

130 CMR 409.000: DURABLE MEDICAL EQUIPMENT SERVICES

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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 non-experimental, non-investigational, 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 130 CMR 409.000, and 130 CMR 450.000: *Administrative and Billing Regulations*. The MassHealth agency may deny enrollment to an applicant or terminate participation of a MassHealth DME provider if the applicant or DME provider does not meet one or more of the requirements in 130 CMR 409.000.

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, 101 CMR 322.00: *Durable Medical Equipment, Oxygen and Respiratory Therapy Equipment*, and in 130 CMR 450.000: *Administrative and Billing Regulations*.

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 used primarily and customarily to modify or enhance the usefulness or functional capability of an item of durable medical equipment and that are generally not useful in the absence of the item of durable medical equipment.

Accrediting Body - an organization acceptable to the Centers for Medicare & Medicaid Services (CMS) that accredits DME providers.

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

Ambulatory Equipment - DME that provide stability and security for members with impaired ambulation.

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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 with assistive/rehabilitation technology who analyzes the equipment needs of persons with disabilities, assists in the selection of DME, 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) - DME that are speech and communication aids that meet the functional speaking needs of members for whom such devices are medically necessary, with the exception of devices covered pursuant to 130 CMR 409.428(E).

Centers for Medicare & Medicaid Services (CMS) - a federal agency responsible for administering the Medicaid and Medicare programs created under the authority of Title XIX of the Social Security Act (42 U.S.C. 1396), Title XXI of the Social Security Act (42 U.S.C. 1397), and Title XVIII of the Social Security Act (42 U.S.C. 1395-1395pp).

Clinical Nurse Specialist - a nurse who is in good standing with, and meets the requirements of, the Massachusetts Board of Registration of Nursing for Clinical Nurse Specialists, and all applicable federal and state requirements.

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.

Consignment Closet - an arrangement in which a DME Provider maintains inventory at an ordering practitioners' location which is not the DME provider's service facility, for delivery to members on behalf of the DME Provider.

Criminal Offender Record Information (CORI) - information regulated by the Criminal History Systems Board (CHSB) and defined under 803 CMR 2.03: *Definitions* 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 delivery of DME to a member in a hospital, nursing facility, or ICF/IID pursuant to 130 CMR 409.415(A)(1)(b), (C), (C)(1)(c) and 130 CMR 409.419(C) or, with prior authorization, services provided in excess of the otherwise applicable service limit pursuant to 130 CMR 409.418(F).

Department of Public Health - an agency of the Commonwealth of Massachusetts, established under M.G.L. c. 17, § 1.

DME - as used in 130 CMR 409.000, DME means the durable medical equipment and medical supplies covered by 130 CMR 409.000.

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DME and Oxygen Payment and Coverage Guideline Tool - a 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 EOHHS and the Center for Health Information and Analysis (CHIA) websites. Subchapter 6 of the Durable Medical Equipment Manual directs providers to the MassHealth website 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 who meets all applicable requirements of 130 CMR 409.404, and 130 CMR 450.000: *Administrative and Billing Regulations*. DME providers may include oxygen and respiratory therapy equipment providers and pharmacy providers eligible to enroll with a DME Specialty under 130 CMR 409.404(C), who also meet all requirements of 130 CMR 409.000.

Durable Medical Equipment (DME) - equipment that

- (1) is used primarily and customarily to serve a medical purpose;
- (2) is generally not useful in the absence of disability, illness or injury;
- (3) can withstand repeated use over an extended period; and
- (4) is appropriate for use in any setting in which normal life activities take place, other than a hospital, nursing facility, ICF/IID, or any setting in which payment is or could be made under Medicaid inpatient services that includes room and board, except as allowed pursuant to 130 CMR 409.415 and 130 CMR 409.419(C).

Durable Medical Equipment Manual - provides DME regulations and other guidance issued by the MassHealth agency or its designee.

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.

EOHHS - the Executive Office of Health and Human Services, established under M.G.L. c. 6A.

Federal DME Face-to-face Requirements - CMS requirements promulgated in 42 CFR 440.70 which include the following requirements for payment for specific items of DME:

- (1) An in-person, face-to-face examination with: a Medical Doctor (MD), Doctor of Osteopathic Medicine (DO), or non-physician practitioner: physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS);
- (2) Documentation from the practitioner or non-physician practitioner performing the face-to-face examination that the individual was evaluated and/or treated for a condition that supports the need for the item(s) of DME ordered; and
- (3) Occurrence of the face-to-face examination during the six months prior to the start of services.

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.

Healthcare Common Procedure Coding System (HCPCS) - for purposes of 130 CMR 409.000, HCPCS refers to the Level II HCPCS codes which are maintained by CMS, and used by providers to bill for certain medical services, devices, and supplies, including all DME services.

Home - unless otherwise specified for purposes of rental and purchase of DME, a member's home may be a dwelling owned or rented by the member, 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 in which normal life activities take place. A home does not include an institutional setting including, but not limited to, a hospital, nursing facility or Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID) or any setting in which payment is or could be made under Medicaid inpatient services that includes room and board, except for items that are allowable pursuant to 130 CMR 409.415.

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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.

Hospital - a facility that is licensed or operated as a hospital by the Massachusetts Department of Public Health or the Massachusetts Department of Mental Health, or an out-of-state hospital facility enrolled as a provider in the MassHealth Acute Hospital or Chronic Disease and Rehabilitation Inpatient Hospital programs that provide diagnosis and treatment on an inpatient or outpatient basis for patients who have any of a variety of medical conditions.

Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID) - a facility, or distinct part of a facility, that provides intermediate care facility services as defined under 42 CFR § 440.150, and that meets federal conditions of participation, and is licensed by the state primarily for the diagnosis, treatment, or rehabilitation for individuals with intellectual disabilities; and provides, in a protected residential setting, ongoing evaluation, planning, 24-hour supervision, coordination, and integration for health or rehabilitative services to help individuals function at their greatest ability.

Marketing - any communication from a DME provider, or its agent, to a member, or his or her family or caregivers, that can reasonably be interpreted as intended to influence the member's choice of DME provider, whether by inducing that member

- (1) to retain that DME provider to provide DME services to the member;
- (2) not to retain DME services from another DME provider; or
- (3) to cease receiving DME services from another DME provider.

MassHealth - the medical assistance and benefit programs administered by EOHHS pursuant to Title XIX of the Social Security Act (42 U.S.C. 1396), Title XXI of the Social Security Act (42 U.S.C. 1397), M.G.L. c. 118E, and other applicable laws and waivers to provider and pay for medical services to eligible members.

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) required to address an individual's medical disability, illness, or injury;
- (2) generally not useful in the absence of illness or injury;
- (3) consumable or disposable;
- (4) not able to withstand repeated use by more than one individual; and
- (5) appropriate for use in any setting in which normal life activities take place, other than a hospital, nursing facility, ICF/IID, or any setting in which payment is or could be made under Medicaid inpatient services that includes room and board.

Medicare Competitive Bid Provider - Medicare-qualified provider chosen to provide Medicare-designated durable medical equipment and supplies in specified geographic areas for Medicare-specified time periods to MassHealth members with both Medicare and Medicaid coverage pursuant to 42 U.S.C. § 1395w-3.

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.

Non-physician Practitioner - a nurse practitioner or clinical nurse specialist working in collaboration with a physician or a physician assistant working under the supervision of a physician, who orders DME and writes the prescription for DME in accordance with 130 CMR 409.416.

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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).

Nursing Facility (NF) - an institution (or a distinct part of an institution) which is primarily engaged in providing skilled nursing care and related services for residents who require medical or nursing care, rehabilitation services for the rehabilitation of injured people, people with disabilities, or sick persons, or on a regular basis, health-related care and services to individuals who because of their mental or physical condition require care and services that meet the requirements of the Social Security Act § 1919(a), (b), (c) and (d) and is licensed under and certified by the Massachusetts Department of Public Health.

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

Office of Inspector General (OIG) - a Federal agency established by law as an independent and objective oversight unit to carry out the mission of preventing fraud and abuse and promoting economy, efficiency, and effectiveness of HHS programs and operations, as defined by 5 U.S.C. App. 1.

Ordering Practitioner - a physician or a non-physician practitioner who meets the requirements in 130 CMR 409.402, who orders DME and writes the prescription for DME in accordance with 130 CMR 409.416. For the purposes of 130 CMR 409.000, podiatrists are not ordering practitioners.

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-per-day, seven-days-per-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 - a medical doctor or doctor of osteopathic medicine who is licensed by the Massachusetts Board of Registration in Medicine or by the appropriate board of registration in the state in which the physician practices.

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.

Prior Authorization (PA) Request - a request submitted by the DME provider, speech and language pathologist, or other entity as specified by MassHealth to the MassHealth agency to determine medical necessity in accordance with 130 CMR 409.417, 409.418, 409.428, 130 CMR 450.204: *Medical Necessity*, and 130 CMR 450.303: *Prior Authorization*.

Recall - action taken by the manufacturer of any item covered by 130 CMR 409.000 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.

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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, accessories, or returns.

Serviceable Backup Mobility System - a manual wheelchair approved by the MassHealth agency as a backup to a power wheelchair as identified in 130 CMR 409.413(D) or a MassHealth member's serviceable retired power wheelchair, that can be safely used by the MassHealth member when a manual backup or suitable loaner chair cannot be provided to meet the member's medical needs pursuant to 130 CMR 409.420(G).

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 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 provided to eligible MassHealth members, subject to the restrictions and limitations described in MassHealth regulations. MassHealth regulations at 130 CMR 450.105: *Coverage Types* 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: *Emergency Aid to the Elderly, Disabled and Children Program*.

(C) Verification of Member Eligibility. For information about verifying member eligibility and coverage type, see 130 CMR 450.107: *Eligible Members and the MassHealth Card*.

409.404: Provider Eligibility

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

(B) General Qualifications. To qualify as a MassHealth DME provider, all applicants and providers must enter into a provider contract or agreement with MassHealth, and:

- (1) have a service facility that
  - (a) is open a minimum of 30 hours per week;
  - (b) is staffed with an employee during posted business hours;
  - (c) is available to members during regular, posted business hours;
  - (d) has available inventory for all products for which the DME provider has been accredited by an Accrediting Body, and for which the DME provider is enrolled in MassHealth, with the exception of items provided by subcontractors;

