4. Program Regulations

The regulations and instructions governing provider participation in MassHealth are published in the Provider Manual Series. MassHealth publishes a separate manual for each provider type.

Manuals in the series contain administrative regulations, billing regulations, program regulations, service codes, administrative and billing instructions, and general information. MassHealth regulations are incorporated into the Code of Massachusetts Regulations (CMR), a collection of regulations promulgated by state agencies within the Commonwealth and by the Secretary of State. MassHealth regulations are assigned Title 130 of the Code. The regulations governing provider participation in MassHealth are assigned Chapters 400 through 499 within Title 130. Pages that contain regulatory material have a CMR chapter number in the banner beneath the subchapter number and title.

Administrative regulations and billing regulations apply to all providers and are contained in 130 CMR Chapter 450.000. These regulations are reproduced as Subchapters 1, 2, and 3 in this and all other manuals.

Program regulations cover matters that apply specifically to the type of provider for which the manual was prepared. For durable medical equipment, those matters are covered in 130 CMR Chapter 409.000, reproduced as Subchapter 4 in the *Durable Medical Equipment Manual*.

Revisions and additions to the manual are made as needed by means of transmittal letters, which furnish instructions for making changes by hand ("pen-and-ink" revisions), and by substituting, adding, or removing pages. Some transmittal letters will be directed to all providers; others will be addressed to providers in specific provider types. In this way, a provider will receive all those transmittal letters that affect its manual, but no others.

The Provider Manual Series is intended for the convenience of providers. Neither this nor any other manual can or should contain every federal and state law and regulation that might affect a provider's participation in MassHealth. The provider manuals represent instead MassHealth’s effort to give each provider a single convenient source for the essential information providers need in their routine interaction with MassHealth and its members.

409.401: Introduction

130 CMR 409.000 describes the requirements for the purchase, rental, and repair of durable medical equipment, and for the purchase of medical supplies under MassHealth. All durable medical equipment and supplies (DME) must be of proven quality and dependability, and must conform to all applicable federal and state product standards. All DME providers participating in MassHealth must comply with MassHealth regulations at 130 CMR 409.000 and 450.000. MassHealth may deny enrollment to an applicant or terminate participation of a MassHealth DME provider if the applicant or provider does not meet one or more of the requirements herein.

409.402: Definitions

The following terms used in 130 CMR 409.000 have the meanings given in 130 CMR 409.402 unless the context clearly requires a different meaning. Payment for services defined in 130 CMR 409.402 is not determined by these definitions, but by application of regulations elsewhere in 130 CMR 409.000, and in 130 CMR 450.000.

Absorbent Products — diapers or brief-like garments, underpads, liners, and shields used to contain and/or manage symptoms of incontinence. Absorbent products may be disposable, reusable, or washable.

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

Agent — the person who has been delegated by the applicant or provider with the authority to obligate or act on behalf of a provider or applicant.

Ambulatory Equipment — products that provide stability and security for members with impaired ambulation.

Applicant — an organization or individual who completes and submits an application to become a provider for MassHealth, but has not yet been determined by the MassHealth agency to be eligible to become a provider.

Assistive Technology Professional (ATP) — an individual with experience in assistive/rehabilitation technology who analyzes the equipment needs of persons with disabilities, assists in the selection of the equipment, and trains the person with the disability on how to use the specific equipment. This equipment may include manual and power wheelchairs, seating and alternative positioning, ambulation assistance, environmental control, alternate computer access, augmentative and alternative communication devices, and products of daily living.

Augmentative and Alternative Communication Devices (AAC) — speech and communication aids that meet the functional speaking needs of members for whom such devices are medically necessary.

Compression Devices — products that are used for the treatment of lymphedema or chronic venous insufficiency with the goal of preventing the onset or worsening of venous stasis ulcers.

Criminal Offender Record Information (CORI) — information regulated by the Criminal History Systems Board (CHSB) and defined under CHSB regulations at 801 CMR 2.03 to include records and data in any communicable form compiled by a criminal justice agency that concern an identifiable individual and relate to the nature or disposition of a criminal charge, an arrest, a pre-trial proceeding, other judicial proceedings, sentencing, incarceration, rehabilitation, or release.

Customized Equipment — durable medical equipment that

(1) is uniquely constructed, adapted, or modified solely for the full time use of the member for whom the item is purchased;
(2) is made to order or adapted to meet the specific needs of the member; and
(3) is uniquely constructed, adapted, or modified to permanently preclude the use of such equipment by another individual.

Date of Service — the date the DME is delivered to or picked up by the member, with the exception of 130 CMR 409.419(C).

DME — as used in 130 CMR 409.000, DME means durable medical equipment and medical supplies.

DME and Oxygen Payment and Coverage Guideline Tool — MassHealth Web-based application that contains DME and oxygen service descriptions for all covered products and services, applicable modifiers, place-of service codes, prior authorization requirements, individual consideration requirements, service limits, markup information, and links to other applicable information, such as Division of Health Care Finance and Policy (DHCFP) Web site. Subchapter 6 of the *Durable Medical Equipment Manual* directs providers to the MassHealth Web site for the DME and Oxygen Payment and Coverage Guideline Tool.

DME Provider — an organization or individual that has enrolled with MassHealth and has signed a provider contract with the MassHealth agency in accordance with 130 CMR 409.404 and 450.000.

Durable Medical Equipment — equipment that

(1) is fabricated primarily and customarily to fulfill a medical purpose;
(2) is generally not useful in the absence of illness or injury;
(3) can withstand repeated use over an extended period; and
(4) is appropriate for use in the member's home.

Enteral Nutrition — nutrition requirements that are provided via the gastrointestinal cavity by mouth (orally) or through a tube or stoma that delivers the nutrients distal to the oral cavity.

Food and Drug Administration (FDA) — an agency of the United States Department of Health and Human Services that is responsible for the safety regulation of most types of foods, drugs, medical devices, and certain other products.

Glucose Monitor — a device for measuring blood glucose levels.

Home — for purposes of rental and purchase of DME, a member's home may be the member's own dwelling, an apartment, a relative's or other person's home in which the member resides, a rest home, assisted living, or another type of group residence or community setting.

Home Infusion Therapy (HIT) Services — the administration of medications to a member in a home setting using delivery devices through intravenous, subcutaneous, or epidural routes. Drug therapies commonly administered include antibiotics, chemotherapy, pain management, parenteral nutrition, and immune globulin.

