package then pending; we had been operating from an earlier version. The changes now being proposed to the definitions of custom fabricated and custom fitted generally seek to update the Ohio language in accordance with the most recent version (October 2008) of those national standards.

I am also attaching to this message a document that shows only the custom fab and fit language from the rule in three versions: a "marked-up" copy, showing how the language is proposed to be changed compared to current language; a clean copy of the proposed new version; and a clean copy of the language currently in effect.

The short answer to your question would have been: the hearing is to provide an opportunity for discussion of and testimony regarding the proposed changes to the Definitions rule from current language, as well as other rule changes evident in the packages. I thought it might be helpful to put that answer in a broader context. As regards "custom fabricated" and "custom fitted", we are seeking to better define these terms as they are understood at the federal level while still maintaining the Ohio-specific details as required by the language of ORC Chapter 4779, and especially ORC Section 4779.01.

Question 2: " … have you included all manufactures, as well as representatives from the ABC & BOC in the disbursement of the notice of this meeting?"

Answer: We maintain a "stakeholders" distribution list of persons and organizations that are known to have an interest in actions taken by the Board, including anyone who has asked to receive information about Board operations. Anyone who wants to be on that list need only send us a notice by mail, fax or email. The list includes representatives of a number of associations representing parties interested in the allied healthcare fields, and I can advise that ABC and BOC contact points are included on that list. OAC rule 4779-1-01 includes language advising about notice for these matters, and our outreach efforts are consistent with that language. I note that your email address is on that list. I cannot certify that "all manufactures" are represented on the list; I can guarantee you that none have been excluded.

Question 3: "If there are changes or new criteria that you will be proposing at this meeting I would appreciate a copy to review prior to this meeting."

Answer: Given my understanding that you received our email notice in this regard, I'm not sure I understand your question. All the information is available, as indicated in the email that advised you about the hearing, at the website at the following link:

http://opp.ohio.gov/rp.stm

If you are requesting that I send you by US Mail a print-out of the proposed rule changes, please

advise. Otherwise, I believe complete information is found at the website and is supplemented by information provided by this message.

Mark B. Levy, Board Director
State Board of Orthotics, Prosthetics and Pedorthics
77 S. High St., 18th Floor
Columbus, OH 43215
tel: 614-466-1157
fax: 614-387-7347
email: bopp@exchange.state.oh.us

From: MHouskaMRL@aol.com [mailto:MHouskaMRL@aol.com]
Sent: Thursday, June 17, 2010 12:17 PM
To: Levy, Mark B
Subject: Re: ABC info

Mark,

I also would like to address the Public Meeting you have scheduled for July 14, 2010 beginning at 11:15 am, I would like for you to clarify your planned discussion of section 4779-3-02, is this to determine who can fit custom product vs off the shelf products / custom fit vs custom fabricated? If so, have you included all manufactures, as well as representatives from the ABC & BOC in the disbursement of the notice of this meeting? If there are changes or new criteria that you will be proposing at this meeting I would appreciate a copy to review prior to this meeting.

Sincerely,
Michael J. Houska
Medical Resources Limited
President
800-998-4199
Cell: 330-697-4845

From:	Levy, Mark B
To:	"MHouskaMRL@aol.com"; Michael J. Houska (mhouskamrl@cs.com)
Subject:	Minimal fitting; statutory language
Date:	Wednesday, July 21, 2010 4:18:00 PM
Attachments:	4779-3-02 revised 07.12.10.pdf Copy of ODJFS O-P Appendix-exceptions- 04 15 10 mtg draft.pdf rc 4779 01- 02 - hililte doesnotinclude.pdf

Mike, thanks for attending the hearing, I hope we were able to clarify at least a couple of points.

I'm not sure, but it seems one of the areas of disagreement, if that's what it should be called, is that you may assume the Board has more authority than in fact we have. One of the things I need to recognize in my job are the things we can do something about, and those that we can't do anything about. The statutory language of the Practice Act is a static status quo that we all have to live with. Thus, when the statute says that an Orthotic Device is:

> **a custom fabricated or fitted medical device used to support, correct, or alleviate neuromuscular or musculoskeletal dysfunction, disease, injury, or deformity. (rc 4779.01-E)**

… we know that, for example, an LSO or a KAFO that is designed to be custom fitted meets that definition, and is not excluded by the "does not include" list of 4779.01-D:

- upper extremity adaptive equipment used to facilitate the activities of daily living,
- finger splints, wrist splints,
- prefabricated elastic or fabric **abdominal supports** with or without metal or plastic reinforcing stays and other prefabricated **soft goods** requiring minimal fitting

Having said that, there are some products, such as prefabricated post-surgical boots, that are not subject to customizing and that might be considered an unmodified over the counter shoe (see the "does not include" list in rc 4779.01-G).