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- (e) is accessible to all members, including members with disabilities;
  - (f) has clear access and space for individualized ordering, returns, repair, and storing of business records;
  - (g) has a sign visible from outside the facility identifying the business name and hours that the service facility is open. If the DME 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 facility is located;
  - (h) 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, or voice message system; and
  - (i) during off hours, must maintain a voice message system and/or answering service;
- (2) obtain separate approval from the MassHealth agency and a separate provider number for each service facility operated by the DME provider;
  - (3) except for specialty providers described in 130 CMR 409.404(C), primarily engage in the business of providing DME, or DME repair services, to the public;
  - (4) be accredited by an Accrediting Body to participate or enroll in the Medicare program as a DME provider for the same business and service facility for which the applicant is applying to become a MassHealth provider, unless the provider supplies only items not covered by Medicare;
  - (5) meet all applicable federal, state, and local requirements, certifications, and registrations;
  - (6) conduct applicable Office of Inspector General (OIG) verifications on all staff;
  - (7) 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: *Administrative and Billing Regulations*, and updated documentation in accordance with 130 CMR 450.223(B) and 130 CMR 450.215: *Provider Eligibility: Notification of Potential Changes in Eligibility*, including:
    - (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.
      1. DME providers who furnish mobility systems corresponding to one of the HCPCS codes for which CMS requires a certified ATP must employ at least one certified ATP at each service facility.
      2. The ATP at each service facility 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 DME provider has recently been purchased by another entity or has purchased the company for which they are applying to become a MassHealth DME 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);
  - (l) Controlled Substances Registrations through the Commonwealth of Massachusetts Department of Public Health, Division of Food and Drug (if provider provides oxygen);
  - (m) a Sterilization/Sanitation of Bedding, Upholstered Furniture, and Filling Materials License through the Department of Public Health, Division of Food and Drug (if applicable);

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- (8) for a provider of home infusion services, be a licensed pharmacy in Massachusetts or in the state where the provider is located, and be accredited by an Accrediting Body, and be assigned a DME specialty by the MassHealth agency (*see* 130 CMR 409.404(C));
- (9) conduct pre-employment CORI checks on employees and subcontractors and keep CORIs on file at the DME provider's place of business;
- (10) not accept prescriptions for MassHealth DME from any ordering practitioner who has a financial interest in the DME provider;
- (11) cooperate with the MassHealth agency or its designee during the application and recredentialing process including, but not limited to, site visits or periodic inspections to ensure compliance with 130 CMR 409.000 and applicable state and federal laws and regulations; and
- (12) comply with applicable CMS provider requirements, including supplier standards listed at 42 CFR 424.57(c) and any CMS or MassHealth quality standards.

(C) 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: *Oxygen and Respiratory Therapy Equipment* or pharmacy services under 130 CMR 406.000: *Pharmacy Services*;
- (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; or
- (4) the MassHealth agency has determined that the applicant proposes to provide repairs of DME and meets the MassHealth agency requirements for participation as a DME repair provider.

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

(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 only if the following condition is met:

- (1) all applicable requirements under 130 CMR 409.000 and 130 CMR 450.000: *Administrative and Billing Regulations*, 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;
- (3) the DME provider participates in the Medicare program, unless the DME provider provides only PERS or absorbent products;
- (4) the provider has a service facility that can readily replace and repair products when needed by the member; and
- (5) the MassHealth agency has determined that the out-of-state applicant proposes to provide durable medical equipment or supplies that meet a need identified by the MassHealth agency.

409.405: Provider Responsibilities

In addition to meeting all other provider requirements set forth in 130 CMR 409.000 and 130 CMR 450.000: *Administrative and Billing Regulations*, the DME provider must:

- (A) accept, as payment in full, rates of payment established by EOHHS through regulations at 101 CMR 322.00: *Durable Medical Equipment, Oxygen and Respiratory Therapy Equipment*, including as determined by the MassHealth agency through a preferred supplier contracting process or by other means;



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(B) comply with all applicable Medicare billing and authorization requirements and make diligent efforts to identify and obtain payment from all other liable parties including Medicare, before billing MassHealth, in accordance with 130 CMR 450.316: *Third-party Liability: Requirements* through 130 CMR 450.318: *Third-party Liability: Payment Limitations on Medicare Crossover Claim Submissions*, and all subregulatory guidance. This includes appealing a denied claim, before filing a MassHealth claim, when the service is payable in whole or in part by Medicare or other liable parties or payers. If documentation requested by the MassHealth agency, or its designee, is not received within the timeframe specified by the MassHealth agency or its designee, or the documentation is incomplete or does not support coverage by MassHealth, the associated claims will be denied. Failing to seek payment from all other liable parties may result in an overpayment pursuant to 130 CMR 450.235(A)(4).

(C) comply with Medicare Competitive Bid Provider requirements for items subject to the CMS competitive bid process, which require that only qualified Medicare Competitive Bid Providers may provide DME that is subject to Medicare's competitive bid process to members with both MassHealth and Medicare coverage. MassHealth reimbursement is pursuant to 130 CMR 450.318: *Third-party Liability: Medicare Payment Limitations on Medicare Crossover Claim Submissions*.

