

**TESTIMONY OF THE
NEW ENGLAND MEDICAL EQUIPMENT DEALERS ASSOCIATION
RELATIVE TO THE DURABLE MEDICAL EQUIPMENT MANUAL
SUBCHAPTER 4 REGULATION 130 CMR 409.000
JUNE 26, 2008**

My name is Karyn Estrella. I am the executive director of The New England Medical Equipment Dealers Association (NEMED). We thank you for the opportunity to comment on proposed changes to the Durable Medical Equipment manual, Subchapter 4 Regulation 130 CMR 409.000 that are scheduled to become effective on or after August 1, 2008. NEMED is the regional trade association representing respiratory, rehab/assistive technology, durable medical equipment and home infusion therapy providers in the six New England states. We represent 60 companies in multiple locations throughout the Commonwealth of Massachusetts and estimate that our members provide products and services to 80% of the Medicaid beneficiaries in Commonwealth.

GENERAL COMMENTS

In the ten years since this regulation was adopted, NEMED and the EOHHS have developed a relationship that is based on mutual cooperation and respect. It has been a long road but we believe that the communication between the provider community and the EOHHS has been beneficial to all parties, including MassHealth members.

We are pleased with the work that the EOHHS has done to strengthen the regulations as they apply to provider eligibility and recertification. NEMED supports all efforts that ensure that MassHealth providers demonstrate sound business practices and provide quality products and services to residents in the Commonwealth. We believe that mandatory accreditation will help achieve this.

These comments are the result of compiling numerous comments from our members and several conference calls. We appreciate your consideration of our recommendations and we continue to offer ourselves as a resource to work with you in the future.

409.402 Definitions

Customized Equipment – (3) is sufficiently specialized or modified to preclude the use of such equipment by another individual.

NEMED recommends replacing this definition with the description from Medicare's Program Integrity Manual:

is uniquely constructed or substantially modified for a specific beneficiary according to the description and orders of the beneficiary's treating physician.

[from Medicare Program Integrity Manual] Define customized DME as being items of DME which have been uniquely constructed or substantially modified for a specific beneficiary

according to the description and orders of the beneficiary's treating physician. For instance, a wheelchair which has been: (1) measured, fitted or adapted in consideration of the patient's body size, disability, period of need, or intended use, (2) assembled by a supplier or ordered from a manufacturer who make available customized features, modifications, or components for wheelchairs, and (3) is intended for an individual patient's use in accordance with instructions from the patient's physician would be considered "customized".

Accessories - products that are fabricated primarily and customarily to modify or enhance the usefulness of another piece of equipment and that are generally not useful in the absence of that other piece of equipment.

NEMED recommends adopting Medicare's definition: Accessories - products that are a required interface between the equipment and the end user and/or are fabricated primarily and customarily to modify or enhance the usefulness of another piece of equipment and are generally not useful in the absence of that other piece of equipment e.g. nasal interface or tubing for a CPAP machine.

Adjusted Acquisition Cost – (1) except where the manufacturer is the provider, the adjusted acquisition cost is the actual amount paid by the provider to the manufacturer or any other supplier of DME, excluding all associated costs such as shipping, handling, and insurance in accordance with the regulations of the Division of Health Care Finance and Policy (DHCFFP). Where the manufacturer is the provider, the adjusted acquisition cost is the actual cost of manufacturing such DME.

The cost of delivery is becoming an increasing problem for providers. They have a higher percentage of redeliveries due to re-education, wrong product, etc. DME providers are seeing increases in freight charges and surcharges due to the increase in gasoline prices. NEMED recommends changing "excluding all associated costs such as shipping, handling and insurance" to "including all associated costs such as shipping, handling and insurance."

Durable Medical Equipment

(4) is appropriate for use in the member's home.

NEMED recommends changing all references of "member's home" to "member's residence or the community setting" throughout the regulation.

We are concerned that this definition will limit access to equipment that will meet the recipient's needs in and outside their residence as well as assist them with activities of daily living (ADL). Activities of daily living (ADLs) are "the things we normally do in daily living including any daily activity we perform for self-care (such as feeding ourselves, bathing, dressing, grooming), work, homemaking, and leisure." NEMED recommends changing the definition to:

is appropriate for use where the member resides, in the community and to assist them with activities of daily living.

Special Adaptive Mobility System — a mobility system that is customized for the personal full-time use of a member residing in a nursing facility.

NEMED recommends removing “residing in a nursing facility”. Custom is custom regardless of where the recipient resides.