Medical Supplies — consumable or disposable supplies or devices for home use necessary for the treatment of a specific illness, injury, disease, or disability, including, but not limited to test strips, syringes, ostomy products, and surgical items that are

(1) fabricated primarily and customarily to fulfill a medical purpose;
(2) used in the treatment of a specific medical condition;
(3) generally not useful in the absence of illness or injury;
(4) nonreusable and disposable; and
(5) appropriate for use in the member's home.

Member — a person determined by the MassHealth agency to be eligible for MassHealth.

Mobility System — a manual or power wheelchair or other wheeled device, such as a scooter, including a base, a seating system, its components, accessories, and modifications.

Nurse Practitioner — a registered nurse who has successfully completed a formal education program for nurse practitioners as required by the Massachusetts Board of Registration of Nursing. (the Board), who is in good standing with the Board, and who is responsible for oversight of the member's health care. A nurse practitioner who prescribes medication must be certified by the federal Drug Enforcement Agency (DEA).

Nutritional Supplements — commercially prepared products primarily used to treat a diagnosed deficiency in the member's diet or nutrition.

Ostomy Supplies — products used to contain diverted urine or fecal contents outside the body for patients who have a surgically created opening (stoma).

Parenteral Nutrition — nutrient requirements provided by means of a subcutaneous or intravenous route.

Personal Emergency Response System (PERS) — an electronic device connected to a person's land-line telephone. In an emergency, it can be activated either by pushing a small button on a pendant or bracelet, pressing the help button on the console unit, or by an adaptive switch set-up. When the device is activated, a person from the 24-hours-a-day, seven-days-a week central monitoring station answers the call, speaks to the member via the console unit, assesses the need for help, and takes appropriate action.

Physician Assistant — a mid-level medical practitioner who works under the supervision of a licensed physician (MD) or osteopathic physician (DO) and who has graduated from an accredited physician assistant program and is certified by and in good standing with the Massachusetts Board

of Physician Assistant Registration.

Prescribing Provider — the member's physician, nurse practitioner, or physician assistant who prescribes and writes the prescription for DME in accordance with 130 CMR 409.416.

Prior Authorization (PA) Request — a request submitted by the DME provider to the MassHealth agency to determine medical necessity in accordance with 130 CMR 409.417, 409.418, 450.204, and 450.303.

Recall — action taken by the manufacturer to retrieve, replace, or repair dangerous or defective DME, whether or not such action is taken at the direction of the Food and Drug Administration (FDA).

RESNA — the Rehabilitation Engineering and Assistive Technology Society of North America, or its successor.

Seating System — a seated positioning system, including its components, accessories, and modifications, which may be attached to a base wheelchair and is designed to meet the individualized medical needs of a member.

Service Facility — a DME business or branch of a DME business where MassHealth members can obtain services, equipment, and supplies, including, but not limited to, repairs, replacements, or accessories.

Subcontractor — an individual, agency or organization
(1) to which a MassHealth provider has contracted or delegated some of its management functions or responsibilities of providing medical care or services to its members; or
(2) with which a fiscal agent has entered into a contract, agreement, purchase order, or lease (or leases of real property) to obtain space, supplies, equipment, or services provided under the MassHealth agreement.

Support Surfaces — beds, mattresses, or overlays used to reduce or relieve pressure, prevent the worsening of pressure ulcers, or promote wound healing.

409.403: Eligible Members

(A) MassHealth Members. MassHealth covers DME services provided to eligible MassHealth members, subject to the restrictions and limitations described in MassHealth regulations. MassHealth regulations at 130 CMR 450.105 specifically state, for each coverage type, which services are covered, and which members are eligible to receive those services.

(B) Recipients of the Emergency Aid to the Elderly, Disabled and Children Program. For information on covered services for recipients of the Emergency Aid to the Elderly, Disabled and Children Program, see 130 CMR 450.106.

(C) Verification of Member Eligibility. For information about verifying member eligibility and coverage type, see 130 CMR 450.107.

409.404: Requirements for Provider Participation

(A) Provider Participation Requirements. Payment for services described in 130 CMR 409.000 is made only to providers who are participating in MassHealth as a DME provider or have been assigned a DME specialty in accordance with 130 CMR 409.404(D) as of the date of service. Applicants must meet the requirements in 130 CMR 450.000 as well as the requirements in 130 CMR 409.000. Participating providers must continue to meet provider eligibility participation requirements throughout the period of their provider contract with the MassHealth agency.

(B) Letter of Intent. 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 contracts with other payers; and
(4) the service areas in which services will be provided.

(C) General Qualifications. To qualify as a MassHealth DME provider, all applicants and providers must

(1) have a service facility that
  (a) is available to members during regular, posted business hours;
  (b) is physically accessible to members with disabilities;
  (c) has clear access and space for individualized ordering, returns, repair, and storing of business records;
  (d) has a sign visible from outside the facility identifying the business name and hours that the service facility is open. If the provider's place of business is located within a building complex, the sign must be visible at the main entrance of the building where the service is located;
  (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, and that has TTY transmission and reception capability. During business hours, this number cannot be a pager, answering service, voice message system, or cell phone; and
  (f) maintains a 24-hour voice message system;
(2) obtain separate approval from the MassHealth agency and a separate provider number for each service facility operated by the provider.
(3) except for specialty providers described in 130 CMR 409.404(D), primarily engage in the business of providing DME, or durable medical equipment repair services, to the public;
(4) participate in the Medicare program as a DME provider, unless the provider supplies only PERS or absorbent products;
(5) have a Medicare provider number that is assigned to the same business and service facility and location for which the applicant is applying to become a MassHealth provider;
(6) be accredited by an accrediting body that is acceptable to the Centers for Medicare & Medicaid Services unless the provider supplies only PERS or absorbent products;
(7) meet all applicable federal, state, and local requirements, certifications, and registrations;
(8) at the time of application and recredentialing, or any other time as requested by the MassHealth agency, provide all required documentation specified in 130 CMR 450.000 as well as the following:
  (a) a list of contracted manufacturers used for purchased products