(D) except as provided in 130 CMR 409.405(O) regarding change in scope of service or business, 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) and 130 CMR 450.215(A) including, but not limited to, change of ownership, change of address, change in scope of the provider's Medicare accreditation, and addition of, or reduction in service locations. The DME provider must maintain records of all such communications and transactions and make such records available to the MassHealth agency for review upon request;

(E) ensure that the DME provided is from the least costly, reliable source, and are consistent with MassHealth and industry quality standards, given the medical need for which the DME is prescribed and the member's medical condition;

(F) ensure that EOHHS-specified absorbent products meet the quality performance standards for disposable adult absorbent products used by the National Association for Continence (NAFC) or other such standards as EOHHS may adopt;

(G) ensure that all DME are free from defects and are 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;

(H) report to the proper authorities any suspected abuse or neglect that staff may observe when providing service to a member, as mandated by M.G.L. c. 111, § 72G, M.G.L. c. 119 § 51A, M.G.L. c. 19A § 15, M.G.L. c. 19C, § 10, and any regulations promulgated under these laws, as well as any other suspected abuse or neglect as required by state and federal law;

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

(J) not alter any invoice or medical documentation;

(K) not solicit members to purchase additional DME;

(L) submit prior authorization requests, as specified by 130 CMR 409.418, to the MassHealth agency or its designee, only when the DME is medically necessary and when prior authorization is a prerequisite in accordance with 130 CMR 409.418, or required by MassHealth agency guidance;

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(M) not share a service facility or physical location (including a consignment closet, unless permitted by specific MassHealth guidance) with an ordering practitioner, or other provider who is authorized to prescribe DME or with another supplier of DME, except as permitted by 42 CFR 424.57(c) (Medicare Supplier Standard 29);

(N) have a complaint resolution protocol to promptly address members' complaints by responding to any member complaints within two business days, 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). MassHealth may request a copy of the provider's complaint log/records and may specify the time period for the requested records in accordance with 130 CMR 409.426;

(O) provide MassHealth members and the MassHealth agency 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 certain products, if the scope of the provider's Medicare accreditation changes, or if a provider will be disenrolling as a MassHealth provider. 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 non-billed units remaining on the PA; and
  - (b) a copy of the original PA approval from MassHealth for the member to provide to the new DME provider;

(P) 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(K);

(Q) 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;

(R) upon request, submit to the MassHealth agency or its designee a statement of fiscal soundness attesting to the financial viability of the DME provider supported by documentation to demonstrate that the provider has adequate resources to finance the provision of services in accordance with 130 CMR 409.000; and

(S) upon request, submit to the MassHealth agency or its designee, data demonstrating the DME provider's performance related to customer service, delivery of equipment, supplies and timeliness of repairs in accordance with 130 CMR 409.426.

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

The MassHealth agency pays for all medically necessary DME services for EPSDT-eligible members in accordance with 130 CMR 450.144: *EPSDT Services: Diagnosis and Treatment*, without regard to service limitations described in 130 CMR 409.000, and with prior authorization pursuant to 130 CMR 409.418.

409.412: MassHealth Procurements and Subcontracted Services

(A) The MassHealth agency, in accordance with M.G.L. c. 118E, § 12, may issue procurements seeking qualified DME providers or suppliers to submit applications for consideration, in accordance with policies set by EOHHS.

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(B) Subcontracted Services. 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: *Administrative and Billing Regulations* 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 applicable requirements specified in 130 CMR 409.404 and 409.405.

(C) A DME provider must ensure that its subcontractors of DME meet all applicable 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 or setting in which normal life activities take place, and in certain circumstances described in 130 CMR 409.415 for use in facilities. All DME must be approved for community 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, the DME and Oxygen Payment and Coverage Guideline Tool, and any successor guidance issued by the MassHealth agency or its designee. Providers may request prior authorization for medically necessary DME if the corresponding service code is not listed in Subchapter 6 or the DME and Oxygen Payment and Coverage Guideline Tool. Covered DME includes, but is not limited to

- (1) absorbent products;
- (2) ambulatory equipment, such as crutches and canes;
- (3) compression devices;
- (4) augmentative and alternative communication 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 (including, but not limited to, commodes, grab bars, and tub benches).

(C) MassHealth covers the repair of DME, including repairs to medically necessary back-up mobility systems, 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 for repair;

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- (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 primary mobility system only when the DME provider has obtained prior authorization and

- (1) the existing primary mobility system exceeds five years of age or is no longer reliable as a primary mobility system in all settings in which normal life activities take place;
- (2) the cost of repairing or modifying the existing primary mobility system would exceed the value of that system; or
- (3) the member's physical condition has changed enough to render the existing mobility system ineffective.

409.414: Non-covered Services

The MassHealth agency does not pay for the following:

- (A) DME that is experimental or investigational in nature;
- (B) DME that is determined by the MassHealth agency not to be medically necessary pursuant to 130 CMR 409.000, and 130 CMR 450.204: *Medical Necessity*. 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, disability, 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 DME that is not identified as a covered service in Subchapter 6 of the Durable Medical Equipment Manual, the DME and Oxygen Payment and Coverage Guideline Tool or any other guidance issued by the MassHealth agency;
- (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 DME that is owned by the member;
- (F) DME that is not of proven quality and dependability, consistent with 130 CMR 409.404(B)(12);
- (G) DME furnished through a consignment/stock and bill closet (unless permitted by specific MassHealth guidance, pursuant to 130 CMR 409.405(M));
- (H) DME that has not been approved by the federal Food and Drug Administration (FDA) for community use;
- (I) evaluation or diagnostic tests conducted by the DME provider to establish the medical need for DME;
- (J) home or vehicle modifications including, but not limited to, ramps, elevators, or stair lifts;
- (K) common household and personal hygiene items generally used by the public including, but not limited to, washcloths, wet wipes, and non-sterile swabs;
- (L) products that are not DME (except for augmentative and alternative communication devices covered pursuant to M.G.L. c. 118E, § 10H under 130 CMR 409.428);

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- (M) certain DME provided to members in facilities in accordance with 130 CMR 409.415; and
- (N) provider claims for non-covered 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 130 CMR 450.000: *Administrative and Billing Regulations*, 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 \$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). If a MassHealth member needs a custom positioning seating system the nursing facility must check its existing inventory for a wheelchair base that can be used for a customized seating system for the sole use of a member. If the facility provides a base, the nursing facility is not responsible for the \$500.00 toward the purchase of a customized positioning/seating system.