I would further invite constructive dialogue on the proposed changes to the definitions language in the rule series. If you follow the links on the website, you will see how closely we are trying to conform state regulatory language to the national standard.

Given the discussion at the hearing, I feel I do need to clarify that the language to better define "minimal fitting" will only provide guidance for those items to which the term "minimal fitting" attaches in the statute, and that the Board does not have the authority by administrative rule to apply the "minimal fitting" qualifier across a broader spectrum of orthotic devices. That's just the way it is.

After we can move forward with the changes to the rules language and especially the definitions, which will help to provide an appropriate basis, I am hopeful we can complete the big project we have in the works regarding the Medicaid O&P HCPCS inventory. I think that will provide you the kind of "what's in, what's out" list that you're seeking, but I can't just make that appear without engaging in an appropriate process and giving appropriate consideration to the different things that need to be, how else can I say, considered.

I've given you here the most recent version of our "work-in-progress" on the ODJFS HCPCS appendix. This is not a document the Board has fully reviewed/approved. It's a working paper, but hopefully it will give you some insight into the careful approach we're taking. (Codes/items that appear to be missing may have already been addressed as custom fab or custom fit based on classification or HCPCS narrative – this is only part of the list, but the part we're grappling with now.) You'll note a number of items are not "rated" so to speak; if you have any input regarding the unrated items, or even the rated ones, please pitch in – all help is welcome.

But for the current deadline concern, if you have changes you want to suggest or written concerns you want to

state regarding the pending rule language, please do so by July 30th. And if you want to talk any of it through, feel free to call, I'll set aside the time.

Mark B. Levy, Board Director
State Board of Orthotics, Prosthetics and Pedorthics
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Columbus, OH 43215
tel: 614-466-1157
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email: bopp@exchange.state.oh.us
website: http://opp.ohio.gov

From: Levy, Mark B
To: "MHouskaMRL@aol.com"
Cc: zhaughawout@jcarr.state.oh.us
Subject: RE: Minimal fitting, stautory language
Date: Friday, July 30, 2010 10:20:00 AM

Mr. Houska, thank you for submitting your concerns in writing. I note that you are choosing to not offer any specific suggestions for changes to the existing or proposed language. I must also state again as I have before that this Board has no authority to alter the statutory language as provided in the Practice Act, RC Chapter 4779. The present process is about creating administrative processes, definitions, and clarifications to guide both the Board and regulated persons in compliance with that language.

Let me respectfully suggest your message indicates you are looking at the issue from the bottom up instead of the top down; in Ohio, the "top" being the statutory language in the Practice Act.

ORC §4779.01 contains the basic statutory definitions delineating the regulated professions (Orthotics, Prosthetics and Pedorthics); the scope of practice that is regulated (generally, the "evaluation, measurement … assembly, fitting, adjusting, servicing or training in the use of the … device[s]"); the scope of devices dispensed that fall within the realm of regulation (custom fabricated and custom fitted devices); and the types of devices or the characteristics of devices that are excepted from regulation.

NOT INCLUDED in the scope of regulation of Orthotic devices, as provided for in RC 4779.01 (D) are: "upper extremity adaptive equipment used to facilitate the activities of daily living, finger splints, wrist splints, prefabricated elastic or fabric abdominal supports with or without metal or plastic reinforcing stays and other prefabricated soft goods requiring minimal fitting, nontherapeutic accommodative inlays, shoes that are not manufactured or modified for a particular individual, prefabricated foot care products, durable medical equipment, dental appliances, pedorthic devices, or devices implanted into the body by a physician."

NOT INCLUDED in the scope of regulation of Pedorthic devices, as provided for in RC 4779.01 (G) are: "an arch support, a nontherapeutic accommodative inlay, nontherapeutic accommodative footwear, prefabricated footcare products, or unmodified, over-the-counter shoes."