(b) a copy of all current liability insurance policies;
(c) a copy of the property lease agreement pertinent to the service facility, or a copy of the most recent property tax bill if applicant owns the business site;
(d) for mobility providers only, a copy of current RESNA ATP certificate for each certified staff member. DME providers who furnish mobility systems must employ at least one certified ATP at each service facility. The ATP must possess knowledge of the standards of acceptable practice in the provision of DME including ordering, assembling, adjusting, and delivering DME, and providing ongoing support and services to meet a person's rehabilitation equipment needs;
(e) a copy of all current signed employee professional licenses, as applicable;
(f) a copy of current accreditation letters;
(g) a copy of the purchase and sale agreement if the applicant or provider has recently purchased the company for which they are applying to become a MassHealth provider;
(h) a copy of subcontracts, if applicable, as described in 130 CMR 409.412. For PERS providers, the subcontract must include the central monitoring station contract, if applicable;
(i) a copy of the applicant's emergency preparedness plan as approved by the accrediting body;
(j) a copy of written policies and procedures, including the customer service protocol, customer complaint tracking and resolution protocol, the protocol on transfer and discharge of members, staff training; and
(k) for PERS providers only, a copy of documentation demonstrating compliance with UL Standards 1637 in accordance with 130 CMR 409.429(C);

(9) for a provider of home infusion services, be a licensed pharmacy in Massachusetts and be accredited by an accrediting body, as approved by the Centers for Medicare & Medicaid Services, and be assigned a DME specialty by the MassHealth agency. See 130 CMR 409.404(D);
(10) conduct CORI checks on employees and subcontractors in accordance with procedures outlined in EOHHS CORI regulations at 101 CMR 15.00 et seq.;
(11) not accept prescriptions for MassHealth DME from any prescribing provider who has a financial interest in the DME provider; and
(12) cooperate with the MassHealth agency or its designee during the application and recredentialing process, including participation in a site visit.

(D) Providers Assigned DME Specialty. Applicants or providers whose primary business is not DME may qualify to provide DME services if the following conditions are met:
(1) the applicant or provider is enrolled as a MassHealth provider of oxygen and respiratory therapy equipment services under 130 CMR 427.000 or pharmacy services under 130 CMR 406.000;
(2) the applicant or provider meets all other conditions under 130 CMR 409.404 to provide DME services; and
(3) MassHealth has assigned a specialty of DME to the applicant's or provider's existing provider number for oxygen and respiratory therapy equipment services or pharmacy services.

(E) In State. To qualify as an in-state provider of DME, the applicant or provider must have a service facility located in Massachusetts that meets the criteria described in 130 CMR 409.404(C)(1).

(F) Out of State. An applicant or provider of DME with a service facility located outside of

Massachusetts may qualify as a MassHealth DME provider only if the following additional conditions are met:

(1) all requirements under 130 CMR 409.000 and 450.000, and 42 CFR 431.52 are met

(2) the out-of-state DME provider participates in the Medicaid program of the state in which the provider primarily conducts business, unless the out-of-state DME provider solely provides PERS;

(3) the DME provider participates in the Medicare program of the state in which the provider primarily conducts business, unless the DME provider provides only PERS or absorbent products; and

(4) the provider has a service facility that can readily replace and repair products when needed by the member.

409.405: Provider Responsibilities

In addition to meeting all other provider requirements set forth in 130 CMR 409.000 and 450.000, the provider must

(A) accept rates of payment established by the Division of Health Care Finance and Policy (DHCFP) for all DME provided to MassHealth members, unless otherwise determined by the MassHealth agency through a contracting process or by other means;

(B) notify the MassHealth agency in writing at least 14 days prior to any changes in any of the information submitted in the provider application in accordance with 130 CMR 450.215 and 450.223(B), including but not limited to, change of ownership, change of address, change in scope of service, 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;

(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 medical condition;

(D) ensure that all DME is free from defects and is in proper working order. This includes, but is not limited to, prompt amelioration, repair or replacement of DME that has been provided to a member and is subject to recall, in accordance with the specifications in the recall notice. For recalls of potentially dangerous or defective DME that predictably could cause serious health problems or death, the DME provider must give the member a copy of the recall notice and fully address the recall as specified in the recall instructions no later than five business days from the date the DME provider receives the recall notice;

(E) purchase the DME from the least costly reliable source;

(F) fill all orders from its own inventory or have a written subcontract for the purchase of items necessary to fill orders in accordance with 130 CMR 409.412;

(G) report to the proper authorities any suspected abuse or neglect that staff may observe when providing service to a member;

(H) give employees a picture identification to be presented to a member when making a delivery;

(I) adhere to the supplier standards set forth by the Centers for Medicare & Medicaid Services (CMS);

(J) not alter any invoice or medical documentation;

(K) not solicit members to purchase additional DME;

(L) submit prior authorization requests to the MassHealth agency only when the DME is medically necessary and when prior authorization is a prerequisite in accordance with 130 CMR 409.418.

(M) respond within two business days to members' complaints about their DME.

(N) not share a service facility with another provider of DME, including a physician or physician group or another supplier of DME;

(O) have a complaint resolution protocol to promptly address members' complaints and keep written complaints, related correspondence, and any notes of actions taken in response to written and oral complaints, and maintain such information in accordance with 130 CMR 409.430(I).

(P) provide MassHealth members with written notification at least 60 days in advance of any change in the DME provider's scope of business or services (for example, if a provider decides to no longer provide absorbent products). Notification to the member must include

(1) a statement that the member can contact MassHealth Customer Service to request a list of DME providers in their area; and

(2) if prior authorization is required for the service

(a) the number of nonbilled units remaining on the PA; and

(b) copy of the original PA approval from MassHealth for the member to provide to the new DME provider;

(Q) instruct the member, or the member's caregiver, in the appropriate use of the DME furnished to the member. Such instruction must include, but not be limited to, the provision of appropriate information related to setup, features, routine use, troubleshooting, cleaning, infection control practices, and other issues related to the use and maintenance of all DME provided. Instructions must be commensurate with the risks, complexity, and manufacturer's instructions and specifications for the DME. The DME provider must tailor training and instruction materials and approaches to the needs, abilities, learning preferences, and language of the member and caregivers, as appropriate. The DME provider must document the provision of such instruction in the member's record in accordance with 130 CMR 409.430(J); and

(R) ensure that the member and the member's caregivers, as appropriate, can use all DME provided safely and effectively in the settings of anticipated use.

409.406: Services Provided to Members in Another State

The MassHealth agency pays for DME provided to MassHealth members in another state by a MassHealth DME provider in accordance with 42 CFR 431.52(b) and 130 CMR 450.109.

409.407: Early and Periodic Screening, Diagnosis and Treatment (EPSDT) Services

The MassHealth agency pays for all medically necessary DME services for EPSDT-eligible members in accordance with 130 CMR 450.140 et seq., without regard to service limitations

described in 130 CMR 409.000, and with prior authorization.