(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 130 CMR 450.000: *Administrative and Billing Regulations*, 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 up to ten business days prior to 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. 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 MassHealth agency does not pay DME providers for the following services for members residing in nursing facilities.

(a) 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 purchase, rental, or repair of standard, manual wheelchairs. This includes, but is not limited to, transport chairs, standard manual wheelchairs, standard hemi wheelchairs, lightweight wheelchairs, high-strength lightweight wheelchairs, ultra-lightweight 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 DME provided to a MassHealth member who is an inpatient in a hospital, except for DME delivered to the member in accordance with 130 CMR 409.419(C).

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(C) MassHealth Members Who Are Residing in Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID).(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 130 CMR 450.000: *Administrative and Billing Regulations*, when purchased solely for the full-time use of a member residing in an ICF/IID (if the customization precludes the use of equipment by other individuals in the ICF/IID).

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

(c) Durable Medical Equipment for Members to Be Discharged from an ICF/IID. The MassHealth agency allows a DME provider to deliver equipment to an ICF/IID, 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/IID, and provide such documentation to the MassHealth agency upon request. For equipment delivered to a ICF/IID for use by a member after discharge from the facility, the date of service is the date of discharge.

(2) Non-covered 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/IID.

409.416: Requirements for Prescriptions or Letters of Medical Necessity Completed by the Ordering Practitioner

(A) LOMN and Prescriptions. The DME provider must obtain either a prescription or letter of medical necessity (LOMN), or a combination of a prescription and LOMN for the purchase or rental of DME. The prescription, LOMN, or a combination of a prescription and LOMN that meets the requirements of 130 CMR 409.416, must be in writing, signed by the ordering practitioner, 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 or LOMN must be signed by such medical professionals. If the DME requires prior authorization, the prescription or LOMN must be dated prior to the date the prior authorization request is submitted to the MassHealth agency.

(B) Required Prescription or LOMN Information. The initial and subsequent prescriptions or the LOMN must contain the following information as applicable with the exception of item (5), which may be provided in additional supporting documentation.

- (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, NPI number, and signature of the ordering practitioner and date signed;
- (5) medical justification for the item(s) being requested, including diagnosis or ICD-10 code;
- (6) the equipment settings, hours to be used per day, options, or additional features, as they pertain to the equipment;
- (7) length of need;
- (8) the expected outcome and therapeutic benefit of providing the requested item(s) or treatment, when requested; 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, upon request.

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(C) Prescription or LOMN Formats. The MassHealth agency accepts either written prescriptions or letters of medical necessity for DME in the following formats, provided the requirements of 130 CMR 409.416(B) 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 website.

(2) If the forms described in 130 CMR 409.416(C)(1) are not used by the DME provider, the MassHealth agency accepts prescriptions and letters of medical necessity written on one of the following, if the form and format include all requirements in 130 CMR 409.416(B); and comply with MassHealth administrative and billing regulations and instructions; and state and federal law and regulations:

- (a) the ordering practitioner's prescription pad;
- (b) the ordering practitioner's letterhead stationery;
- (c) the hospital prescription pad, if the member is being discharged from a hospital;
- (d) electronic prescriptions (escripts) that comply with state and federal requirements;
- (e) 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(C)(1); or
- (f) 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(E)).

(D) Electronic Transmission of Prescriptions. Prescriptions may be transmitted electronically to the DME provider by the member's ordering practitioner in accordance with the MassHealth agency's administrative and billing instructions and applicable state and federal laws.

(E) Documentation for Prescriptions for Members in Nursing Facilities. 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 ordering practitioner, 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.

(F) 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 member's authorized representative, provided at the time the prescription is to be refilled. The possession by a provider of a prescription with remaining refills does not constitute approval from the member to refill the prescription.

(4) The DME provider must keep records of all member or authorized representative approval of refills in accordance with 130 CMR 409.430(L).

409.417: Medical Necessity Criteria

(A) All DME covered by MassHealth must meet the medical necessity requirements set forth in 130 CMR 409.000 and in 130 CMR 450.204: *Medical Necessity*, and any applicable medical necessity guidelines for specific DME published on the MassHealth website.

(B) For items covered by MassHealth for which there is no MassHealth item-specific medical necessity guideline, and for which there is a Medicare Local Coverage Determination (LCD)

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indicating Medicare coverage of the item under at least some circumstances, the provider must demonstrate medical necessity of the item consistent with the Medicare LCD. However, if the provider believes the durable medical equipment is medically necessary even though it does not meet the criteria established by the local coverage determination, the provider must demonstrate medical necessity under 130 CMR 450.204: *Medical Necessity*.

(C) For an item covered by MassHealth for which there is no MassHealth item-specific medical necessity guideline, and for which there is a Medicare LCD indicating that the item is not covered by Medicare under any circumstance, the provider must demonstrate medical necessity under 130 CMR 450.204: *Medical Necessity*.

409.418: Prior Authorization

(A) 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 or other guidance specified by the MassHealth agency or its designee as requiring prior authorization, or pursuant to 130 CMR 409.413(B), for service codes not listed in Subchapter 6 or in the DME and Oxygen Payment and Coverage Guideline Tool.