409.404 Provider Eligibility

(A) All applicants must submit a letter of intent prior to receiving and completing a MassHealth provider application for DME. The letter of intent must describe:

- (1) the applicant’s primary scope of business, including which DME services and products the applicant intends to provide;
- (2) a list of any subcontractors the applicant intends to use and for what purpose;
- (3) existing contacts with other payers, and
- (4) service area(s) in which services will be provided.

NEMED requests the following:

- **Please provide a better definition of sub-contractor.**
- **Is a letter of intent required for a new location only?**
- **What is the timeline for approval of the letter of intent?**
- **Suggested language for (3) – replace with: a list of the top 5 contracts with other payers.**

(B) (e) has a primary business telephone number listed in the name of the business with a local toll-free telephone number that is answered by customer service staff during business hours. During business hours, **this number cannot transfer to an out-of-state number**, and cannot be a pager, answering machine, answering service, or cell phone.

This is contrary to many business models where a provider may have a centralized customer service staff. Restricting the transfer of call to an out-of-state service center, pager, etc. is restricting business practices and may reduce services to the patient. Additionally, this may be necessary as part of an emergency preparedness plan. In the event of a natural disaster, phones could be forwarded to a location that is outside the disaster area. NEMED suggests deleting the last sentence of this regulation.

(B) (j) a copy of written policies and procedures, including: the service facility customer service protocol; customer complaint tracking and resolution protocol; and staff training.

NEMED suggests replacing the word “including” with “regarding”.

(5) ...all applicants and providers must be accredited by an accrediting body, acceptable to the Centers for Medicare and Medicaid Services.

An August 1, 2008 deadline for accreditation is not sufficient time for DME providers to become accredited. In December 2007, CMS announced that all DME providers must be accredited by September 30, 2009. Since that time, many DME providers have begun the process but many are still in the early stages. Additionally, due to the accreditation requirement for all DME providers in DME competitive bidding areas, there is a backlog of companies waiting to be surveyed. NEMED recommends adopting the CMS deadline for accreditation of September 30, 2009. If CMS extends the deadline, MassHealth should follow suit.

(7) at the time of application and re-credentialing, or any other time as requested by the MassHealth agency, provide all required documentation specified in 130 CMR 450.000 and:

(j) a copy of written policies and procedures, including: the service facility customer service protocol; customer complaint tracking and resolution protocol; and staff training.

Under (j), NEMED suggests replacing the word “including” with “regarding”.

(E) Out of State. An applicant or provider of DME with a service facility located outside of Massachusetts may qualify as a MassHealth DME provider if the following conditions are met:

It is NEMED’s position that a MassHealth DME provider should be required to have a physical location in the Commonwealth or a bordering town.

409.405: Provider Responsibilities

When and under what circumstances can a provider collect monies from a MassHealth member?

Additionally,

- **If a prior authorization is denied, can the MassHealth member pay for the item?**
- **If the MassHealth member wants to purchase additional units over and above what MassHealth will allow, can the MassHealth member pay for the item?**

(B) notify the MassHealth agency in writing within 14 days of any changes in any of the information submitted in the provider application in accordance with 130 CMR 450.223(B), including but not limited to, change of ownership, change of address, and additional service locations. The provider must maintain records of all such communications and transactions and make such records available to the MassHealth agency for review upon request.

NEMED recommends adopting Medicare guidelines by replacing “notify the MassHealth agency in writing within 14 days of any changes” to “notify the MassHealth agency in writing within 30 days of any changes.”

(C) ensure that the DME provided is the most cost effective, given the medical need for which the DME is prescribed and the member's limitations;

This regulation infers that the DME provider is the prescriber and puts responsibility on the provider to determine the most appropriate piece of equipment. NEMED recommends removing this requirement.

(D) purchase the item from the least costly reliable source;

Purchase prices will vary from one DME provider to another depending on their size, purchasing volume, if they are part of a buying group, etc. DME providers are aware that they must provide the least costly alternative. NEMED recommends removing this requirement.

(K) not solicit members to purchase additional DME;

NEMED recommends changing this regulation to:

not solicit members to purchase additional DME via cold calling clients not already on service i.e telemarketing.

(M) respond within one business day to members' complaints regarding their DME.

NEMED recommends adopting the Medicare guideline of three (3) business days.