(130 CMR 409.408 through 409.411 Reserved)

409.412: Subcontracted Services

(A) A DME provider may subcontract with other entities to provide DME. The DME provider continues to be responsible for complying with 130 CMR 450.000 and 130 CMR 409.000 when activities are performed by a subcontractor. The subcontract must be in writing and must contain, at a minimum, the following:

(1) names, addresses, phone numbers, and contact names for both companies;
(2) the contract term (begin and end dates);
(3) a description of the DME covered under the subcontract, including the cost of each item;
(4) signatures of both parties, including signature dates and position titles;
(5) an established credit limit that is reasonable, based on the value of the products and services to be provided by the contractor. Collect on delivery (COD) terms are not acceptable; and
(6) provisions requiring the subcontractor to meet all requirements specified in 130 CMR 409.404 and 409.405.

(B) A DME provider must ensure that its subcontractors of DME meet all requirements specified in 130 CMR 409.404 and 409.405.

409.413: Covered Services

(A) MassHealth covers medically necessary DME that can be appropriately used in the member's home, and in certain circumstances described in 130 CMR 409.415 for use in facilities. All durable medical equipment must be approved for home use by the federal Food and Drug Administration (FDA). DME that is appropriate for use in the member's home may also be used in the community.

(B) MassHealth covers the DME listed in Subchapter 6 of the *Durable Medical Equipment Manual*. Providers may request prior authorization for medically necessary DME if the corresponding service code is not listed in Subchapter 6. Covered DME includes, but is not limited to

(1) absorbent products;
(2) ambulatory equipment, such as crutches and canes;
(3) compression devices;
(4) speech augmentative devices;
(5) enteral and parenteral nutrition;
(6) nutritional supplements;
(7) home infusion equipment and supplies (pharmacy providers with DME specialty only);
(8) glucose monitors and diabetic supplies;
(9) mobility equipment and seating systems;
(10) personal emergency response systems (PERS);
(11) ostomy supplies;
(12) support surfaces;
(13) hospital beds and accessories;
(14) patient lifts; and
(15) bath and toilet equipment and supplies (commodes, grab bars, tub benches, etc.).

(C) MassHealth covers the repair of durable medical equipment, including repairs to medically necessary back-up durable medical equipment, subject to the requirements of 130 CMR 409.420.

(D) The MassHealth agency pays for a manual wheelchair, including any necessary repairs, as a backup to a power mobility system if the member is not residing in a nursing facility, or the member is residing in a nursing facility and has a written discharge plan, and one of the following conditions applies:

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

(E) The MassHealth agency pays for the replacement of a member's mobility system only when
(1) (a) the cost of repairing or modifying the existing mobility system would exceed the value of that system; or
(b) the member's physical condition has changed enough to render the existing mobility system ineffective; and
(2) the DME provider has obtained prior authorization.

(F) The MassHealth agency pays for routine periodic testing, cleaning, regulating, and checking of durable medical equipment. Routine maintenance of durable medical equipment is covered through the rates established by DHCFP, unless the durable medical equipment is owned by the member.

409.414: Noncovered Services

The MassHealth agency does not pay for the following:

(A) DME that is experimental in nature;

(B) DME that is determined by the MassHealth agency not to be medically necessary pursuant to 130 CMR 450.204. This includes, but is not limited to items that:
(1) cannot reasonably be expected to make a meaningful contribution to the treatment of a member's illness or injury;
(2) are more costly than medically appropriate and feasible alternative pieces of equipment; or
(3) serve the same purpose as DME already in use by the member with the exception of the devices described in 130 CMR 409.413(D);

(C) the repair of any durable medical equipment that is not identified as a covered service in Subchapter 6 of the *Durable Medical Equipment Manual*;

(D) the repair of any equipment where the cost of the repair is equal to or more than the cost of purchasing a replacement;

(E) routine periodic testing, cleaning, regulating, and checking of durable medical equipment that is owned by the member;

(F) DME that is not of proven quality and dependability;

(G) durable medical equipment that has not been approved by the federal Food and Drug Administration (FDA) for home use;

(H) evaluation or diagnostic tests conducted by the DME provider to establish the medical need for DME;

(I) home or vehicle modifications, such as ramps, elevators, or stair lifts;

(J) common household and personal hygiene items generally used by the public, including but not limited to washcloths, wet wipes, and non-sterile swabs;

(K) products that are not DME;

(L) certain durable medical equipment provided to members in facilities in accordance with 130 CMR 409.415; and

(M) provider claims for noncovered services under 130 CMR 409.414 for MassHealth members with other insurance, except as otherwise required by law.

409.415: Durable Medical Equipment Provided to Members in Facilities

(A) MassHealth Members Residing in Nursing Facilities.

(1) The MassHealth agency pays for the following services for members residing in nursing facilities.

(a) Mobility Systems for Members in Nursing Facilities with No Written Discharge Plan. The MassHealth agency pays DME providers for the purchase, rental, or repair of medically necessary mobility systems, positioning seating systems and add-ons, subject to all limitations and conditions of payment in 130 CMR 409.000 and 450.000, when purchased solely for the full-time use of the member while residing in a nursing facility, with the exception of equipment described under 130 CMR 409.415(A)(2). The nursing facility in which the member resides is responsible for payment to the DME provider for the first $500 toward the purchase of the mobility system, unless the member has a written discharge plan in accordance with 130 CMR 409.415(A)(1)(b).

(b) Mobility Systems for Members in Nursing Facilities Who Have a Written Discharge Plan. The MassHealth agency pays DME providers for the purchase, rental, or repair of medically necessary mobility systems, positioning seating systems, and add-ons, subject to all limitations and conditions of payment in 130 CMR 409.000 and 450.000, when purchased solely for the full-time use of the member while residing in a nursing facility, with the exception of equipment described under 130 CMR 409.415(A)(2). The DME provider may deliver equipment to a nursing facility before the member's scheduled discharge date, for the purpose of teaching the member how to use the equipment, taking measurements, or adjusting equipment to be used in the member's home (see 130 CMR 409.419(C)). The DME provider must document the member's discharge plan and discharge date in the member's record before the equipment is delivered to the nursing facility, and provide such documentation to the MassHealth agency upon request. For equipment delivered to a nursing

facility for use by a member after discharge from the facility, the date of service is the date of discharge.

(c) Support Surfaces. The MassHealth agency pays DME providers for the rental or purchase of support surfaces for the exclusive full-time use of a member residing in a nursing facility.

(2) The following services are not covered for members residing in nursing facilities.