(B) Prior Authorization for MassHealth Covered Services. Prior authorization for MassHealth-covered services is a determination of medical necessity only and does not establish or waive any other prerequisites for payment, such as member eligibility or requirements to seek payment from other liable parties, including Medicare.

(C) Documentation of Medical Necessity.

Prior authorization requests submitted by the provider for DME must include

- (1) a completed MassHealth Prior Authorization Request (PA-1) form (if request is submitted on paper);
- (2) a prescription or letter of medical necessity that meets the requirements of 130 CMR 409.416, including any additional documentation as required by 42 CFR 440.70 or other state or federal law; and
- (3) 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 language pathologists, nurses, respiratory therapists, and occupational therapists who have expertise in the applicable area.

(D) Documentation for Prior Authorization Items Requiring Individual Consideration (IC) or Adjusted Acquisition Cost (AAC). For DME that is identified in the DME and Oxygen Payment and Coverage Guideline Tool or in other guidance issued by the MassHealth agency or its designee as requiring IC or AAC, a copy of the original invoice that reflects the provider's adjusted acquisition costs as set forth in 101 CMR 322.00: *Durable Medical Equipment, Oxygen and Respiratory Therapy Equipment*.

- (1) The MassHealth agency will accept a quote from a MassHealth provider for an item that does not have a rate established by EOHHS 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.
- (2) At the time of a claim submission for items requiring a one-time claim submission, or, at initial claim submission for the authorized period for recurring (monthly) claims, the provider must attach the actual manufacturer's invoice and quote used for MassHealth PA purposes. The provider must keep a copy of the quote and the invoice on file. The MassHealth agency reserves the right to deny claims if a claim is submitted without the appropriate documentation attached.
- (3) For disposable medical supplies, the invoice must be dated within six months of the prior authorization request.
- (4) The MassHealth agency will not accept a printed invoice or order from a manufacturer's website.



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(E) 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.

(F) Prior Authorization Requests for DME Units in Excess of the Maximum Allowable Units. The MassHealth agency 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 or in other guidance issued by the MassHealth agency or its designee.

(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, or its designee, the provider must submit a separate claim with a different date of service other than the date of service for the initial maximum number of units and only for the number of excess units actually provided to the member.

(G) Additional Assessments or Other Information. In making its prior authorization determination, the MassHealth agency or its designee may require additional assessments of the member or require other necessary information in support of the request for prior authorization.

(H) Prior Authorization Requests for Members Who Have Other Insurance. For members for whom MassHealth is not the primary insurer, a provider must make diligent efforts to first identify and obtain payment from all other liable parties, including Medicare, before seeking payment from MassHealth in accordance with 130 CMR 450.316: *Third-party Liability: Requirements*. The MassHealth agency, or its designee, may request documentation of a provider's diligent efforts to collect payment from Medicare or other liable parties, including documentation of compliance with Medicare's billing and authorization requirements. If documentation requested by the MassHealth agency, or its designee, is not received within the timeframe specified by the MassHealth agency or its designee, or the documentation is incomplete or does not support coverage by MassHealth, the associated claims will be denied.

(I) Prior Authorization for Repairs of Durable Medical Equipment. Providers must submit a prior authorization request for repairs, including repairs of a member's serviceable backup power wheelchair, in accordance with 130 CMR 409.420.

(J) Notice of Approval, Denial, or Modification of a Prior-authorization Request.

(1) Notice of Approval. If the MassHealth agency or its designee, approves a prior authorization request for DME, the MassHealth agency will send notice of its decision to the member and the DME provider.

(2) Notice of Denial or Modification. If the MassHealth agency or its designee, denies or approves with a modification a prior authorization request for DME, the MassHealth agency or its designee, will notify 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: *MassHealth: Fair Hearing Rules*.

(3) Right of Appeal. A member may appeal a service denial or modification by requesting a fair hearing in accordance with 130 CMR 610.000: *MassHealth: Fair Hearing Rules*.

(4) Notice of Deferral. If the MassHealth agency or its designee defers a prior authorization request due to an incomplete submission or lack of documentation to support medical necessity, the MassHealth agency or its designee will notify the member and the durable medical equipment provider of the deferral, the reason for the deferral, and provide an opportunity for the provider to submit the incomplete or missing documentation. If the provider does not submit the required information within 21 calendar days of the date of deferral, the MassHealth agency or its designee will make a decision on the prior authorization request using all documentation and forms submitted to the MassHealth agency and will send notice of its decision to the provider and the member in accordance with 130 CMR 409.418(H).

409.419: Delivery of Durable Medical Equipment

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

- (1) The DME provider must ensure that DME orders are delivered within a reasonable time after DME provider receipt of a prescription or LOMN and any required documentation or prior approval for the item. Providers must make alternate arrangements such as contracting with subcontractors, or referring the member to another DME provider, when timely delivery cannot be made by the DME provider. The MassHealth agency, reserves the right to issue additional subregulatory guidance on reasonableness of delivery times for specific DME.
- (2) Except as provided in 130 CMR 409.419(D), 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.
- (3) 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/IID. 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/IID, 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/IID in Anticipation of Discharge. A provider may deliver DME to a facility for a member who is being discharged from a hospital, a nursing facility, or ICF/IID for the purpose of fitting or training the member in its proper use up to ten 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 DME must be solely for use in the member's home or community. The provider may not bill for DME 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 by a Shipping Service.

- (1) For medical supplies delivered to a member 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 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 shipping date.
- (3) A shipping service tracking slip that meets the above requirements is an acceptable form of a delivery ticket (*see* 130 CMR 409.430).