(O) DME providers who change their primary scope of business and will no longer provide the scope of DME services and products that were provided at the time MassHealth approved the DME application must provide MassHealth and members with written notification at least 60 days in advance. Notification to the member must include:

1. a list of DME providers who can provide the service in the member's area; and
2. if prior authorization is required for the service;
 - a. the number of non billed units remaining on the PA
 - b. a copy of the original PA approval from MassHealth for the member to provide to the new DME provider.

NEMED recommends deleting #1. Although we agree that MassHealth members should be given the freedom to choose their homecare provider, we believe that it should be the Department's responsibility to provide a list of eligible providers for the service. We recommend replacing #1 with the following:

MassHealth contact information.

409.413 Covered Services

(D) MassHealth will pay for a manual wheelchair as a backup to a power wheelchair, under the following conditions:

- (1) the level of customization of the primary power wheelchair would preclude the use of a substitute rental wheelchair if the primary wheelchair is removed from the home for repair.
- (2) the member requires frequent outings to a destination that is not accessible to a power wheelchair (for example, stairs without an elevator)
- (3) it is not possible to fit the primary chair in any of the vehicles available to the member for transportation.

NEMED recommends adding “power wheelchair back up” as a covered service in addition to the manual wheelchair back up in order to keep MassHealth members with high-level customized wheelchairs mobile since they are not able to use a manual wheelchair. Some MassHealth members keep their old power wheelchairs to use a back up. In order to keep MassHealth members independent, DME providers need to keep these power wheelchairs maintained.

These members are independent individuals with very individual needs and their power wheelchairs have been uniquely constructed to meet those needs. This includes appropriate drive controls, proper positioning, tie down systems, etc. A back up power wheelchair would keep them independent while their primary wheelchair is being serviced.

NEMED wants to ensure that the MassHealth members who rely on this highly specialized equipment are able to remain independent in light of a reduced provider base. In 1998, there were more than 17 DME companies who supplied custom wheelchairs. Today there are three.

409.415: DME Provided to Members in Facilities

(A) Skilled Nursing Facilities

(1) Covered Services

- (a) Customized seating and mobility equipment: the Mass Health agency pays for the purchase, rental, or repair of specialized mobility systems, seating systems, and add-ons . . . when provided for the exclusive full-time use of a member residing in a nursing facility (providing the customization precludes the use of equipment by other individuals in the nursing facility).

This definition discriminates against MassHealth members in nursing homes as compared to other places of service. It is NEMED’s position that MassHealth should evaluate prior authorization requests on the basis of medical necessity regardless of the place of service.

- (A) (1) (c) Durable Medical equipment for members to be discharged from a nursing home the DME provider must document the member’s discharge plan and discharge date in the member’s record before equipment is delivered to the nursing facility . . .

NEMED recommends following Medicare guidelines. Medicare allows the delivery of equipment up to 48 hours prior to discharge so the clinical staff at the facility can fit/adjust the equipment and instruct the patient on how to use the equipment.

409.416: Prescription Requirements

(A) . . . The prescription must be written, signed and dated prior to delivery to the member.

If the prescription must be signed and dated prior to delivery, this will cause a patient access problem. Medicare allows most items to be delivered without a Written Order Prior to Delivery (WOPD). This regulation would be a problem with facilitating discharge, especially those patients who have Medicare at their primary insurance since Medicare does not require a prescription in advance for the delivery of most DME. Some equipment/products cannot be held until a prescription is received, for example respiratory and nutritional products to name a few. NEMED recommends adopting Medicare guidelines with regard to verbal orders which allows providers to deliver but hold billing until the written order is received.

(B) MassHealth agency accepts written prescriptions in the following formats:

- (1) the prescribing provider's prescription pad;
- (2) the prescribing provider's letterhead stationery;
- (3) the hospital or nursing facility prescription pad, if the member is being discharged from a facility;
- (4) the MassHealth agency Documentation of Need for Durable Medical Equipment and Supplies General Prescription form;
- (5) the Region A Durable Medical Equipment Carrier (DME MAC) Certificate of Medical Necessity (CMN) completed in accordance with the instructions established by the Region A DME MAC and in compliance with 130 CMR 409.416(A).

NEMED's MassHealth workgroup would like to work with MassHealth to revise the existing DME and Supplies General Prescription form to address medical necessity criteria.

Additionally, more and more providers are using technology to facilitate more efficient and better care of MassHealth members. Every DME billing software program has various forms. NEMED recommends adding a 6th format that allows a computer-generated form from the DME provider with the seven (7) elements of a prescription. Once a verbal order is taken, the DME provider would confirm the order by printing a desktop pad prescription that is sent to the physician for his/her review and signature. Once this document is returned to the DME provider, they would then submit their bill. Medicare accepts computer-generated forms.