NOT INCLUDED in the scope of regulation of Prosthetic devices, as provided for in RC 4779.01 (I) are: "devices implanted into the body by a physician, artificial eyes, intraocular lenses, dental appliances, ostomy products, cosmetic devices such as breast prostheses, eyelashes, wigs, or other devices that do not have a significant impact on the musculoskeletal functions of the body."

To respond to particular points or statements you set forth in the message below, let me try to address them as you present them.

1. "the national standards are well defined as to exactly who can and cannot fit devices that are either custom fabricated based on the model of the patient or any other device."

> Response: This may represent the major concern you express: under CMS standards, **in states without licensure**, certain CMS-defined certification standards provide the base-level certification required to fit devices subject to reimbursement under the DMEPOS schedule. While we have gone to great lengths to conform Ohio language to the CMS language, as I have clearly indicated and illustrated previously, we cannot ignore the particular Ohio requirements. Where states license, certify or register beyond the CMS requirements, CMS standards defer or default to the state regulatory language. That is why we are engaged in the present process – to provide better definition of the state-required differentials.

2. "What if a prefabricated brace (using 2 measurements sizes , S, M, L etc) has the ability to be heat molded but the patient doesn't require any custom modifications for the brace to fit properly. Which individuals are or are not qualified to fit that particular brace?

Response: As I believe you are aware, there exists a wide array of bracing choices in the marketplace to address particularized, individualized consumer needs. I would respectfully suggest that a properly educated and ethical practitioner could choose/recommend/fit a brace that is not manufactured or designed to be custom fitted or custom modified if the consumer does not require custom fitting or modification in his or her bracing needs. An appropriately licensed, qualified, educated and ethical practitioner would be able to assist your consumers and your provider partners in making those appropriate choices. I should also point out that braces designed and manufactured to be custom fitted, including heat moldable components, reimburse at a significantly higher rate (dollar value) than those that do not require customizing, because the reimbursement allowable anticipates the higher level of care, measurement, fitting and follow-up required for a custom fitted item.

3. "There should be a clearly defined difference between custom fitted with minimal fitting requirements – every brace can be adjusted in some way. It seems as though the current language you have explains all products as custom fitted in some manner resulting in a very limited amount of experienced professionals qualified to service these patient's needs. It is evident that the Minimal Fitting Definition contradicts that of the previous outlined guidelines on custom fitted devices putting all braces basically in the same category."

Response: All I can do here is to refer you to the statutory language and exceptions as cited above, and the pending rule revision which you claim is inadequate, but for which you seem unable or unwilling to offer specific changes, amendments, or alternative language suggestions. As I have stated in previous correspondence and discussion, the language to better define "minimal fitting" will only provide guidance for those items to which the term "minimal fitting" attaches in the statute; the Board does not have the authority by administrative rule to apply the "minimal fitting" qualifier across a broader spectrum of orthotic devices.

The statute uses the term "minimal fitting" in its description of the following excepted orthotic devices:

- prefabricated elastic or fabric abdominal supports with or without metal or plastic reinforcing stays and other prefabricated soft goods requiring minimal fitting

In the proposed rule language (OAC 4779-3-02), we have carried that language forward as follows, incorporating the CMS Quality Standards definition of custom fitted:

(E) "Custom fabricated or fitted medical device" as referenced in division (E) of section 4779.01 of the Revised Code means an orthotic, prosthetic or pedorthic device that is individually made (custom fabricated) or fitted (custom fitted) for a specific patient. Further, it is a device the provision of which requires access to a facility with the equipment necessary to fulfill the ongoing consumer-care responsibility to provide follow-up treatment, including modification, adjustment, maintenance and repair of the item(s).

***

(2) A custom fitted item is defined as 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.