(E) Refills. For DME provided as refills to an original prescription, the provider must contact the member or the member's designee up to seven 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) Automatic Deliveries. 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) DME Adjustments. 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 DME that the MassHealth agency previously determined to be medically necessary for the member. A prescription or LOMN are required if the MassHealth agency has not previously determined the medical necessity of the item requiring repair in order to establish medical necessity for the device.

(B) Repairs of Purchased Durable Medical Equipment Requiring Removal from the Member. When member-owned equipment has been determined to be unusable and requires repair, MassHealth will pay for temporary replacement equipment. The provider must attempt to 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 101 CMR 322.00: *Durable Medical Equipment, Oxygen and Respiratory Therapy Equipment*.

(C) Repairs of Rented Durable Medical Equipment Requiring Removal from the Member. When a repair service for rented durable medical equipment requires removing the equipment from the member, 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 EOHHS at 101 CMR 322.00: *Durable Medical Equipment, Oxygen and Respiratory Therapy Equipment*, but no extra rental charge is allowed for this substitute equipment.

(D) Prior Authorization When Total Repair Exceeds \$1,000. DME providers must submit a prior authorization request for total repairs or modifications that exceed \$1,000 per repair. For purposes of calculating total repair/modification, providers must include parts and components, including labor, based on EOHHS's rates established at 101 CMR 322.00: *Durable Medical Equipment, Oxygen and Respiratory Therapy Equipment*. For purposes of calculating the total repair/modification, the amount is inclusive of all HCPCS codes that have "No", "Sometimes", and "Yes", in the Prior Authorization Approval column on the DME/OXY 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 or loaner would be comparable, and the repair is not covered under the warranty (*see* 130 CMR 409.413(C), (D), and (E)).

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

- (a) a completed MassHealth Prior Authorization Request (PA-1) form (if request is submitted on paper);
- (b) evidence of MassHealth PA for the item requiring repair or a prescription or letter of medical necessity that meets 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 as applicable;
- (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.

(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) ensuring that repairs are completed within a reasonable time after requests for repair, and any authorizations required for repair, are received by the provider. Providers must make alternative arrangements such as using subcontractors if the provider is unable to repair within a reasonable amount of time. The MassHealth agency reserves the right to issue additional subregulatory guidance on reasonableness of repair times for specific DME;
- (4) taking advantage of all manufacturer warranties;

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(5) 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;

(6) providing the member with regular updates regarding the status of the repairs and the expected delivery date of the equipment being repaired; and

(7) responding in a timely fashion to a member's complaint regarding the repair of the equipment.

(F) Coverage for Replacement Equipment. Coverage for replacement equipment will be provided only when the existing device or system no longer effectively addresses the member's medical needs, or if the cumulative cost of the repair exceeds the cost to replace the equipment.

(G) Repairs of a Member's Serviceable Backup Power Wheelchair. MassHealth pays for repairs for a member's serviceable retired backup power wheelchair in the following instances:

(1) the DME provider must obtain prior authorization from the MassHealth agency or its designee as a prerequisite for any repair of a member's serviceable retired backup power wheelchair;

(2) the member's medical complexity prevents them from being able to use a manual wheelchair or loaner power wheelchair when the primary mobility system needs repair;

(3) the total cost of the repair of the serviceable backup power wheelchair does not exceed \$1,000.00 per calendar year, unless the MassHealth agency exercises discretion to approve the total cost of the repair. The MassHealth agency will review requests exceeding \$1,000.00 on a case-by-case basis;

(4) the MassHealth agency will only pay for the repair of one serviceable backup power wheelchair per calendar year;

(5) DME providers must document the serial number of the repaired serviceable backup power wheelchair and submit the documentation listed at 130 CMR 409.420(D)(2)(c), (d), and (e); and

(6) all documentation regarding the repaired serviceable backup power wheelchair must remain in the member's file.

409.426: Quality Management

DME providers must participate in any quality management and program integrity processes established by the MassHealth agency including making any necessary data including, but not limited to, member complaint data under 130 CMR 409.405(N) and (S), available and providing access to the provider's place of business upon request by the MassHealth agency or its designee, within the time frame designated by the MassHealth agency.

409.427: Payment for Durable Medical Equipment

(A) MassHealth pays for DME for eligible members as required by 130 CMR 450.231: *General Conditions of Payment* and in accordance with the applicable payment methodology and rate schedule established by EOHHS at 101 CMR 322.00: *Durable Medical Equipment, Oxygen and Respiratory Therapy Equipment*.

(B) Payments are subject to the conditions, exclusions, and limitations set forth in 130 CMR 409.000, and 130 CMR 450.000: *Administrative and Billing Regulations*.

(C) MassHealth pays for DME only if:

(1) medically necessary and, if subject to PA, the MassHealth agency or its designee determines that the DME is medically necessary;

(2) the member meets applicable clinical eligibility criteria for the DME;

(3) the provider has obtained a prescription or letter of medical necessity for the purchase or rental of DME in accordance with 130 CMR 409.416; and, if necessary, prior authorization for purchase, rental or repair of DME in accordance with the requirements set forth in 130 CMR 409.418; and

(4) provider has diligently sought payment from all other liable parties in accordance with 130 CMR 409.418(D), and 130 CMR 450.316: *Third-party Liability: Requirements*.

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(D) 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: *Out-of-state Services*. The DME provider must keep a record for each member in accordance with 130 CMR 409.430, and 130 CMR 450.205: *Recordkeeping and Disclosure*, and make this record available to the MassHealth agency or its designee upon request.