(C) A prescription may be transmitted electronically to the DME provider by the member's prescribing provider in accordance with the MassHealth agency's billing instructions and applicable state and federal law.

Are faxed prescriptions acceptable? If they are, will DME providers be required to obtain the original, signed prescription as well? NEMED recommends allowing faxed prescriptions without the original, signed prescription similar to Medicare guidelines.

(D) Prescriptions for members residing in nursing facilities must include a copy of the current month's order sheet, a copy of the medical justification from the member's nursing facility record, and may include additional documentation necessary to support medical necessity. Additional documentation may include physician progress notes, relevant laboratory or diagnostic test results, and nursing, nutrition, or therapy assignments and notes.

We need clarification of what products will fall under this regulation. Depending on the item, this requirement will place an administrative burden on DME providers.

409.417 Medical Necessity Criteria

(A) In addition to prescription requirements described in 130 CMR 409.416, DME providers must obtain a letter of medical necessity (LOM) for the purchase and rental of durable medical equipment and medical supplies, which must be signed and dated by the member's prescribing provider. The letter of medical necessity must be provided in one of the following formats:

- (1) the MassHealth Medical Necessity Review form developed by the MassHealth agency must be used for specific products as defined by the MassHealth agency.
- (2) the Region A Durable Medical Equipment Carrier (DME MAC) Certificate of Medical Necessity (CMN) completed in accordance with the instructions established by the Region A DME MAC and in compliance with 130 CMR 409.416(A).
- (3) if there is no MassHealth Medical Necessity Review form for the product(s), the MassHealth agency will accept a letter of medical necessity that includes the following documentation:
 - (a) the member's diagnosis and prognosis, including an indication of whether the diagnosis is a pre-existing condition or a presenting condition;
 - (b) the ICD-9 diagnosis code for which the durable medical equipment or medical supply is being prescribed;
 - (c) a description of the member's medical condition;
 - (d) medical justification for the item(s) being requested;
 - (e) the equipment settings, hours to be used per day, options, or additional features, as they pertain to the equipment;
 - (f) the recommended timetable of the prescribed item or treatment;
 - (g) the expected outcome and/or therapeutic benefit of providing the requested item(s) or treatment;
 - (h) a summary of any previous treatment plan, including outcomes, which were used to treat the diagnosed condition for which the prescribed treatment is being recommended;
 - (i) the prescribing provider's name, address, and signature;
 - (j) the date the prescription was signed by the prescribing provider; and
 - (k) the signature of the member's prescribing provider and the date the LOM was signed.

NEMED strongly recommends deleting this section and adopting Medicare guidelines. Medicare does not require all of these elements. For general DME, these requirements

would place an administrative burden on both the DME provider and the physician and will result in delays in equipment delivery. This regulation will lead to increased costs to the Medicaid program due to increased hospital/facility stays. Discharges cannot be facilitated with this requirement.

(A) (3) (a) the members diagnosis and prognosis, including indication of whether the diagnosis is a pre-existing condition or a present condition

NEMED recommends deleting this requirement for the same reasons above.

409.418 Prior Authorizations

This section replaces 409.408 and does not include a timeframe that MassHealth must make a decision on PA requests. Providers must to be able to inform the patient, clinicians, etc. when they may anticipate receiving the product. NEMED recommends retaining the language from the previous regulation:

The Division will take no longer than 15 days after the date of receipt to decide on a prior authorization request. The Division will confirm the date of receipt and the date of the decision upon written request. If, after 15 days, the Division is notified that it has not yet acted on a prior authorization request, the Division will so act within 24 hours of receiving such notice. When, in the event of an emergency medical need, the 15-day period to act would jeopardize the member's health, a prior-authorization request may be made by telephone to the Division's Prior Authorization Unit. If authorization is granted, a prior-authorization number will be given by telephone, and a written follow-up will be sent upon receipt of the required documentation from the provider.

(A) (1) (b) (i) if diagnostic test results are used as a means to document medical necessity, the test results must be interpreted, signed, and dated by a physician, or include documentation from an appropriate health care professional other than the DME provider that supports the need for DME including, but not limited to, physical therapists, speech therapists, nurses, respiratory therapists, and occupational therapists who have expertise in the applicable area.

NEMED recommends accepting an electronic signature similar to the hospital/pharmacy regulations.