(a) A custom fitted item/device as referenced in division (E) of section 4779.01 of the Revised Code does not include:

***

(iii) Prefabricated elastic or fabric abdominal supports with or without metal or plastic reinforcing stays requiring **minimal fitting**;

(iv) Other prefabricated soft goods requiring **minimal fitting**;

***

(G) "**Minimal fitting**" as used in Section 4779.01 of the Revised Code and Section 4779-3-02 of the Administrative Code means a prefabricated device which is fit for size by use of not more than two simple body size measurements; which is sized as small, medium, large, extra large, 2xl, 3xl; which is fastened or fit to the body or body part by use of elastic or self-fastening straps, buttons or strips; which is not trimmed, bent, molded, assembled, or otherwise customized by the consumer-care provider to fit the consumer; and which is not provided by the manufacturer with items or component parts which are intended or designed to be custom molded, heat moldable or custom fitted.

While the formal record of the Board's public hearing held on July 12, 2010, which you attended, closes today, please be assured that all correspondence and comments received regarding this matter will be available for the Board's consideration at its next meeting on September 1, 2010, and in fact the Board is willing to take and consider further comments and correspondence that it may receive during the month of August.

Thank you for taking the time to express your concerns and submit your comments in writing.

Mark B. Levy, Board Director
State Board of Orthotics, Prosthetics and Pedorthics
77 S. High St., 18th Floor
Columbus, OH 43215
tel: 614-466-1157
fax: 614-387-7347
email: bopp@exchange.state.oh.us

From: MHouskaMRL@aol.com [mailto:MHouskaMRL@aol.com]
Sent: Thursday, July 29, 2010 4:33 PM
To: Levy, Mark B
Cc: zhaughawout@jcarr.state.oh.us
Subject: Re: Minimal fitting, stautory language

Dear Mark,

Upon careful review of the information you sent, I have several concerns regarding the language for "Minimal fitting" as used in Section 4479.01 of the Revised Code and Section 4779-3-02 of the Administrative Code. The language is left very open for interpretation. If as you indicated it is based on the national standard it is clearly evident that the national standards are well defined as to exactly who can and cannot fit devices that are either custom fabricated based on the model of the patient or any other device.
The language you present is very unclear.

Example:

What if a prefabricated brace (using 2 measurements sizes , S, M, L etc) has the ability to be heat molded but the patient doesn't require any custom modifications

for the brace to fit properly. Which individuals are or are not qualified to fit that particular brace?

The language under Minimal Fitting leaves this very vague. I strongly agree that only Pedorthists, Orthotists, and Prosthetists should be able to fit custom fabricated braces. However, it seems more than adequate that custom fit prefabricated braces with minimal fitting requirements can be fit by credentialed and/or licensed professionals as are defined in the National Standards. There should be a clearly defined difference between custom fitted with minimal fitting requirements – every brace can be adjusted in some way. It seems as though the current language you have explains all products as custom fitted in some manner resulting in a very limited amount of experienced professionals qualified to service these patient's needs. It is evident that the Minimal Fitting Definition contradicts that of the previous outlined guidelines on custom fitted devices putting all braces basically in the same category.

The above outlines my concerns with the current pending rule language. If you would like to further discuss please contact me.

Sincerely,
Michael J. Houska
800-998-4199
Cell: 330-697-4845

From:	Levy, Mark B
To:	"mjcunningham5@yahoo.com"
Subject:	Minimal fitting; statutory language
Date:	Wednesday, July 21, 2010 4:03:00 PM
Attachments:	4779-3-02 revised 07.12.10.pdf Copy of ODJFS O-P Appendix-exceptions- 04 15 10 mtg draft.pdf rc 4779 01- 02 - hililte doesnotinclude.pdf

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Jennifer, thanks for attending the hearing, I hope we were able to clarify at least a couple of points.

One of the things I need to recognize in my job are the things we can do something about, and those that we can't do anything about. The statutory language of the Practice Act is a static status quo that we all have to live with. Thus, when the statute says that an Orthotic Device is:

> **a custom fabricated or fitted medical device used to support, correct, or alleviate neuromuscular or musculoskeletal dysfunction, disease, injury, or deformity. (rc 4779.01-E)**

… we know that, for example, an LSO or a KAFO that is designed to be custom fitted meets that definition, and is not excluded by the "does not include" list of 4779.01-D:

- upper extremity adaptive equipment used to facilitate the activities of daily living,
- finger splints, wrist splints,
- prefabricated elastic or fabric **abdominal supports** with or without metal or plastic reinforcing stays and other prefabricated **soft goods** requiring minimal fitting

Having said that, there are some products, such as prefabricated post-surgical boots, that are not subject to customizing and that might be considered an unmodified over the counter shoe (see the "does not include" list in rc 4779.01-G).

