



Commonwealth of Massachusetts
Executive Office of Health and Human Services
Office of Medicaid
www.mass.gov/masshealth



MassHealth
Transmittal Letter DME-42
May 2023

TO: Durable Medical Equipment Providers Participating in MassHealth

FROM: Mike Levine, Assistant Secretary for MassHealth

RE: *Durable Medical Equipment Manual* (Changes to Program Regulations Regarding Provider Enrollment)

Introduction

MassHealth has amended the durable medical equipment (DME) services regulation, 130 CMR 409.000, to update and clarify certain enrollment requirements, as described below. These regulations became effective April 28, 2023. The updates concern entities that are engaged in, and meet enrollment requirements for, multiple lines of business as providers of DME, oxygen and respiratory therapy equipment (OXY), orthotics (ORT), or prosthetics (PRT) services. This transmittal letter also provides submission instructions for enrollment applications, billing instructions, and a reminder regarding notice to MassHealth and to members of changes in or updates to information in provider enrollment materials.

Definitions: 130 CMR 409.402

MassHealth has updated the definition of “DME Provider” to support provider enrollment amendments.

Providers of DME may include qualified MassHealth enrolled OXY, ORT, or PRT services who apply for and sign a provider contract to provide DME services that meet all applicable requirements of 130 CMR 409.000 and 130 CMR 450.000.

Provider Eligibility: 130 CMR 409.404

MassHealth is expanding DME provider eligibility to OXY, ORT, or PRT services providers who have completed a MassHealth DME provider application and who meet all program-specific requirements. See 130 CMR 409.404(A).

The amendments to this regulation are designed to align with the OXY, ORT, and PRT program regulations and:

- Remove the requirement that DME, OXY, ORT, or PRT services providers identify and enroll with a primary line of business among these four provider types.
- Remove provisions that limit providers who otherwise meet all enrollment requirements for multiple lines of business to enrollment in only one additional program among these four provider types. For example, under the regulation in effect for enrollment applications filed before April 28, 2023, providers enrolled as DME providers could only additionally enroll as OXY providers and the reverse; ORT providers could only additionally enroll as PRT providers and the reverse.

- Remove the requirement that otherwise qualified providers of multiple lines of service maintain separate service locations for each line of business among the four provider types (DME, OXY, ORT, or PRT services).
- Clarify that the agency policy regarding the circumstance in which MassHealth-enrolled pharmacy providers may enroll with a DME or OXY services provider specialty continues and is unchanged. See 130 CMR 409.404(C).

Submission of Applications

Applications for new applicants or existing providers can be submitted

- Through the MassHealth LTSS Provider Portal at the URL listed at the end of this Transmittal Letter,
- By following instructions to complete the provider application process; or
- By filling out a paper application and submitting via email, fax, or mail to the addresses listed at the end of this Transmittal Letter.

Applicant enrolling with a **single** location must

- Complete a MassHealth provider enrollment application and identify the provider types (PT) they wish to enroll at the service location (DME, OXY, ORT, or PRT), and
- Complete a supplemental form for each PT identified on the application for the single service location.

Provider enrolling with **multiple** locations must

- Complete a MassHealth provider enrollment application listing **each location** and identify each of the PT they wish to enroll (DME, OXY, ORT, or PRT) at each service location, and
- Complete the appropriate supplemental form for each provider type identified on the application for **each** service location.

Existing MassHealth provider requesting to add a PT to a service location must

- Complete a MassHealth provider enrollment application listing each service location and identify the PT they wish to add to each service location and
- Complete a supplemental form for each PT identified on the application for each service location.

Billing Instructions

Upon approval of a provider's application, a Provider Identification/Service Location number (PID/SL) will be provided.

Providers will be able to use this PID/SL to bill claims for the PT associated with each service location using the PID/SL linked to that location.

- Example: Service Location 1: 123456789A
Service Location 2: 123456789B
Service Location 3: 123456789C

OXY Providers Previously Enrolled with a DME Specialty

Upon revalidation, OXY providers who choose to continue to provide DME will need to complete a DME provider application.

Upon completing the required form, providers must list or attach all the DME product categories their organization is accredited to provide. Providers can only be enrolled in MassHealth to provide accredited products.