(A) (1) (c) (iii) the MassHealth agency will not accept a printed invoice or order from a manufacturer's website.

NEMED recommends accepting a quote or an invoice from a manufacturer's website if the document has either a confirmation number or the patient's last name.

(B) The provider must submit the request for prior authorization to the MassHealth agency no later than 45 calendar days from the date of the prescription. Failure to submit the request within the 45-day period may result in a denial of the prior authorization request.

NEMED recommends maintaining the current time frame of 90 days, which is similar to Medicare guidelines. Medicare allows three months from the initial date on the CMN or DME Information Form (DIF). Depending on the product being delivered, some equipment requires a longer period to collect documentation in order to prepare the PA.

(E) Repairs of durable medical equipment.

(4) Providers must submit a prior authorization request for repairs of a member's back up wheelchair if the repair exceeds \$300.

NEMED recommends allowing a \$1,000 limit as stated earlier in this regulation.

NEMED recommends adding a category - Prior Approval for chronically debilitated members

Members who are designated as being in a chronic state of illness or have been assigned to case management should be allowed longer prior approval periods and have specific testing criteria waived as needed. Examples: requiring oxygen saturations for patients who are on ventilators, life long enteral formula needs due to genetic deficiencies that will not resolve. NEMED's MassHealth workgroup would like to work with MassHealth to create the criteria and guidelines for qualifying a chronic state of illness.

409.419 Delivery of DME

(A) Delivery to a Member's Home.

(1) The provider must maintain in the member's record a copy of the delivery slip signed by the member or the person accepting delivery on behalf of the member, and dated at the time of delivery. The date of the signature on the delivery slip must be the same as the date of delivery.

NEMED recommends replacing "member's home" with "member's residence."

(B) Delivery to a Nursing Facility. The provider must obtain and maintain in the member's record documentation as required in 130 CMR 409.415(A), including documentation from the facility that the equipment will only be used for the member to whom the equipment was delivered. This documentation must be in the form of a note signed by the facility nurse or physician. The delivery slip must be signed by the member or a designee from the facility, and otherwise meet the requirements of 130 CMR 409.418(B).

NEMED recommends deleting this regulation and combining it with (A) above. There should be no differentiation of the delivery of equipment to a member's residence or nursing facility.

(D) Delivery Service or Shipping Service

(2) The delivery or shipping service's tracking slip must refer to each package delivered, the delivery address, and the corresponding package identification number assigned by the

delivery service. The date of service on the claim must match the shipping date. The member or the member's designee must sign for the DME in accordance with 130 CMR 409.419(A).

NEMED recommends adopting Medicare guidelines. Medicare does not require the DME provider to obtain the member's signature as proof of delivery.

(E) Refills.

(1) For DME provided as refills to an original prescription, the provider must contact the member or the member's designee no later than five business days before shipping or delivering the refill to ensure that the refill is necessary and to confirm any changes to the order. If the member or designee declines a delivery, the provider must not make the delivery and must not submit a claim to the MassHealth agency for the item(s).

NEMED recommends replacing the five (5) business day requirement with "the provider must contact the member or the member's designee prior to shipping or delivering . . .". We also recommend adding language that will allow the MassHealth member to contact the DME provider to schedule or cancel a delivery.

409.431 Recordkeeping Requirements

The DME provider must keep a record at the service facility for each member. The record must include all purchases, rentals, and repairs of DME provided for each member in accordance with the recordkeeping requirements set forth in 130 CMR 450.205. The provider must make such records available to the MassHealth agency upon request. Payment for services is conditioned upon the complete documentation in the member's record. In addition to fulfilling the requirements of 130 CMR 450.205, the provider must ensure that each member's record includes:

In the first sentence, NEMED recommends deleting "at the service facility".

NEMED recommends defining the length of time that a DME provider would have to respond to a request for records. Our recommendation is 14 business days.

NEMED seeks clarification to the following questions:

- **How does this regulation apply to a DME provider who is using Electronic Data Management (EDM), i.e. document scanning, and no longer has a physical record on site?**
- **Is an electronic copy sufficient? Many providers have already gone paperless and we anticipate this trend to grow.**

(D) written confirmation of receipt of the prescribed DME, including refills, signed by the member or the member's designee,

NEMED recommends following Medicare guidelines concerning confirmation of receipt.

Thank you again for the opportunity to comment on this regulation. I will be happy to answer any questions you may have.

Respectfully submitted,

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