(a) The MassHealth agency does not pay DME providers for medical supplies, including but not limited to absorbent products, urological supplies, ostomy supplies, diabetic supplies, and enteral/parenteral products or supplies for MassHealth members residing in nursing facilities.

(b) The MassHealth agency does not pay for the purchase, rental, or repair of standard, manual wheelchairs for the use of members residing in nursing facilities. This includes, but is not limited to transport chairs, standard manual wheelchairs, standard hemi wheelchairs, lightweight wheelchairs, high-strength lightweight wheelchairs, ultralightweight wheelchairs, heavy duty wheelchairs, semi-reclining wheelchairs, amputee wheelchairs, and extra heavy duty wheelchairs.

(B) MassHealth Members Who Are Inpatients in Acute, Chronic Disease and Rehabilitation, and Psychiatric Hospitals. The MassHealth agency does not pay DME providers for medical supplies, including but not limited to absorbent products, or the purchase, rental, or repair of durable medical equipment provided to a MassHealth member who is an inpatient in a hospital, except for durable medical equipment delivered to the member in accordance with 130 CMR 409.419(C).

(C) MassHealth Members Who Are Residing in Intermediate Care Facilities for the Mentally Retarded (ICF/MR).

(1) Covered Services.

(a) Customized Seating and Mobility Equipment. The MassHealth agency pays DME providers for the purchase, rental, or repair of customized medically necessary mobility systems, positioning seating systems, and add-ons, subject to all limitations and conditions of payment in 130 CMR 409.000 and 450.000, when purchased solely for the full-time use of a member residing in an ICF/MR (if the customization precludes the use of equipment by other individuals in the ICF/MR).

(b) Other Customized Durable Medical Equipment. The MassHealth agency pays DME providers for other durable medical equipment that is purchased solely for the full-time use of a member residing in an ICF/MR (if the customization precludes the use of equipment by other individuals in the ICF/MR).

(c) Durable Medical Equipment for Members to Be Discharged from an ICF/MR. The MassHealth agency allows a DME provider to deliver equipment to an ICF/MR, before the member's scheduled discharge date, for the purpose of teaching the member how to use the equipment, taking measurements, or adjusting equipment to be used in the member's home (see 130 CMR 409.419(C)). The DME provider must document the member's discharge plan and discharge date in the member's record before the equipment is delivered to the ICF/MR, and provide such documentation to the MassHealth agency.

(2) Noncovered Services. The MassHealth agency does not pay a DME provider for medical supplies, including but not limited to absorbent products, or the purchase, rental, or repair of non-customized DME provided to a member residing in an ICF/MR.

409.416: Prescription and Letter of Medical Necessity Requirements

(A) The DME provider must obtain a prescription and letter of medical necessity (LOMN) for the purchase or rental of DME. The prescription and the letter of medical necessity must be in writing, signed by the prescribing provider, and dated prior to the date the claim is submitted to the MassHealth agency. For certain DME that requires a prescription by specified medical professionals, the prescription and LOMN must be signed by such medical professionals. If the DME requires prior authorization, the prescription must be dated prior to the date the prior authorization request is submitted to the MassHealth agency. The initial and subsequent prescriptions must contain the following information as applicable:

(1) the member's name;
(2) the date of the prescription;
(3) the name and quantity of the prescribed item and the number of refills (if appropriate);
(4) the name, address, and signature of the prescribing provider and date signed;
(5) medical justification for the item(s) being requested;
(6) the equipment settings, hours to be used per day, options, or additional features, as they pertain to the equipment;
(7) the recommended timetable of the prescribed item or treatment;
(8) the expected outcome and therapeutic benefit of providing the requested item(s) or treatment; and
(9) a summary of any previous treatment plan, including outcomes, that was used to treat the diagnosed condition for which the prescribed treatment is being recommended.

(B) The MassHealth agency accepts written prescriptions and letters of medical necessity for DME in the following formats, provided the requirements of 130 CMR 409.416(A) are met.

(1) If the MassHealth agency has published a MassHealth Medical Necessity Review form for specific DME, providers may use the MassHealth Medical Necessity Review form as the prescription and letter of medical necessity specific to the DME being furnished. These forms can be found on the MassHealth Web site.
(2) If the forms described in 130 CMR 409.416(B)(1) are not used by the DME provider, the MassHealth agency accepts prescriptions and letters written on one of the following:
(a) the prescribing provider's prescription pad;
(b) the prescribing provider's letterhead stationery;
(c) the hospital or nursing facility prescription pad, if the member is being discharged from a facility;
(d) the MassHealth agency's Durable Medical Equipment and Medical Supplies General Prescription and Medical Necessity Review Form (DME-2), unless there is a product-specific Medical Necessity Review form as stated in 130 CMR 409.416(B)(1); or
(e) the Region A Durable Medical Equipment Carrier (DME Medicare Administrative Contractor (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) For prescription and letter of medical necessity requirements for members residing in nursing facilities, see 130 CMR 409.416(D).

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

(D) For members residing in nursing facilities, the prescription is the actual order in the member's medical record. The prescription must include a copy of the current month's order sheet that is signed and dated by the prescribing provider, a copy of the medical justification from the member's nursing facility record, and must include any additional documentation necessary to support medical necessity. Additional documentation may include physician progress notes; relevant laboratory or diagnostic test results; nursing, nutrition, or therapy assessments and notes; or wound assessments with pictures done with specialized wound photography.

(E) Refills of DME.
(1) The MassHealth agency may allow payment of refills of DME prescribed up to a maximum of 12 months.
(2) The absence of an indication to refill by the prescriber renders the prescription nonrefillable.
(3) The MassHealth agency does not pay for any refill without approval from a member or caregiver provided at the time the prescription is to be refilled. The possession by a provider of a prescription with remaining refills authorized does not in itself constitute a request to refill the prescription.

409.417: Medical Necessity Criteria

All DME covered by MassHealth must meet the medical necessity requirements set forth in 130 CMR 409.000 and in 450.204, and medical necessity guidelines for specific DME published on the MassHealth Web site. If the MassHealth agency has not published product-specific medical necessity guidelines, DME providers must adhere to the Current Local Coverage Determination (LCD) policy developed by the Centers for Medicare & Medicaid Services (CMS) when demonstrating medical necessity.