I would further invite constructive dialogue on the proposed changes to the definitions language in the rule series. If you follow the links on the website, you will see how closely we are trying to conform state regulatory language to the national standard.

Given the discussion at the hearing, I feel I do need to clarify that the language to better define "minimal fitting" will only provide guidance for those items to which the term "minimal fitting" attaches in the statute, and that the Board does not have the authority by administrative rule to apply the "minimal fitting" qualifier across a broader spectrum of orthotic devices. That's just the way it is.

After we can move forward with the changes to the rules language and especially the definitions, which will help to provide an appropriate basis, I am hopeful we can complete the big project we have in the works regarding the Medicaid O&P HCPCS inventory. I've given you here the most recent version of our "work-in-progress." This is not a document the Board has fully reviewed/approved. It's a working paper, but hopefully it will give you some insight into the careful, considered approach we're taking. (Codes/items that appear to be missing may have already been addressed as custom fab or custom fit based on classification or HCPCS narrative – this is only part of the list, but the part we're grappling with now.) You'll note a number of items are not "rated" so to speak; if you have any input regarding the unrated items, or even the rated ones, please pitch in – all help is welcome.

But for the current deadline concern, if you have changes you want to suggest or written concerns you want to state regarding the pending rule language, please do so by July 30th. And if you want to talk any of it through, feel free to call, I'll set aside the time.

Mark B. Levy, Board Director

From:	Levy, Mark B
To:	"bigdaddyjeffd@netzero.net"
Cc:	"Greg Fouche"; zhaughawout@jcarr.state.oh.us
Subject:	RE: certified fitters not recognized by State of Ohio
Date:	Friday, July 30, 2010 12:57:00 PM
Attachments:	Houska-Levy email 07.29-.7.30.2010.pdf

Mr. Daniels, I have been forwarded your message below from the staff at JCARR for response, as we have a set of rules revisions pending for review and hearing by that body. However, it is not clear why you addressed your message to that body, and you put me in a somewhat awkward position as you seem to be raising in your message a concern regarding a separate process in which we are engaged regarding an individual employed at your workplace.

I have to assume you received the email notifications sent from this office regarding the rules proposals pending review. That information is posted at our website here: http://opp.ohio.gov/rp.stm Licensees and stakeholders were invited and encouraged to submit comments to this office whether in conjunction with the public hearing we held on July 12, 2010, or otherwise. I do not believe you submitted any comments, concerns, testimony or proposals to this office in that regard.

The rules proposals of all agencies go through a well-defined process that includes review by JCARR. You can find more information regarding JCARR's mission and role at its website: https://www.jcarr.state.oh.us/

We also include information about JCARR review in the document posted at our website regarding the rule promulgation process: http://opp.ohio.gov/pdf/OPPrulemaking.pdf

In addition, you should be aware that there are provisions under the Practice Act for an unlicensed individual to provide services under the supervision of a licensee. You can find our published guidelines regarding these standards here: http://opp.ohio.gov/pdf/supervision.pdf

Since all comments, testimony, and correspondence submitted to the Board is maintained in the public record of the Board's process, I am providing you a copy of an exchange I had with another concerned party as I believe the discussion there is related to the concerns you raise. The primary concern you raise -- that the Ohio Practice Act for O&P does not provide for licensing of orthotic fitters -- is beyond the scope of what the Board can address in its rule making process. For that concern you may wish to contact your elected state representative and senator to discuss possible legislative remedies. For any further concerns you wish to express regarding the pending administrative rule language, feel free to come back here.