Reminder: Provider Responsibility: 130 CMR 409.405

Providers are reminded that they must notify MassHealth of any changes to provider contract information submitted in their provider applications. Specifically, in addition to 130 CMR 450.215 and 130 CMR 450.223, MassHealth calls providers' attention to DME regulation 130 CMR 409.405(D) and (O), which require that providers:

(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.

...

(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.

MassHealth Website

This transmittal letter and attached pages are available on the MassHealth website at www.mass.gov/masshealth-transmittal-letters.

[Sign up](#) to receive email alerts when MassHealth issues new transmittal letters and provider bulletins.

Questions

If you have any questions about the information in this transmittal letter, please contact the LTSS Provider Service Center.

The MassHealth LTSS Provider Service Center is open from 8 am to 6 pm ET, Monday through Friday, excluding holidays. LTSS providers should direct questions about this transmittal letter or other MassHealth LTSS Provider questions to the LTSS Third Party Administrator (TPA) as follows:

Phone: Toll-free (844) 368-5184

Email: support@masshealthltss.com

Portal: www.MassHealthLTSS.com

Mail: MassHealth LTSS
PO Box 159108
Boston, MA 02215

FAX: (888) 832-3006

NEW MATERIAL

(The pages listed here contain new or revised language.)

Durable Medical Equipment Manual

Pages 4-3, 4-4, and 4-7 through 4-12.

OBSOLETE MATERIAL

(The pages listed here are no longer in effect.)

Durable Medical Equipment Manual

Pages 4-3, 4-4, and 4-7 through 4-12 — transmitted by Transmittal Letter DME-39

Commonwealth of Massachusetts MassHealth Provider Manual Series Durable Medical Equipment Manual	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-3
	Transmittal Letter DME-42	Date 04/28/23

DME and Oxygen Payment and Coverage Guideline Tool – MassHealth web-based application that contains DME and oxygen service descriptions for all covered products and services, applicable modifiers, place-of service codes, prior authorization requirements, individual consideration requirements, service limits, markup information, and links to other applicable information, such as 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 providers also enrolled as MassHealth participating oxygen and respiratory therapy equipment and supplies (OXY) providers, orthotic services providers, or prosthetic services providers who meet all program-specific requirements; and MassHealth pharmacy providers eligible to enroll with a DME specialty under 130 CMR 409.404(C), who also meet all applicable 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 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.

Commonwealth of Massachusetts MassHealth Provider Manual Series Durable Medical Equipment Manual	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-4
	Transmittal Letter DME-42	Date 04/28/23

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.

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.

Commonwealth of Massachusetts MassHealth Provider Manual Series Durable Medical Equipment Manual	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-7
	Transmittal Letter DME-42	Date 04/28/23

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 130 CMR 409.000 and 130 CMR 450.000: *Administrative and Billing Regulations*. 130 CMR 450.105: *Coverage Types* specifically states, 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 to DME providers who, as of the date of service, are participating in MassHealth; to providers also enrolled as MassHealth-participating OXY providers, orthotic services providers, or prosthetic services providers and who meet all program-specific requirements; and to MassHealth-enrolled pharmacy providers who 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.

Commonwealth of Massachusetts MassHealth Provider Manual Series Durable Medical Equipment Manual	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-8
	Transmittal Letter DME-42	Date 04/28/23

(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;
 - (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) 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.

Commonwealth of Massachusetts MassHealth Provider Manual Series Durable Medical Equipment Manual	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-9
	Transmittal Letter DME-42	Date 04/28/23

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);
- (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. An applicant or provider enrolled as a MassHealth provider of pharmacy services under 130 CMR 406.000: *Pharmacy Services* may qualify to provide DME services if the following conditions are met:

- (1) the applicant or provider meets all other conditions under 130 CMR 409.404 and 405 to provide DME services; and

Commonwealth of Massachusetts MassHealth Provider Manual Series Durable Medical Equipment Manual	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-10
	Transmittal Letter DME-42	Date 04/28/23

(2) MassHealth has assigned a specialty of DME to the applicant's or provider's existing provider number for pharmacy services; or

(3) 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;

(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).

Commonwealth of Massachusetts MassHealth Provider Manual Series Durable Medical Equipment Manual	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-11
	Transmittal Letter DME-42	Date 04/28/23

(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.

Commonwealth of Massachusetts MassHealth Provider Manual Series Durable Medical Equipment Manual	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-12
	Transmittal Letter DME-42	Date 04/28/23

(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.