409.418: Prior Authorization

The DME provider must obtain prior authorization from the MassHealth agency or its designee as a prerequisite for payment of DME identified in the DME and Oxygen Payment and Coverage Guideline Tool as requiring prior authorization. Prior authorization does not waive any other prerequisites for payment including, but not limited to, requirements relating to member eligibility or other health insurance payments. All prior authorization requests must be submitted in accordance with Subchapter 5 of the *Durable Medical Equipment Manual*.

(A) Documentation of Medical Necessity.
(1) Prior authorization requests submitted by the provider for DME must include
(a) a completed MassHealth Prior Authorization Request (PA-1) form (if request is submitted on paper);
(b) a prescription and letter of medical necessity that meets the requirements of 130 CMR 409.416;
(c) 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 that supports the need for DME from an appropriate health care professional other than the DME provider, including, but not limited to, physical therapists, speech therapists, nurses, respiratory therapists, and occupational therapists who have expertise in the applicable area; and

(d) for DME that is identified in the DME and Oxygen Payment and Coverage Guideline Tool as requiring individual consideration (IC), a copy of the original invoice that reflects the provider's adjusted acquisition costs as set forth in the regulations of the Division of Health Care Finance and Policy (DHCFP) at 114.3 CMR 22.00.

(i) MassHealth will accept a quote from a MassHealth provider for an item that does not have a rate established by the Division of Health Care Finance and Policy if the equipment has not been purchased by the provider at the time of the prior authorization request, and when the item being purchased is not an item that the provider normally purchases for its scope of business. The quote must be on the manufacturer's letterhead or form and must be addressed to the provider.

(ii) MassHealth will not accept a quote attached to a claim. At the time of a claim submission the provider must attach the actual manufacturer's invoice. The provider must keep a copy of the quote and the invoice on file.

(iii) For disposable medical supplies, the invoice must be dated within six months of the prior authorization request.

(iv) The MassHealth agency will not accept a printed invoice or order from a manufacturer's Web site.

(B) 90-Day Requirement for Submission of Prior Authorization Requests. The provider must submit the request for prior authorization to the MassHealth agency no later than 90 calendar days from the date of the prescription. Failure to submit the request within the 90-day period will result in a denial of the prior authorization request.

(C) Prior Authorization Requests for DME Units in Excess of the Maximum Allowable Units. MassHealth requires prior authorization for certain DME provided to the member if the number of units requested exceeds the maximum units described in the DME and Oxygen Payment and Coverage Guideline Tool.

(1) The provider must include documentation that supports the medical necessity of the additional units, including requirements under 130 CMR 409.417 and 409.418.

(2) If the PA request is authorized by the MassHealth agency, the provider must submit a separate claim for which PA is authorized.

(D) Prior Authorization Requests for Members Who Have Other Insurance. For members for whom MassHealth is not the primary insurer and for whom the provider is seeking payment from another insurer, the provider must also request a prior authorization from the MassHealth agency according to the timelines established in 130 CMR 409.418, if the provider intends to seek secondary payment from MassHealth.

(E) Repairs of Durable Medical Equipment. Providers must submit a prior authorization request for repairs of durable medical equipment that exceed $1000 per repair, unless otherwise indicated in the DME and Oxygen Payment and Coverage Guideline Tool.

(1) MassHealth pays for repairs to medically necessary mobility systems, including back-up systems, when either the member's primary or back-up systems are customized, adapted, or modified to the extent that no rental equipment would be comparable, and the repair is not covered under the warranty.

(2) The DME provider must submit the following documentation with the prior authorization request:

(a) a completed MassHealth Prior Authorization Request (PA-1) form (if request is submitted on paper);

(b) a prescription and letter of medical necessity that meet the requirements of 130 CMR 409.416 if the MassHealth agency has not yet determined the medical necessity of the durable medical equipment requiring repair;
(c) a description of the customization or modification of the member's mobility systems, if applicable;
(d) an invoice or quote for the repaired or replaced item;
(e) a work order log with the estimated number of hours the repair will take;
(f) a detailed description of the circumstances that made the repair necessary; and
(g) an explanation as to why the repaired or replaced item is not covered under any warranty.

(3) DME providers must furnish the member with substitute equipment in accordance with 130 CMR 409.420 when a repair service requires removal of the equipment from the member's home.
(4) Providers must submit a prior authorization request for repairs of a member's back-up mobility system if the repair exceeds $1,000.

(F) Notice of Approval, Denial, or Modification of a Prior-Authorization Request.
(1) If the MassHealth agency approves a prior authorization request for DME, the MassHealth agency will send notice of its decision to the member and the DME provider.
(2) If the MassHealth agency denies or modifies a prior authorization request for DME, the MassHealth agency will send notice of its decision to the member and the DME provider. The notice will state the reason for the denial or modification, and will inform the member of the right to appeal and of the appeal procedure in accordance with 130 CMR 610.000.
(3) If the MassHealth agency defers a prior authorization request due to an incomplete submission or lack of documentation to support medical necessity, the MassHealth agency will notify the member and the DME provider of the deferral, and will inform the DME provider of the reason for the deferral and provide an opportunity for the provider to submit the incomplete or missing documentation.
(4) If the provider does not submit the required information within 21 calendar days of the date of deferral, the MassHealth agency will deny the prior authorization request and will send notice of its decision to the provider and the member in accordance with 130 CMR 409.418(F)(2). The provider may resubmit a new prior authorization request that includes all required documentation.

409.419: Delivery of Durable Medical Equipment

(A) Delivery of Durable Medical Equipment to a Member's Home.

(1) The DME provider must maintain in the member's record a copy of its delivery slip signed by the member or the member's designee 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.
(2) The MassHealth agency accepts the member's mark or a signature stamp as proof of delivery on behalf of a member whose disability inhibits the member's ability to write. A signature stamp may be used only by the member or the member's designee. A signature stamp may not be used by anyone associated with either the provider or the delivery service.

(B) Delivery of Durable Medical Equipment to a Nursing Facility or ICF/MR. The provider must obtain and maintain in the member's record documentation as required in 130 CMR 409.430, including documentation from the facility that the equipment will be used only for the member to whom the equipment was delivered. The DME provider's delivery slip must be signed by the member, the member's designee or a designee from the nursing facility or ICF/MR, and otherwise meet the requirements of 130 CMR 409.430(D).

(C) Delivery of Durable Medical Equipment to a Hospital, a Nursing Facility, or an ICF/MR in Anticipation of Discharge. A provider may deliver durable medical equipment to a facility for a member who is being discharged from a hospital, a nursing facility, or ICF/MR for the purpose of fitting or training the member in its proper use up to 10 business days prior to the member's discharge date. The DME provider's delivery slip must be signed by the member, or the member's designee or a designee from the facility, and otherwise meet the requirements of 130 CMR 409.430(D). The durable medical equipment must be solely for use in the member's home or community. The provider may not bill for durable medical equipment for the days that the member was receiving training or fitting in the facility. The provider must use the date of the member's discharge from the facility as the date of service on the claim.