409.428: Augmentative and Alternative Communication Devices and Speech Generation 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 severe expressive communication impairment. Examples of AAC devices are

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

(B) Requirements for Coverage. MassHealth covers AAC devices when

- (1) The device or software is recommended by the member's multidisciplinary team, following a formal face-to-face evaluation and assessment by a licensed, certified, speech and language pathologist meeting nationally accepted knowledge and skill qualifications for AAC delivery, within six months prior to the date of the written prior authorization request. The speech-language pathologist must not be affiliated with the AAC provider. An ordering practitioner must prescribe the device or software, in accordance with the requirements in 130 CMR 409.416.

Information from other professionals may be included as needed for demonstrating motor or other needs, such as physical access to the device;

- (2) The member has the cognitive, visual, language, and physical abilities to effectively use, or to learn how to effectively use, an AAC;
- (3) The member meets all clinical coverage criteria in the Guidelines for Medical Necessity Determination for Augmentative and Alternative Communication Devices; and
- (4) The provider has obtained prior authorization from the MassHealth agency for the AAC device. The request for a prior authorization request must include the MassHealth Prescription and Medical Necessity Review Form for DME, and documentation in accordance with 130 CMR 409.418 and documentation demonstrating that the conditions in the clinical coverage criteria 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 or letter of medical necessity pursuant to 130 CMR 409.416;
  - (b) a prior-authorization request pursuant to 130 CMR 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 Non-coverage. The MassHealth agency will deny coverage of an AAC device or software for reasons including, but not limited to, the following:

- (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

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satisfaction that the device is medically necessary;

(3) the requested device is not a dedicated speech device; and

(4) the member does not meet the clinical criteria in MassHealth's Guidelines for Medical Necessity for Augmentative and Alternative Communication Devices.

(E) Coverage of AAC Devices Not Eligible for Federal Financial Participation. Coverage of AAC devices pursuant to M.G.L. c. 118E, § 10H must be in accordance with policies set by EOHHS for augmentative and alternative communication devices not eligible for Federal Financial Participation, in particular for augmentative and alternative communication devices not primarily and customarily used to serve a medical purpose.

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 landline 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) Mandated PERS Inclusion. PERS must meet the definition in 130 CMR 409.402 and must include all of the following:

(1) a 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 per-day, seven-days-per-week.

(C) PERS Compliance with Underwriter Laboratories (UL) Standards. 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) Other PERS Requirements. 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; and

(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 authorized 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.

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(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 ordering practitioner'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 ordering practitioners before the installment of PERS.

(2) The form must be renewed and signed by the member's ordering practitioner 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 Non-coverage. 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-days-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: *Recordkeeping and Disclosure*. The DME provider must make all records retained in accordance with 130 CMR 409.430 and 450.205 available to the MassHealth agency, or its designee 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 DME provider must ensure that each member's record includes the following, except where noted that the record must be available upon request:

(A) a completed, signed, and dated prescription and letter of medical necessity that meets the requirements set forth in 130 CMR 409.416, and 42 CFR 440.70, and any other applicable state or federal law or regulation;

(B) a copy of the prior-authorization request submitted to the MassHealth agency, or its designee, including a copy of the MassHealth agency decision;

(C) the face-to-face encounter related to the primary reason the member requires DME must be documented in the member's record either on the plan of care or in other medical notes sufficient to make the link between the member's health conditions, the DME ordered, and an appropriate face-to-face encounter that occurred within six months of the start of services of DME consistent with 42 CFR 440.70. This documentation must include the name of the practitioner and date of the encounter;

(D) if the member has third-party liability, including Medicare, the DME provider must also maintain a copy of all documentation of their efforts to diligently seek prior authorization and payment from other liable parties;

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

(F) written confirmation of receipt of the prescribed DME, including refills, signed by the member or the member's designee, except as permitted by 130 CMR 409.419(D) regarding signed delivery tickets, 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.

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- (G) a copy of the invoice showing the cost to the DME provider of the items delivered must be available to the MassHealth agency upon request;
- (H) for repair services, a complete description of all repair services, including the manufacturer, brand name, model number, and serial number of the repaired item;
- (I) copies of written warranties and any discounts;
- (J) documentation of any oral or written complaints received by the member in accordance with 130 CMR 409.405(P). 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.
- (K) confirmation that 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(R), signed and dated by the provider staff who provided the instruction or orientation with the exception of items delivered by a shipping service 130 CMR 409.419(D);
- (L) a written description or an electronically dated note of all contacts the provider has had with the member or the member's caregiver, including member or authorized representative approval for refills, signed and dated by the provider staff who had the contact; and
- (M) 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.

409.431: Prohibited Marketing Activities

A DME provider must not:

- (A) with the knowledge that a member is enrolled in a MassHealth capitated program, engage in any practice that would reasonably be expected to have the effect of steering or encouraging the member to disenroll from the MassHealth capitated program in order to retain the provider to provide services on a fee-for-service basis;
- (B) offer to a member, or his or her family or caregivers, in-person or through marketing, any inducement to retain the provider to provide DME services, such as a financial incentive, reward, gift, meal, discount, rebate, giveaway, or special opportunity;
- (C) pay a "finder's fee" to any third-party in exchange for referring a member to the orthotic provider; or
- (D) engage in any unfair or deceptive acts or practices in connection with any marketing.

REGULATORY AUTHORITY

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