Mark B. Levy, Board Director
State Board of Orthotics, Prosthetics and Pedorthics
77 S. High St., 18th Floor
Columbus, OH 43215
tel: 614-466-1157
fax: 614-387-7347
email: bopp@exchange.state.oh.us

-----Original Message-----
From: Greg Fouche [mailto:gfouche@jcarr.state.oh.us]
Sent: Friday, July 30, 2010 9:16 AM
To: Levy, Mark B
Subject: FW: certified fitters not recognized by State of Ohio

-----Original Message-----
From: Zach Haughawout

Sent: Friday, July 30, 2010 8:24 AM
To: Carrie Kuruc
Cc: Greg Fouche
Subject: FW: certified fitters not recognized by State of Ohio

-----Original Message-----
From: bigdaddyjeffd@netzero.net [mailto:bigdaddyjeffd@netzero.net]
Sent: Friday, July 30, 2010 8:15 AM
To: Zach Haughawout
Subject: certified fitters not recognized by State of Ohio

I am writing this in regards to a fellow peer who has been told he can no longer apply prescribed off the shelf items because due to someones interpretation in Ohio's laws,precludes him what he is credential to do under national guidelines.He is certified by both ABC,and BOC credentialing bodies as a certified fitter.I believe that as a certified fitter he should be allowed the right to apply off the shelf ,prefabricated device,that has minimal fitting,or adjustments,since this is what he was trained and certified for.Language in the law describing minimal fit or custom fit items,and who can fit them within there scope of practice needs to be clarified or legislation introduced to include certified fitters.Mabe a list of allowable items to be applied by certified fitters? I hope you will look into this over sighted injustice and seek to resolve it promptly. Sincerely, Jeffrey Daniels CO, Licensed Orthotist State of Ohio

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<http://thirdpartyoffers.netzero.net/TGL3232/4c52c28dcbd7f4aa2afst06vuc>

From:	Claudia Zacharias
To:	Levy, Mark B
Cc:	chagrin@footsolutions.com; akedniehaus@aol.com; bill@neulimbs.com; dmdeluccia@columbus.rr.com; cjackman@hanger.com; Chris Caston (ccaston11@sbcglobal.net)
Subject:	comment on two rules, 4779-3-02 and 4779-5-03
Date:	Friday, July 30, 2010 12:23:21 PM

Mark B. Levy, Board Director
State Board of Orthotics, Prosthetics and Pedorthics
77 S. High St., 18th Floor
Columbus, OH 43215

Via email: Mark.B.Levy@exchange.state.oh.us

Mr. Levy: Many thanks for the opportunity to comment on two rules, 4779-3-02 and 4779-5-03.

I am writing on behalf of the Board, staff, and practitioner certificants of the Board of Certification/Accreditation, International (BOC). We represent 41 Certified Orthotic Fitters (COFs) in the state of Ohio, as well as more than 100 Ohio certificants in the areas of Orthotics, Prosthetics, Mastectomy Fitters, and Pedorthics. In addition, BOC's orthotic fitter certification is the only NCCA-accredited COF certification available. (In fact, BOC is the only O&P certification body that has earned NCCA accreditation for all its certifications.)

NCCA is the acronym for The National Commission for Certifying Agencies; NCCA uses a peer review process to evaluate the administrative, technical and psychometric aspects of how a certification's requirements and assessment tools are developed and maintained. The process includes a detailed review of the development of certification requirements and assessment tools, including the qualification and diversity of subject matter experts and the psychometric tools used to verify validity and reliability of the program. By following NCCA's administrative and psychometric requirements, BOC demonstrates that its certification programs are valid and reliable.

For these reasons, I believe our voice should be heard.

As I understand it, these rules name just about any Lcode, if not all, as "Custom" and say that only a Certified Orthotist can fit them. I want to ensure that the rules do not have what I am certain is the unintended consequence of limiting the livelihood of Certified Orthotic Fitters who have done quality work for years.

Here are the links to the online Scopes of Practice for the BOC Orthotist and BOC COF.

- BOC Orthotist: http://www.bocusa.org/BOCOScopeofPractice.pdf
- BOC COF: http://www.bocusa.org/COFScopeofPractice.pdf

As you can see, a COF is not a "Junior Orthotist." The two roles are distinct, perhaps most notably in their use of different technologies. COFs receive ongoing training in their specialty area, and are recognized in National Standards, which state that "individuals supplying the item set out in this appendix must possess specialized education, training, and experience in fitting, and certification and/or licensing" … and these standards also identify who can fit Orthotics. (See:
http://www.cms.gov/MedicareProviderSupEnroll/Downloads/DMEPOSAccreditationStandards.pdf

.)

I am also concerned about Ohio's' restorative patients and their appropriate treatment and access to care.