(D) Delivery Service or Shipping Service.

(1) For medical supplies delivered to a member by the DME provider or by a shipping service, the DME provider is responsible for maintaining in the member's record a copy of the delivery services tracking slip attached to the provider's shipping invoice. The shipping invoice must include:

(a) the name of the member;
(b) the quantity of the supply delivered;
(c) a detailed description of the items delivered including the brand name and, if applicable, the serial number; and
(d) the delivery service's package identification number.

(2) The DME provider's or the shipping service's tracking slip must refer to each package delivered, the delivery address, and the corresponding package identification number assigned by the shipping service. The date of service on the claim must match the delivery date (if delivered by the DME provider), or shipping date, if delivered by a shipping service.

(E) Refills. For DME provided as refills to an original prescription, the provider must contact the member or the member's designee up to at least 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 items.

(F) MassHealth does not allow automatic deliveries. DME that is delivered to a member on a recurring basis must meet 130 CMR 409.419(E).

(G) For items picked up by the member or delivered to the member's home by the DME provider, the date of service is the date the DME was picked up by or delivered to the member.

(H) The DME provider responsible for the delivery of the DME is also responsible for providing adjustments needed for proper fit and function and instructing the member on the use of the DME.

409.420: Repairs to Durable Medical Equipment

(A) Prescription Requirements. The MassHealth agency does not require a prescription or a letter of medical necessity for the repair of durable medical equipment that the MassHealth agency previously determined to be medically necessary for the member.

(B) Repairs of Purchased Durable Medical Equipment. When a repair service for purchased durable medical equipment requires removing the equipment from a member's home, the provider must supply, on a rental basis, properly working substitute equipment that is comparable in most respects to the equipment to be repaired. Rental of substitute equipment is covered by MassHealth in accordance with rates established by DHCFP until repair to the equipment is complete and the original equipment is returned to the member.

(C) Repairs of Rented Durable Medical Equipment. When a repair service for rented durable medical equipment requires removing the equipment from the member's home, the provider must supply the member with properly working substitute equipment that is comparable in most respects to the equipment to be repaired. Providers may continue to bill a rental fee in accordance with rates established by DHCFP, but no extra rental charge is allowed for this substitute equipment.

(D) Prior Authorization. MassHealth requires the DME provider obtain prior authorization for repairs that exceed $1,000 per repair. See 130 CMR 409.418(E).

(E) Provider Responsibility. The DME provider who submits a claim to the MassHealth agency for repair of durable medical equipment is responsible for

(1) ensuring quality of workmanship and parts;
(2) ensuring that the repaired equipment is free of defects and in proper working condition;
(3) taking advantage of all manufacturer warranties;
(4) complying with the requirements of the Wheelchair Lemon Law (M.G.L. c. 93, § 107) and any other applicable provisions of federal and state laws pertaining to the service provided;
(5) providing the member with regular updates regarding the status of the repairs and the expected delivery date of the equipment being repaired; and
(6) responding in a timely fashion to a member's complaint regarding the repair of the equipment.

(130 CMR 409.421 through 409.426 reserved)

409.427: Payment for Durable Medical Equipment

Providers of DME must accept MassHealth payment in full for DME according to the rates and regulations established by the Division of Health Care Finance and Policy at 114.3 CMR 22.00. Payments are subject to the conditions, exclusions, and limitations set forth in 130 CMR 409.000 and 450.000.

409.428: Augmentative and Alternative Communication Devices (AAC)

(A) Covered Services. AAC devices are defined in 130 CMR 409.402. An AAC device must be a dedicated speech device, used solely by the member who has a severe expressive communication impairment. Examples of AAC devices are

(1) communication boards or books;
(2) electro larynxes;
(3) speech/voice amplifiers; and
(4) electronic devices that produce speech or written output.

(B) Requirements for Coverage. MassHealth covers AAC devices when the following conditions are met.

(1) The member must have a communication disability with a diagnosis of severe dysarthria, apraxia, and/or aphasia as evidenced by documentation from the member's physician;
(2) The device must be prescribed by the member's physician and recommended by a licensed speech and language pathologist who is not affiliated with the AAC provider and who has conducted a thorough evaluation of, and has a treatment plan for, the member's condition that includes use of the recommended device.
(a) The treatment plan must describe the specific components of the AAC services and the required amount, duration, and scope of the AAC services, and include documentation that demonstrates
(i) the requested AAC device and the AAC services constitute the least costly form of treatment that will have the comparable effect of overcoming or ameliorating communication limitations that preclude or interfere with the member's meaningful participation in current and planned daily activities;
(ii) the impairment or disability has caused communication limitations that preclude or interfere with the member's meaningful participation in daily activities;
(iii) the member is unable to meet communication needs arising in the course of daily activities using other available communication techniques;
(iv) therapies or treatments, including speech, occupational and/or physical therapy that have been provided to the member in relation to the prescribed ACC;
(v) the member has the cognitive, visual, auditory, language, and motor ability necessary to utilize the selected device;
(vi) expected functional communication goals; and
(vii) a plan of care for the use of the device, including anticipated training needs, programming needs, evaluations, etc.
(3) The provider has obtained prior authorization from the MassHealth agency for the AAC device. The request for a prior authorization request must include documentation in accordance with 130 CMR 409.418 and documentation demonstrating that the conditions in 130 CMR 409.428(B) have been met, including a copy of the member's treatment plan.

(C) Trial Period.

(1) A trial-use period of not more than two months may be authorized by the MassHealth agency to determine if the device requested is appropriate for the member.

(2) The provider must submit the following documentation in order to receive a trial period with an AAC device:

(a) a prescription pursuant to 130 CMR 409.416;

(b) a prior-authorization request pursuant to 409.418;

(c) an explanation of the type of AAC device to be used by the member, including all necessary components;

(d) identification of the clinicians or therapists who will assess the trial period; and

(e) the evaluation criteria specific to the member that will be used by the clinician or therapist to determine the success or failure of the trial period.

(3) Success of the trial period will be determined by a current evaluation of the therapeutic benefit of the AAC device completed by a licensed speech/language pathologist experienced in the assessment of AAC services.