Finally, there are legal concerns: nursing homes that can be found out of compliance with federal law (beginning with OBRA legislation of 1987) if they do not have the tools to treat patients with lost range of motion (i.e. physical deformities resulting primarily from neurological conditions).

I encourage you to revise your proposed rules to align with the National Standards that recognize the unique and important role of the COF.

Please let me know if I may provide additional information or clarifications.

Very respectfully,
Claudia Zacharias

Claudia Zacharias, MBA, CAE
President and CEO

Individualization | Activator | Developer | Arranger | Responsibility *(what's this?)*

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claudia.zacharias@bocinternational.org

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From:	chris Caston
To:	Levy, Mark B
Cc:	zhaughawout@jcarr.state.oh.us
Subject:	Rule Comment 4779-3-02/ 4779-5-03
Date:	Friday, July 30, 2010 4:51:48 PM

Mr Levy

In the Boards recent attempt to define the difference between custom fitted and minimum fitted and to make your regulatory language comply with the national standard, I believe there are a few items you that are not being considering. In The DMEPOS Quality Standards they identify "individuals that posses specialized, training and experience in fitting, and certification and/or licensing". My question is; if the BOC and ABC recognize programs and require continuing education and training to be certified, why do you not include or have any acknowledgement of the Orthotic Fitter qualifications or use the scope of practice as a guideline in our the Ohio O&P language?

In your description of (G) on minimum fitted the wording intended or designed leaves a lot of room for question. I would ask that you would say, "They need to be"

Thank You

Chris Caston
Cell 330-327-8486
ccaston11@sbcglobal.net

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From: Levy, Mark B
To: "chris Caston"
Cc: zhaughawout@jcarr.state.oh.us

Subject: RE: Rule Comment 477 -02/ 4779-5-03
Date: Monday, August 02, 2010 11:33:00 AM

Please consider the following in response:

1. "the Boards recent attempt to define the difference between custom fitted and minimum fitted …"

RESPONSE: The language of the rule seeks to define "custom fitted" in general accordance with a national standard as set forth in the most recent CMS Quality Standards language. However, the Ohio statute lists certain exceptions to the range of bracing that may be considered to be "custom fitted," even if such bracing otherwise meets the Ohio statutory definition. Within those exceptions, the term "minimal fitting" is used to modify a certain range/category of bracing options. The new language of proposed rule 4779-3-02 (G) seeks to define "minimal fitting" as used in the statute and the rules.

2. "My question is; if the BOC and ABC recognize programs and require continuing education and training to be certified, why do you not include or have any acknowledgement of the Orthotic Fitter qualifications or use the scope of practice as a guideline in our the Ohio O&P language?"

RESPONSE: The language of the OPP Practice Act as enacted by the 123rd Ohio General Assembly as Am. Sub. SB 238 did not contain provisions for the licensing of, nor language addressing, persons holding "fitter" credentials, nor does or did it confer onto the Board any authority to provide for such licensing. There is very specific language regarding educational and training requirements for persons to attain licenses in the fields of Orthotics, Prosthetics, and Pedorthics. Lacking specific authority from the legislature to provide for licensing of fitters, the Board has no such authority. Thus, fitters are considered unlicensed persons under the terms of the statute and must engage in their practice within the parameters provided by the statute, under the appropriate supervision of a licensee within the regulatory language developed pursuant to Chapter 4779, Ohio Revised Code.

3. "In your description of (G) on minimum fitted the wording intended or designed leaves a lot of room for question. I would ask that you would say, 'They need to be'"

RESPONSE: The full language of the proposed paragraph you are referencing reads as follows:

> (G) "Minimal fitting" as used in Section 4779.01 of the Revised Code and Section 4779-3-02 of the Administrative Code means a prefabricated device which is fit for size by use of not more than two simple body size measurements; which is sized as small, medium, large, extra large, 2xl, 3xl; which is fastened or fit to the body or body part by use of elastic or self-fastening straps, buttons or strips; which is not trimmed, bent, molded, assembled, or otherwise customized by the consumer-care provider to fit the consumer; and which is not provided by the manufacturer with items or component parts which are intended or designed to be custom molded, heat moldable or custom fitted.

Please advise where in that paragraph you believe the words "They need to be" should be inserted.

Mark B. Levy, Board Director
State Board of Orthotics, Prosthetics and Pedorthics