(4) After evaluating all appropriate documentation, the MassHealth agency will decide whether to purchase the equipment or to continue renting up to the purchase price of the device.

(D) Reasons for Noncoverage. The MassHealth agency will deny coverage of an AAC device if it determines that

(1) the criteria set forth in 130 CMR 409.428(B) have not been met;

(2) after a trial period, the member has failed to demonstrate to the MassHealth agency's satisfaction that the device is medically necessary; or

(3) the requested device is not a dedicated speech device.

409.429: Personal Emergency Response System (PERS)

(A) Requirements for Coverage. PERS is indicated for the personal use of a member with medical conditions that cause significant functional limitations or incapacitation and prevents the member from using other methods of summoning assistance in an emergency. The member must

(1) have a functioning land line phone that can accommodate a PERS;

(2) live alone or be routinely alone for extended periods of time such that the member's safety would be compromised without the availability of a PERS unit in the home;

(3) be able to independently use the PERS to summon help;

(4) understand when and how to appropriately use the PERS; and

(5) be at risk of moving to a more structured residential setting, or be at significant risk for falls or other medical complications that may result in an emergency situation.

(B) PERS must meet the definition in 130 CMR 409.402 and must include all of the following:

(1) an in-home communications transceiver;

(2) a remote, portable activator;

(3) the capacity to respond to all incoming emergency signals;

(4) the ability to receive multiple signals simultaneously and ensure that calls are not disconnected or put in a first come, first serve rotation;

(5) the ability to routinely send a signal to the central monitoring system to test the device and ensure the unit is working properly; and

(6) a central monitoring station with back-up systems, staffed by trained attendants 24 hours a

day, seven days a week.

(C) The PERS must meet Underwriter Laboratories (UL) Standards 1637—Home Health Care Signaling Equipment. Providers of PERS must provide documentation upon request to the MassHealth agency demonstrating compliance with these standards.

(D) In addition to the provider responsibilities described in 130 CMR 409.405 and the requirements of 130 CMR 409.429, a MassHealth provider of PERS must

(1) include options such as TDD and TTY capability to meet the needs of those members who are hearing impaired;

(2) provide PERS that can accommodate the needs of non-English speaking members;

(3) provide PERS that can accommodate the needs of members who are physically disabled (for example, providing "Sip-n-Puff" systems);

(4) maintain current data files at the central monitoring station and at each service facility that contain preestablished response protocols, and personal, medical, and emergency information for each member served;

(5) assess the member's need for in-home installation of PERS at the time the provider receives a referral for PERS. The MassHealth agency will pay a DME PERS provider for installation of PERS only if the DME PERS provider's assessment determines that there is no one else available to install the PERS in the member's home, such as the member, the member's caregiver, or a family member. The DME PERS provider must maintain documentation of such assessment in the member's record. If other options exist for members to install PERS, providers may deliver the PERS to the member by mail. Return receipt is required. If PERS is delivered by mail, the provider must not submit a claim to the MassHealth agency for the PERS installation.

(E) Documentation of Medical Necessity. Providers must ensure that PERS is medically necessary. In addition to the applicable record requirements under 130 CMR 409.430, the provider must complete the MassHealth *Personal Emergency Response System (PERS) General Prescription Form* in accordance with the instructions on the form, including obtaining the member's prescribing provider's prescription and medical justification for PERS, and maintain such documentation in the member's record.

(1) The PERS General Prescription form must be completed, dated, and signed by the member's prescribing provider before the installment of PERS.

(2) The form must be renewed and signed by the member's prescribing provider in the event that the member's medical condition or living situation changes such that the member may no longer meet the requirements of coverage of PERS under 130 CMR 409.429(A).

(3) The DME provider must maintain the PERS General Prescription Form in the member's record and make it available to the MassHealth agency upon request.

(F) Reasons for Noncoverage. MassHealth does not pay for PERS when the following conditions apply:

(1) the PERS duplicates equipment already available to the member in an emergency (e.g., emergency call buttons, or other electronic means of calling for help); or

(2) the member has access to help on a 24-hour-per-day, seven-day-per-week basis.

409.430: Recordkeeping Requirements

The DME provider must keep a record, either paper or electronic, 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 all records retained in accordance with 130 CMR 450.205 and 409.430 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 the following:

(A) a completed, signed, and dated prescription and letter of medical necessity that meets the requirements set forth in 130 CMR 409.416;

(B) a copy of the prior-authorization request submitted to the MassHealth agency (if the request was submitted on paper), including a copy of the MassHealth agency decision;

(C) a copy of all documentation submitted with a member's prior authorization request, including any MassHealth agency correspondence and decisions related to such requests;

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

(1) the date the equipment or medical supplies were delivered to the member;
(2) the manufacturer, brand name, model number, and, if applicable, the serial number of the equipment or medical supplies; and
(3) if the delivery slip is signed by the member's designee, an explanation of the designee's relationship to the member. This individual cannot be associated with either the DME provider or the delivery service;

(E) a copy of the original invoice showing the cost to the DME provider of the materials (if the DME provider is not the manufacturer of the materials);

(F) for repair services, a complete description of all repair services, including the manufacturer, brand name, model number, and serial number of the repaired item;

(G) copies of written warranties and any discounts;

(H) documentation of member's other insurance and any documentation submitted to and received from other insurers;

(I) documentation of any oral or written complaints received by the member in accordance with 130 CMR 409.405(O). The documentation must include, at a minimum

(1) the name, address, and telephone number of the member;
(2) the name, address, and telephone number of the person filing the complaint (if not the member);
(3) a summary of the complaint;
(4) the date the complaint was received by the provider;
(5) the name of the person receiving the complaint;

(6) a summary of any investigation or actions taken by the DME provider to resolve the complaint; and

(7) if the DME provider determined that an investigation of the complaint or further action was not necessary, the name of the person making this decision and the reason for the decision.

(J) a written description of any instruction or orientation provided to the member or the member's caregiver on the proper use of the equipment in accordance with 130 CMR 409.405(Q) and (R), signed and dated by the provider staff who provided the instruction or orientation;

(K) a written description or an electronically dated note of all contacts the provider has had with the member or the member's caregiver, signed and dated by the provider staff who had the contact; and

(L) a written description of any action taken by the provider in response to a recall notice, including any communication with members and repair/replacement of equipment, signed and dated by the technician or clinician responsible for implementing the instructions in the recall notice.

REGULATORY AUTHORITY

130 CMR 409.000: M.G.L. c. 118E, §§ 7 and 12.

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